

Inspections

Navigating Produce Positive Samples

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PRODUCE SAFETY

SCPRODUCESAFETY.COM

Regulatory



Inspections



Updating Farm Information

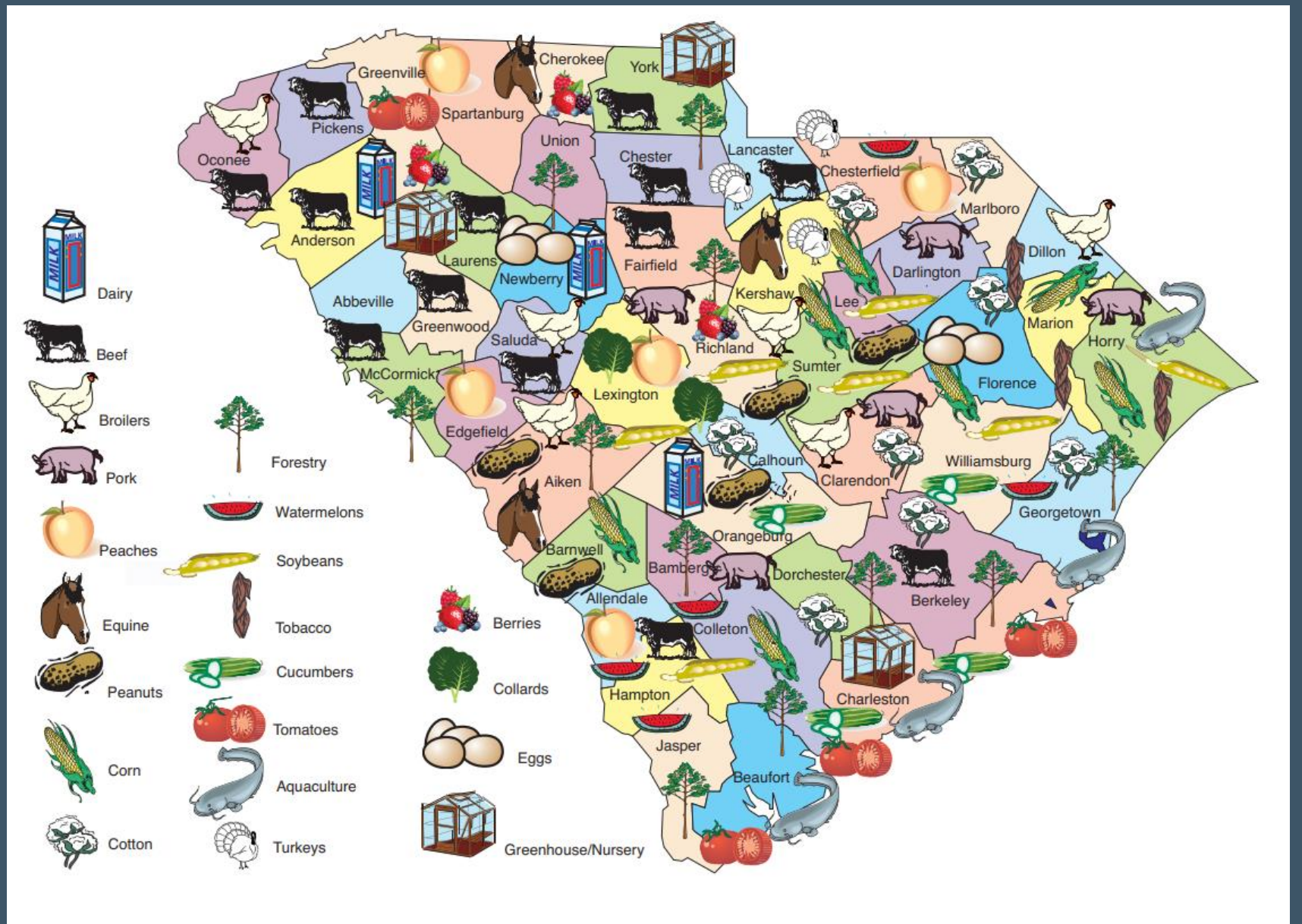


Complaints



Emergency Response, Outbreaks, and Recalls

Where are different type of commodities grown in the state?



Inspections

- Schedule Inspection/Pre-Inspection Call (Expectations/PSR)
- Inspectors prepare for Inspection (PPE, Truck, Phone, Research, Supervisor/Manager)
- Opening Meeting on Inspection Day (Timelines, Questions, Notice of Inspection)
- Conducting the Inspection (Fields, Facilities, Records)
- Discussing Regulatory Concerns
 - Immediate Regulatory Action Needed
- Formally Close the Inspection/Closing Meeting
- Submit Farm Inspection Report and Update any farm new information (WINWAM software)

Where is our data stored?

WinWam Database: .\sqlexpress:P2

File Edit Inspection Info Tools Window Help

Business

ID# 00000011 Name: ██████████ LLC

Address Mail Info Sched History Notes Links

Mailing Address		Billing Address	
Name	██████████ Farm, LLC	Name	
Addr	██████████	Addr	
City	██████████ State SC	City	State
Zip	29██████████	Zip	
Contact	██████████	Contact	

Important Tool – GIS Mapping

Charleston County GIS Viewer

Enter address, road, parcel # or

The map displays a detailed aerial view of a region in Charleston County, South Carolina. Parcel boundaries are outlined in orange, and major roads are shown in white. Numerous parcel numbers are visible, including 580000058, 578000042, 578000035, 578000029, 578000028, 578000030, 578000026, 578000037, 578000018, 578000018, 578000018, 578000063, 578000053, 5780000247, 578000064, 578000065, 578000001, 5620800359, 5620800384, 5620800386, 5620800339, 5620800311, 5620800366, 5620800364, 5620800311, 5801400027, 580140002, 580140008, and 580140009. Street names include N Highway 17, Alice Smalls Rd, Frank Bonneau Rd, Fulton Hall Ln, Children Rd, Cultivator St, Old George Town Rd, Garden Way, Shadow Lake Cir, Parkway Dr, Brickside Ln, McConnell Ln, Mcknight Rd, Max Ln, Giles Ln, and Hamlin Ln. The map also shows agricultural fields and dense forest areas.

Peach Farm
Positive Sample

For-Cause Inspection – Positive Peach Sample

- Received notice on 6/27/22 from Michigan DOA about positive *Listeria monocytogenes* sample from peaches (Harvested and Shipped from South Carolina)
- Peaches traveled from SC to an Indiana distribution center, then to Michigan
- Called farm 6/28/22 to set up a For-Cause Inspection
- Prepped for Inspection 6/29/22
- Day of Inspection 6/30/22
 - 4 SCDA Produce Safety members, 1 FDA member, 1 DHEC member

Additional Information

- Last Inspection was 7/31/19 (They were on the schedule to be inspected the next week!)
- GAP audit 6/9/22 – passed
 - Lack of proper hand washing facility
 - Municipal water used at packing facility
 - Poor ceiling conditions
- They regularly test product for listeria. Saying all results were negative
- Pack date was 6/2/22 and Inspection date was 6/30/22

What are some concerns with this peach harvesting bin?



Trash in the Fields



What happened during the Inspection?

- 2 Teams (John's team DHEC swabbing, Produce Safety Inspection team)
- Food Safety Manager was telling us one thing but the inspectors were seeing another (Bins, Cleaning schedule, Worker training, Clean up)
- Food Safety Manager was willing to do anything he could to cooperate, get the situation figured out, and get the peaches back on the line
- Owners were visibly upset

What is circled
in the
processing
facility?



What happened after the Inspection?

- Talked with Farm Manager, Farm Management, Harvesting Manager
- Owners were uneasy about the pending results
- Constant communication with the Farm on Results (July 4th weekend)
- Peach season was in full swing and they wanted to run peaches but they wanted to know more information before opening the facility again
- Once they knew where the positive was, they cleaned it, tested it again and started to run peaches

Squash Farm
Positive Sample

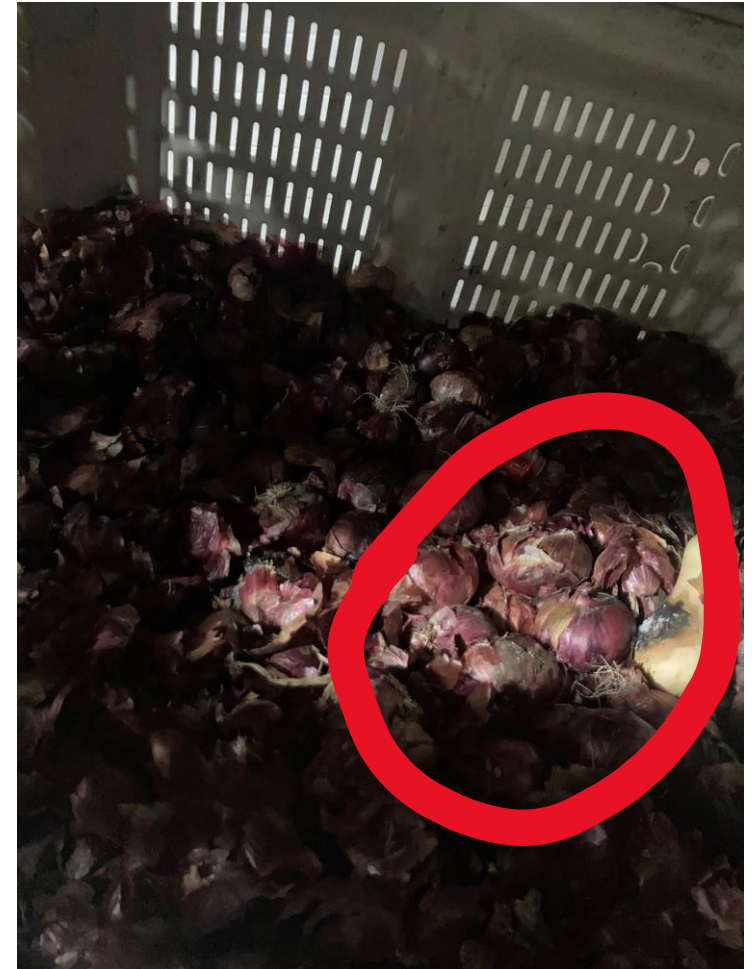
For-Cause Inspection – Positive Squash Sample

- Received notice on 7/7/22 from FDA about positive *Listeria monocytogenes* sample from squash in GA (Harvested and Shipped from South Carolina)
- 40 cases were sliced in the facility
- Reached out to GA DOA Manufactured Food team to make them aware and to inspect the facility in GA
- DHEC Lab was contacted to coordinate sample drop off and preparation needed
- Scheduled inspection on 7/13/22
- Presumptive positive swab on wash tank
- Farm has an inspection in early June with our team

There is it! That
tank tested
positive!



Photos taken during Inspection





What's
wrong with
this picture?

What happened after the Inspection?

- Talked with Farm Manager, Farm Management, Harvesting Manager
- Produce Safety Team spoke with GA to get update with their inspection at the GA processing facility.
 - Swabs/Samples were negative
- There were Listeria M. positives on produce taken from a different lot
- Processor was hesitant to buy from farm
- Farm wanted to know what they could do to get sales back
 - Between buyer/seller, TRUST!

Consumer Confidence

Romaine Lettuce E. Coli Outbreak

- November 2018 – January 2019
- Supply Chain disaster
 - Growers, Processors, Shippers, Wholesalers, Retail Outlets, and Foodservice Establishments
- Big price fluctuations
- Consumption goes down (2018/2019 down, 2020 back up)
- Consumers forgive and forget

Palm Springs, CA 2/2/19

- FDA training for Regulatory Inspections
- Very Large Producer bagging Romaine Lettuce for Wegmans (PA favorite)
- Very clean operation
- 2 weeks later I flew home to PA
- My mother bought Romaine from the same company/date/product on 2/2/19. (3,000 miles away)
- Do you think I was confident that food safety practices were being followed? How do you think my confidence level was?

Questions?



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Compliance

2022 Positive Sample Investigations in South Carolina

Shay Frankenfield



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Summary

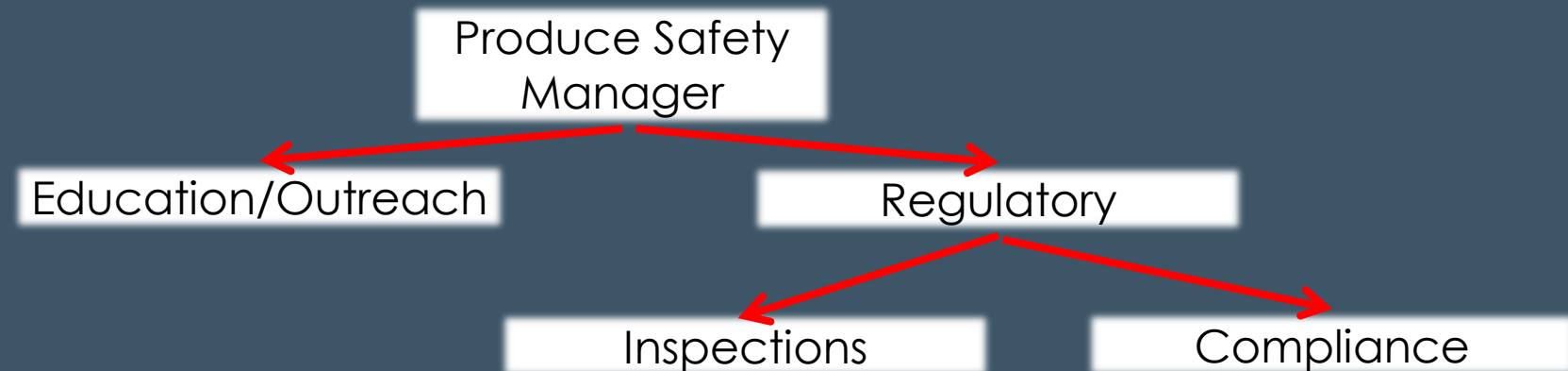
- South Carolina Produce Safety
- Positive Sample Investigations – Peach and Squash
- Considerations and Takeaways
- Questions

SC Produce Safety Team



How is SC Produce Safety Team Organized?

- Path C
- Regulatory and Education branches (includes cross-training)
- Member of SC Emergency Management Division and SC Rapid Response Team



Enforcement Actions

- Follow-up Inspection
- For-cause Inspection
- Regulatory Warning Letter
- Stop Sale
- Office Hearing
- Voluntary Recall
- Civil Penalties

Follow-up vs For-cause Inspections

Follow-up Inspection

- Stems from initial/routine/for-cause inspections
- allows review of an issue or concern that was noted on a previous inspection report

Re-inspection

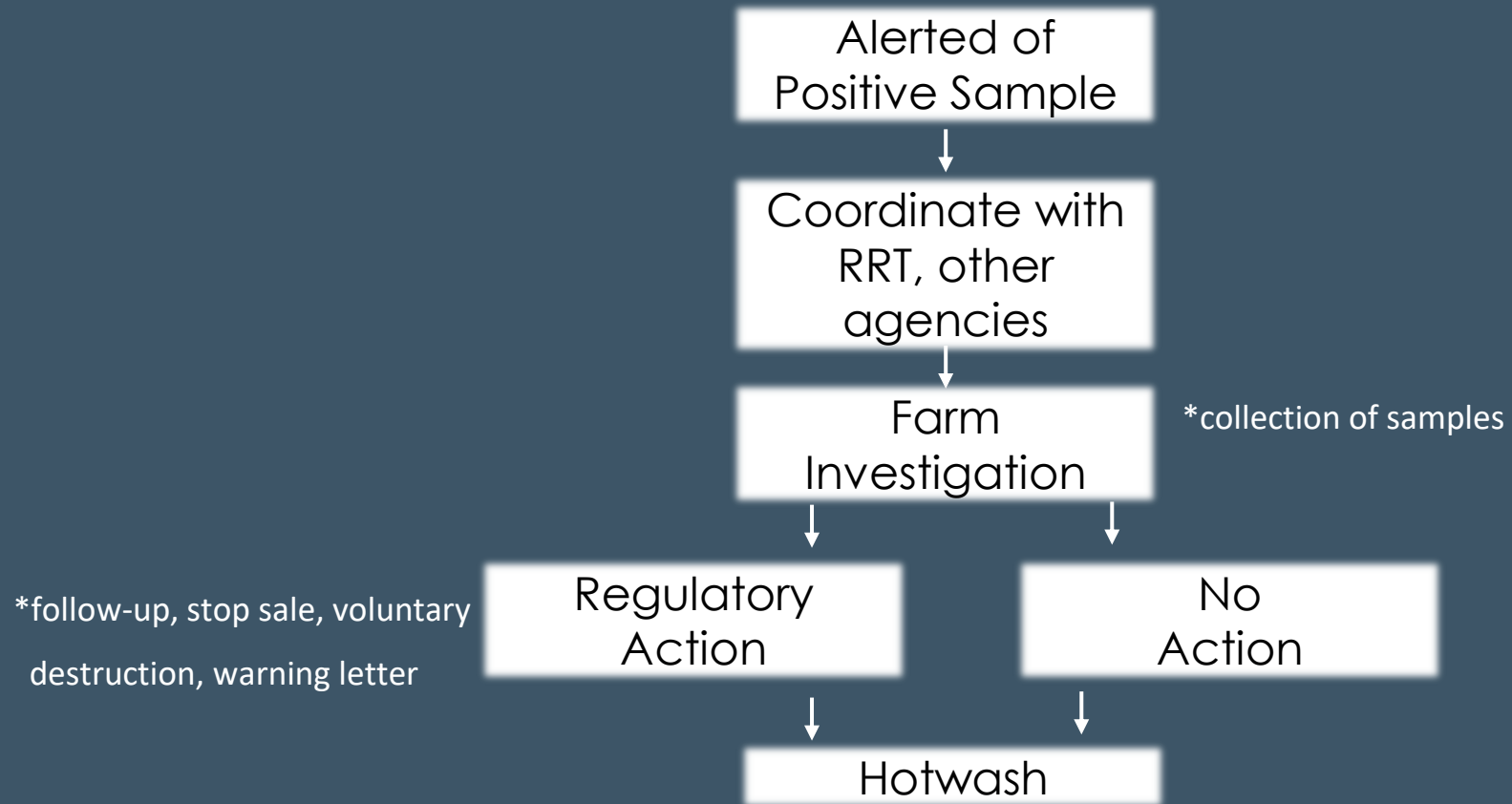
- Can occur after initial, routine or for-cause inspection
- Requires comprehensive inspection instead of review of minor issues (CO will be present)

For-cause Inspection

- Stems from emergency situations such as complaints, outbreaks, recalls, etc
- allows review of an issue or concern noted from an outside source



Positive Sample Process

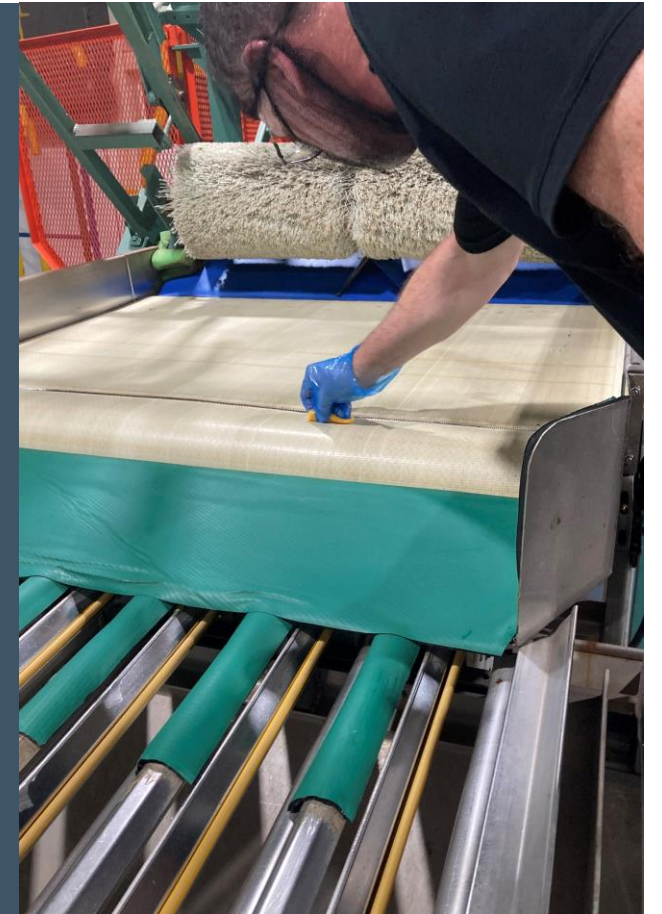




Peach Farm Investigation

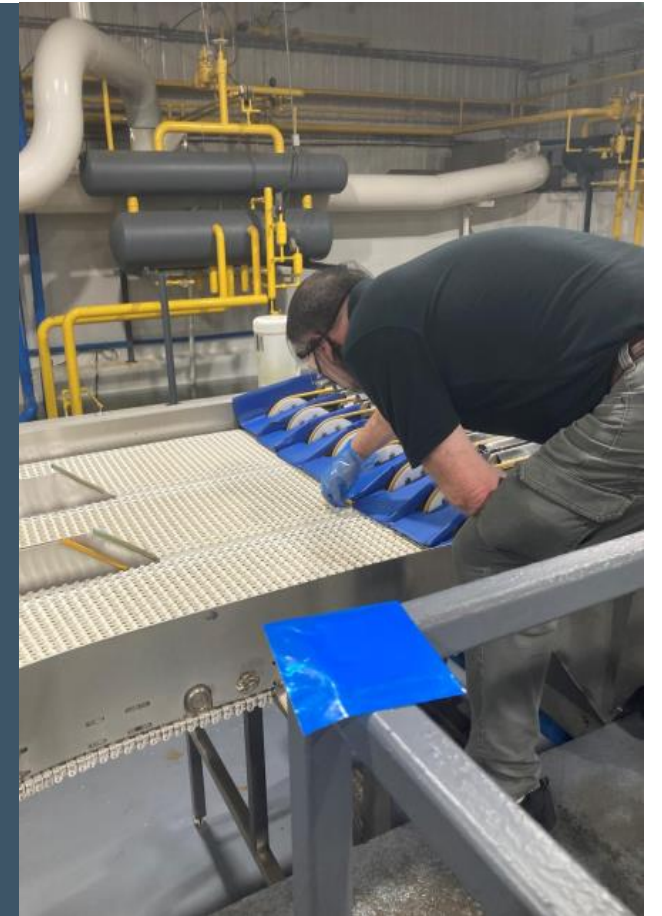
Peach Farm – Timeline of Events

- June 27th, 2022 (Monday) – alerted of positive *Listeria Monocytogenes* product sample
 - SC->IN wholesaler->MI processor, tested with LFFM in Michigan
- June 28th, 2022 (Tuesday) – call with MDARD, FDA, farm, legal team and SC RRT
- June 30th, 2022 (Thursday) - On-farm investigation with sample collection
- July 1st, 2022 (Friday) - Samples at lab for processing
- July 11th, 2022 – Lab testing, reswabbing, hotwash completed



Peach Farm – Swabbing Results

- 50 samples collected for testing at DHEC laboratory
 - 44 environmental samples
 - 1 positive for LM on “bumpers” at beginning of pack line
 - Bumpers were recleaned and swabbed internally by the farm
 - 6 product samples (not representative samples)
 - No + product samples
- Product tested at wholesaler was negative
- No product left at farm



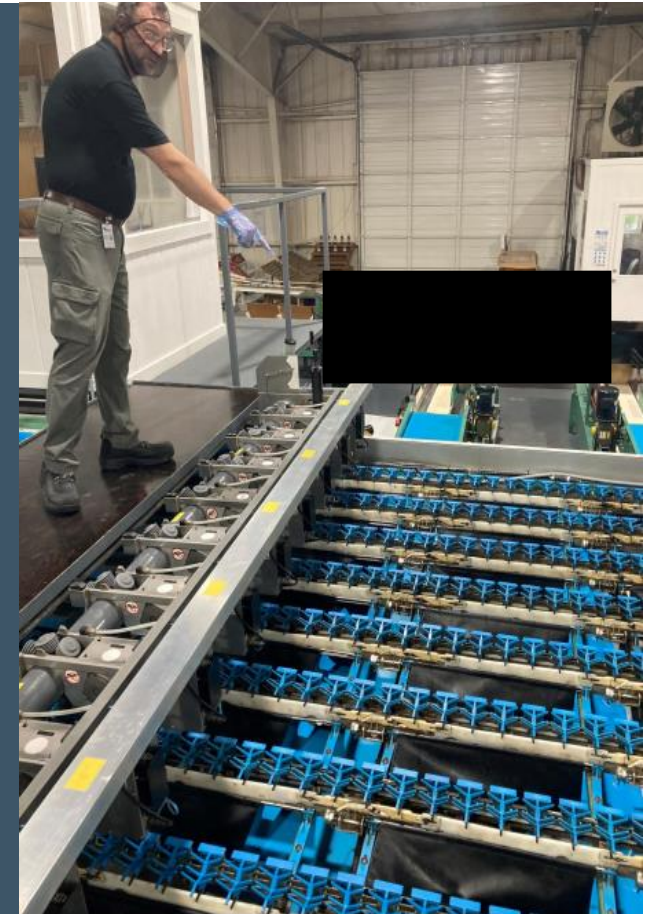
Peach Farm – Compliance Actions

- For-cause inspection at time of sampling by team of inspectors
- Sampling performed by compliance simultaneously to investigate LM positive
- Follow-up inspection performed to verify CA for issues spotted during For-Cause inspection
- No additional compliance actions necessary beyond FC and sampling



Peach Farm – Decision Rationale

- No more swabs taken by SCDA after first visit
 - + on food contact surface, but it was cleaned/replaced
 - Location reswabbed by farm, no additional product ran thru between then (scope)
 - There to investigate what we see, not incriminate beyond that
- Follow-up vs re-inspection
 - Farm was not exhibiting egregious conditions during the inspection process regardless of swab results
 - Inspection frequency increased instead



The background of the slide features several green zucchinis of varying sizes and orientations, set against a dark teal or blue-green background. The zucchinis are slightly out of focus, creating a soft, naturalistic feel. The entire image is framed by a thin, solid orange border.

Squash Farm Investigation

Squash Farm

- July 7th 2022 (Thursday) - alerted of positive sample of *Listeria Monocytogenes* by FDA
 - Squash sliced by processor in GA, tested internally
- July 8th, 2022 (Friday) - Call with GA Manufactured Foods, RRT, and farm
- July 12th, 2022 (Tuesday) - On-farm investigation with sample collection scheduled (peaches and pickling cucumbers)
- July 13th, 2022 (Wednesday) – On-farm investigation performed
- July 13th, 2022 (Wednesday) – samples at lab for processing
- July 15th for additional swabbing due to + results of product and environmental (stop sale put in place)
- July 18th (Monday) - voluntary destruction of product
- July 22nd (Friday) stop sale lifted
- Lab results, hotwash completed by late August



Squash Farm – Swabbing Results

First Visit

- 16 samples collected
- + environmental and squash samples (1 of each)
 - Wash tank in harvest fields came back positive, isolated and re-cleaned

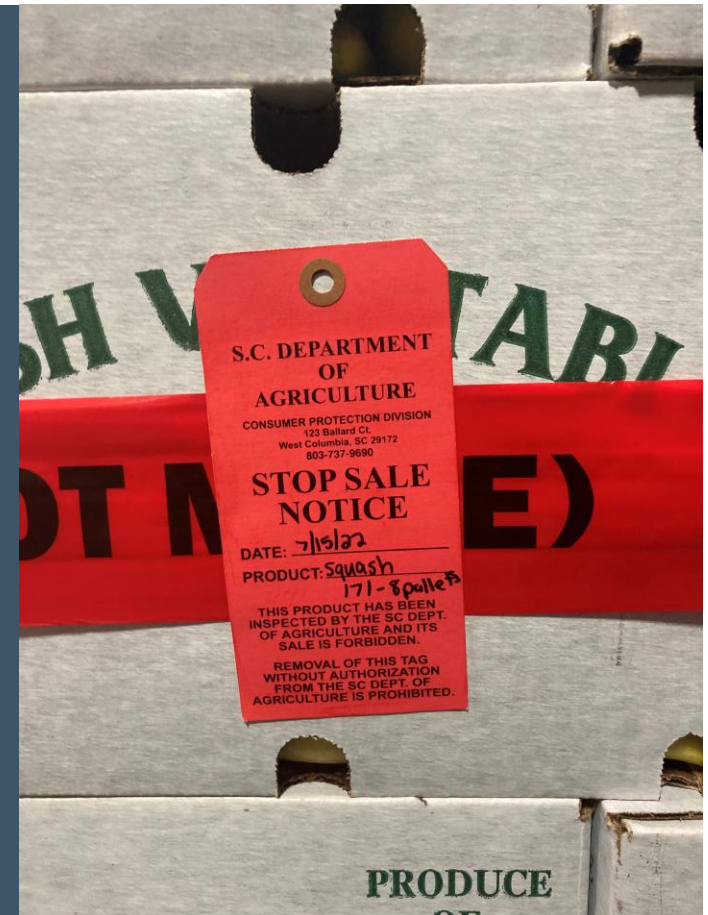
• Second Visit

- 13 samples collected
- Response to first sampling event
 - Wash tank reswabbed and additional product samples collected
- - environmental and product samples



Squash Farm – Compliance Actions

- For-cause inspection was performed at time of sampling by regulatory team to enforce provisions in PSR
- Sampling performed by compliance simultaneously to investigate LM positive
- Voluntary Destruction performed on product that came back positive
- Stop sale occurred for second visit's swabs until negative results received
- No follow-up or reinspection performed



Squash Farm – Decision Rationale

- SCDA took additional swabs on a second visit to the farm
 - Response to + on food contact surface AND product
 - Additional product had been harvested and was scheduled to be
 - Farm was not able to internally swab but risk present
 - Wash tank was being used for more than just squash
- Voluntary Destruction – product tested positive for LM
 - Farm decided not worth the risk to public health
- Stop Sale – lifted due to there being no tangible, definitive proof of risk to additional harvested product
- Farm was not exhibiting egregious conditions during the inspection process regardless of swab results
 - Inspection frequency increased instead



The background of the slide features several green cucumbers of various sizes and orientations, set against a dark blue, slightly textured background. The cucumbers are rendered with a soft, semi-transparent effect, allowing the blue background to show through. The entire composition is enclosed within a thin, solid orange border.

Investigation Takeaways

Possible Challenges



- Experience
 - Have you experienced a positive sample investigation before?
 - What do you know about the pathogens you're testing for?
- Bias
 - Correlation \neq causation
 - Previous interactions with farm
- Limitations
 - What jurisdiction/rights do you have?
 - What's your justification/limitations when it comes to swabbing?
- Pushback from farm
 - "Why are you here", "This is going to harm our business", "You guys are trying to find a reason to shut me down"
 - Important educate while you regulate moment
- Liability
 - "Can you come retest for us?", "If the results are negative, we are ok, right?", "Should we destroy our product?"

Possible Challenges (cont.)



- Consistency
 - Are your observations relevant to the investigation?
 - Are you being fair in regard to previous inspections?
 - Do not link things together that aren't linkable
- Budget constraints
 - Are you able to purchase and maintain swabbing supply?
 - Collaboration with other agencies?
- Timeframes for response
 - How long to perform corrective actions?
 - Make sure to follow-up and take accurate notes
- Further action
 - Will the situation need to be escalated?
 - Keep communication lines open while staying professional

Questions?



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