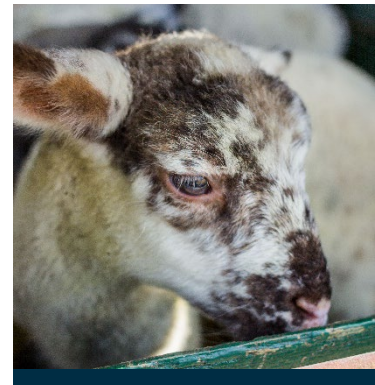
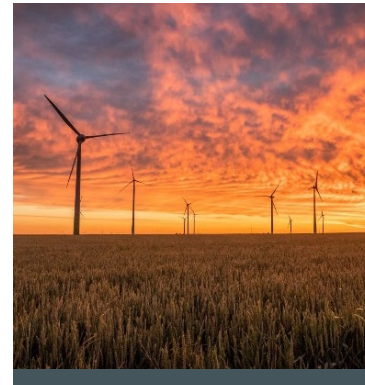


Root Cause Analysis from a Regulatory Framework

Listeria monocytogenes in Hydroponic Leafy Greens



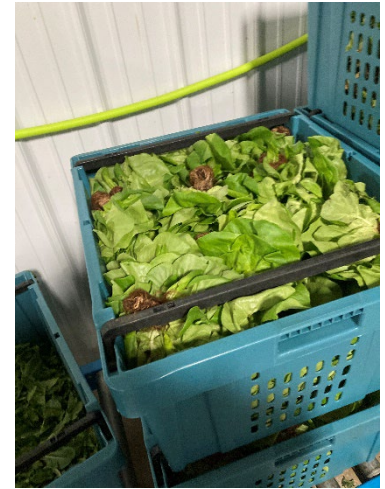
Emily Hollingsworth
Retail Food Program Manager
Bureau of Food Safety and Animal Health

Investigations, Environmental Assessments, and Root Cause Analysis

- Prior to entering firm
 - Know your target organism(s)
 - Make a plan
 - Put together a team – 4 eyes and ears are better than 2
- During investigation
 - Take your time
 - Be ready to scrap your plan
 - Violations don't matter
 - Follow every lead – curiosity is king
 - Share findings as you go
 - Phone a friend
- Post-inspection - RCA
 - Compare notes
 - Don't fear the follow-up question or visit
 - Outbreak details

Hydroponic Farm

- Three-acre greenhouse
- Grows, harvests, and packs a variety of leafy greens
 - Deep water culture (DWC) approx. 1 acre – “Living lettuce” and “cut lettuce”
 - Automated gutter system (AGS) approx. 1 acre – “Teenage lettuce”
- Initial FSMA/PSR Inspection in 2020
 - Several discussion points on the report, including:
 - Cleaning methods (**power washing**) of DWC rafts
 - Flow of rafts from grow, harvest, cleaning, storage areas
 - Storage of cleaning of pole used in DWC





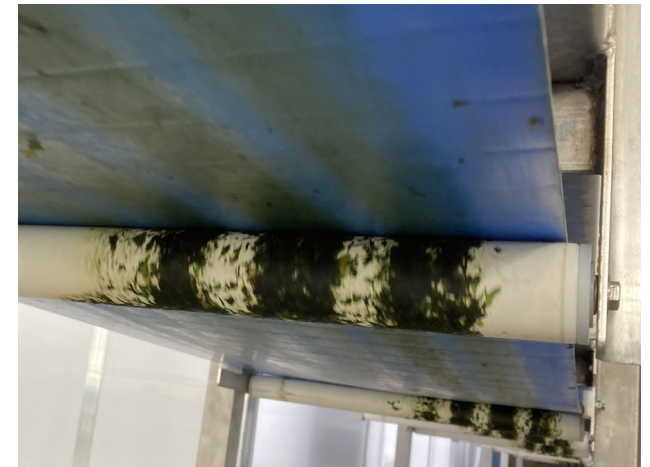
How did we end up here?

- Product sampled from marketplace on March 22
- Positive for *Listeria monocytogenes*
- Two isolates were sent to the Michigan Department of Health and Human Services (MDHHS) for analysis and comparison with Whole Genome Sequencing (WGS)
 - Very closely related (4 bp) to outbreak strain from year prior with multiple hospitalizations and one death.



Investigation & Root Cause Analysis

- Violations observed
 - Condensate buildup and drip
 - Roof leaks
 - Excessive pooled water
 - Power washing in areas where *Listeria* spp. had been found in EMP
 - Inadequate sanitation procedures
 - Overall lack of managerial control and understanding of GAPs
- **Additional contributing factors**



Non-violative conditions that may contribute

No treatment of harvest/post harvest agricultural water in DWC greenhouse

Shore flies

Lack of a clean break established at a routine frequency

Commingling products from outside farms with no clean breaks

Color-coded system for cleaning implements, farm was not implementing or monitoring

Additional roof leaks in the visitor entrance/waiting area – physical facilities

Food Safety culture and basics lacking

- ~ False sense of security – indoor is safer!, captive shoe policy, boot washes, EMP
- ~ Lack of communication between leadership and staff

Throughout the Day

- Sanitize bottoms of waste IBC totes
- Sanitize pallet jack each time it exits the facility

Start of Shift

- Make the sanitizer solution for the Raft Cleaning Machine
 1. Fill to 275 gallons with water (this takes about an hour)
 2. Add 6 liters of SaniDate 5.0
 3. Check and document the reading
- Sanitize pallets for clean and dirty rafts
- Empty red Zone 3 tub and allow for tools to dry

Before Breaks

- Empty back bins from below rails into waste IBC totes
- Empty all black bins from Harvest Room into the waste IBC totes
- Sweep debris from around area
- Power wash area
- Use injector to sanitize all areas/items 8 feet down and floors (garage door, walls, rails, tools, dunnage rack, etc.)

After Breaks

- Squeegee all sanitizer down drain
- Check and document the reading of the sanitizer solution
 1. Re-make the sanitizer solution for the Raft Cleaning Machine if necessary

End of Shift

- Move all full pallets of clean rafts down the hallway to the entrance to the greenhouse
 - Empty back bins from below rails into waste IBC totes
 - Empty all black bins from Harvest Room into the waste IBC totes
 - Sweep debris from around area
 - Clean raft washing machine
 1. Empty IBC by disconnecting both pumps and letting IBC drain
 2. Remove pump from washing machine water pan
 3. Pull bottom water pan from under machine and empty, spray w/ SaniDate injector
 4. Spray out inside of machine with SaniDate injector
 5. Spray down water pan pump with SaniDate injector
 6. Remove filter from floor pump (clear plastic lid) and spray clean w/ SaniDate
 7. Clean floor under IBC
 8. Clean floor under raft washing machine
 9. Re-assemble in reverse order
 - Power wash area
 - Use injector to sanitize all areas/items 8 feet down and floors (garage door, walls, rails, tools, dunnage rack)
- Let the sanitizer sit for 1 minute
1. This includes the back-hall floors and rails
 2. After 1 minute, squeegee the excess water into the drains

ope.

| Sample Name | Lab Sample ID | MATRIX | E. coli spp. AOAC 991.14 cfu/area | Listeria spp. AOAC 2014.06 Present/Absent | Salmonella AOAC 2013.09 Present/Absent | Date/Time Sampled: |
|---|------------------|--------|---|---|--|--------------------|
| R.W. FLOOR IN FRONT OF ROLL-UP DOOR | 1122221410FL-001 | Swab | 10 | ABSENT | - | 11/22/2022 8:00 |
| R.W. FLOOR 1E1S UNDER SLIDING DOOR | 1122221410FL-002 | Swab | <10 | PRESENT | - | 11/22/2022 8:05 |
| R.W. FLOOR 2E3S | 1122221410FL-003 | Swab | 20 | ABSENT | - | 11/22/2022 8:10 |
| P.C. SINK BACKSPASH | 1122221410FL-004 | Swab | <10 | - | ABSENT | 11/22/2022 8:15 |
| P.C. DOOR ENTRANCE EE ENTRANCE | 1122221410FL-005 | Swab | <10 | - | ABSENT | 11/22/2022 8:20 |
| FLOOR-EE BREAKROOM IN FRONT OF DOOR TO FACILITY | 1122221410FL-006 | Swab | <10 | ABSENT | - | 11/22/2022 8:25 |
| NURSERY TRAY TABLE RACKS #1 | 1122221410FL-007 | Swab | <10 | ABSENT | - | 11/22/2022 11:15 |
| NURSERY GROWING TABLE #3 | 1122221410FL-008 | Swab | >2500 | ABSENT | - | 11/22/2022 11:20 |
| NURSERY FLOOR SE1S | 1122221410FL-009 | Swab | >2500 | ABSENT | - | 11/22/2022 11:25 |
| NURSERY FLOOR BEHIND W. RO RETURN | 1122221410FL-010 | Swab | >2500 | ABSENT | - | 11/22/2022 11:30 |

| Sample Name | Lab Sample ID | MATRIX | Listeria spp. AOAC 2014.06 Present/Absent | APC AOAC 998.12 cfu/area | E. coli spp. AOAC 991.14 cfu/area | Salmonella AOAC 2013.09 Present/Absent | Date/Time Sampled: |
|-----------------------------------|------------------|--------|---|--------------------------------|---|--|--------------------|
| LOCKER ROOM FLOOR | 0104221544FL-001 | Swab | - | 1,920,000 | 20 | ABSENT | 1/4/2022 11:40 |
| FLOOR @ SR PED DOOR | 0104221544FL-002 | Swab | ABSENT | 510,000 | <10 | - | 1/4/2022 11:45 |
| FLOOR UNDER RAFT WASH CATCH BASIN | 0104221544FL-003 | Swab | PRESENT | >5,000,000 | 20 | - | 1/4/2022 11:50 |
| WALL SEC 3 NORTH @ FLOOR RC | 0104221544FL-004 | Swab | ABSENT | >5,000,000 | <10 | - | 1/4/2022 11:55 |
| FLOOR SEC 25SE @ WOOD PALLETS RC | 0104221544FL-005 | Swab | ABSENT | >5,000,000 | 10 | - | 1/4/2022 12:00 |

| Sample Name | Lab Sample ID | MATRIX | L. monocytogenes AOAC 2014.07 Present/Absent | Date/Time Sampled: |
|--|------------------|--------|--|--------------------|
| RAFT WASH AREA FLOOR IN FRNT OF ROLL-UP DOOR | 1102221030FL-010 | Swab | PRESENT | 11/1/2022 12:15 |

| Sample Name | Lab Sample ID | MATRIX | E. coli spp. AOAC 991.14 cfu/area | Listeria spp. AOAC 2014.06 Present/Absent | Salmonella AOAC 2013.09 Present/Absent | Date/Time Sampled: |
|---|------------------|--------|---|---|--|--------------------|
| MIX AREA: 1S1E FLOOR | 1102221030FL-001 | Swab | <10 | ABSENT | - | 11/1/2022 11:30 |
| SR HALLWAY-6E4S FLOOR AGAINST P.C. WALL | 1102221030FL-002 | Swab | >2500 | ABSENT | - | 11/1/2022 11:35 |
| SR-FLOOR IN FRONT OF SHED DOCK A OF PS#7 | 1102221030FL-003 | Swab | >2500 | ABSENT | - | 11/1/2022 11:40 |
| SR-FLOOR IN FRNT OF ROLLUP DOOR TO P.C. | 1102221030FL-004 | Swab | <10 | ABSENT | - | 11/1/2022 11:45 |
| SR-S DOOR TO P.C. EE ENTRANCE | 1102221030FL-005 | Swab | <10 | - | ABSENT | 11/1/2022 11:50 |
| SR-FLOOR IN FRNT OF DOOR TO OUTSIDE IN OFFICE | 1102221030FL-006 | Swab | <10 | ABSENT | - | 11/1/2022 11:55 |
| SR-HANDSINK BK SPLASH IN OFFICE | 1102221030FL-007 | Swab | >2500 | - | ABSENT | 11/1/2022 12:00 |
| RAFT WASH AREA: 6E3S TRENCH DRAIN | 1102221030FL-008 | Swab | >2500 | ABSENT | - | 11/1/2022 12:05 |
| 12GRAB AREA FLOOR IN FRNT OF DOOR TO OUTSIDE | 1102221030FL-009 | Swab | <10 | ABSENT | - | 11/1/2022 12:10 |
| RAFT WASH AREA: FLOOR IN FRNT OF ROLL-UP DOOR | 1102221030FL-010 | Swab | >2500 | PRESENT | - | 11/1/2022 12:15 |

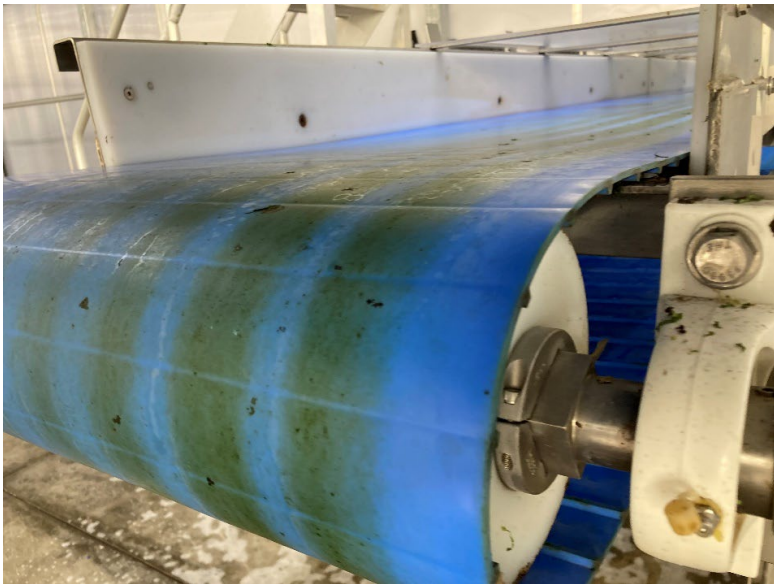
| Sample Name | Lab Sample ID | MATRIX | E. coli spp. AOAC 991.14 cfu/area | Listeria spp. AOAC 2014.06 Present/Absent | Salmonella AOAC 2013.09 Present/Absent | Date/Time Sampled: |
|---|------------------|--------|---|---|--|--------------------|
| RAFT WASH AREA FLOOR IN FRONT OF ROLL-UP DOOR | 1108221350FL-001 | Swab | >2500 | ABSENT | - | 11/8/2022 7:50 |
| P2 H.R. CONV. OUTSIDE OF GUARD N. SIDE | 1108221350FL-002 | Swab | <10 | - | ABSENT | 11/8/2022 7:55 |
| P2 H.R. SUPPORT LEG INC. CONV. N. SIDE | 1108221350FL-003 | Swab | <10 | ABSENT | - | 11/8/2022 8:00 |
| P2 H.R. FLOOR ENTRANCE FROM SEEDING AREA | 1108221350FL-004 | Swab | <10 | ABSENT | - | 11/8/2022 8:05 |
| P2 H.R. TENSIONER ON P.C. CONV. N. SIDE | 1108221350FL-005 | Swab | <10 | - | ABSENT | 11/8/2022 8:10 |
| P2 H.R. FLOOR 2S1W | 1108221350FL-006 | Swab | <10 | ABSENT | - | 11/8/2022 8:15 |
| NURSERY DRAIN ST SECTION 10 | 1108221350FL-007 | Swab | >2500 | ABSENT | - | 11/8/2022 9:55 |
| RAFT WASH FLOOR: SE4S | 1108221350FL-008 | Swab | >2500 | PRESENT | - | 11/8/2022 10:00 |
| RAFT WASH FLOOR 1S1E | 1108221350FL-009 | Swab | <10 | PRESENT | - | 11/8/2022 10:05 |
| RAFT WASH ROLL-UP DOOR | 1108221350FL-010 | Swab | >2500 | ABSENT | - | 11/8/2022 10:10 |

Environmental Monitoring Program

- Eight positives for Listeria spp. in 2022 in the raft wash area where power washing was taking place no less than two times a day in the presence of “clean” food contact surfaces
- Floor scrubber/pallet jacks









Impacts can be devastating

- Total of 442,247 lbs. and \$1,024,003.00 worth of product seized and discarded
- Regulatory Investigation and RCA took more than 40 days to complete, with more than 250 man-hours.
- Farm's RCA and associated CAPA took them 24 days to complete. They also hired outside help.







Corrective Action Plan and Root Cause Analysis

Received from the farm

- Root Cause Analysis – Source of LM on farm
 - Greens from other supplies that have been:
 - Comingled or on shared equipment
 - Possible contaminated seeds, peat, or pallets used in growing/harvesting areas
 - ***Farm concluded that LM was likely transferred throughout the facility and onto food contact surfaces/finished product via high pressure washing methods***
- Corrective action plan
 - High pressure washer was removed from the farm
 - Condensate Policy and continuous monitoring and corrective action
 - Moved raft-wash area
 - Increased frequency for cleaning and sanitizing for food contact surfaces



Challenges to Root Cause Analysis

- As a regulator
 - We only know what we see, ask, and are told
 - Snapshot in time
 - We have limited time and resources
 - EA guidance docs are long and cumbersome
 - Firms and farms have a vested interest in mitigating damages and not sharing what they know
 - RCA is very complex and often no answer

