Controlling *Listeria* in produce facilities and packing houses: a webinar series

Webinar 1: “FSMA and Listeria 101”
Tuesday, October 8th, 1-2 PM EST

Webinar 2: “Listeria Environmental Monitoring Programs”
Tuesday, October 15th, 1-2 PM EST
Food Safety Modernization Act: Applicable Packinghouse Requirements

Gretchen Wall, M.S.
Produce Safety Alliance
October 8, 2019
FSMA Definitions

• Farm versus Facility
  – Farm → Produce Safety Rule
  – Facility → Preventive Controls Rule

• Not all farms were created equal (in FDA’s eyes)
  – Primary production farm
  – Secondary activities farm

• Guidance released Aug. 2016
  – Provided clarification on farm activities
  – Did not provide clarification on terms “under one management” or “in one general physical location”
Why Does Ownership of the Farm or Facility Matter for Food Safety?

From a risk perspective, doing the same type of activity, regardless of ownership or location, should not matter to food safety or dictate which regulation the operation falls under.
Enforcement Discretion Guidance

- In January 2018, FDA announced that they plan to exercise enforcement discretion.
- This means farms/packinghouses that were considered a ‘secondary activities farm’ except for the ownership of the facility are not subject to the PC Rule until the completion of a future rulemaking related to farm activities.
### Produce Safety Rule Compliance

<table>
<thead>
<tr>
<th>Business Size</th>
<th>Years to Comply</th>
</tr>
</thead>
<tbody>
<tr>
<td>All other businesses (&gt;$500K)</td>
<td>1/26/2018</td>
</tr>
<tr>
<td>Small businesses (&gt;$250K-500K)</td>
<td>1/28/2019</td>
</tr>
<tr>
<td>Very small businesses (&gt;$25K-250K)</td>
<td>1/27/2020</td>
</tr>
</tbody>
</table>

*Compliance dates for the agricultural water requirements allow an additional four years beyond each of these compliance dates.*
Off-Farm Packinghouses Still Subject to cGMPs

• Can choose to follow cGMPs (117 Subpart B) or applicable requirements under the Produce Safety Rule

• Some Preventive Control requirements do not have analogues in the Produce Rule:
  – Product testing or environmental monitoring not required in facilities that process, pack, or hold produce RACs as per Produce Safety Rule requirements
  – However, if produce is contaminated with a pathogen, product will be considered adulterated
Pathogens Don’t Discriminate!
Subparts of the Produce Safety Rule

• A – General Provisions
• B – General Requirements
• C – Personnel Qualifications and Training
• D – Health and Hygiene
• E – Agricultural Water
• F – Biological Soil Amendments of Animal Origin and Human Waste
• I – Domesticated and Wild Animals
• K – Growing, Harvesting, Packing, and Holding Activities
• L – Equipment, Buildings, Tools, and Sanitation
• M – Sprouts
• N – Analytical Methods
• O – Records
• P, Q, R – Variances, Compliance, and Withdrawal of Qualified Exemptions
Training Requirements: Field Harvesters

• Workers who harvest must be trained to:
  – Recognize when produce cannot be harvested due to contamination risks
  – Inspect harvest containers and equipment to be sure they are functioning properly, clean, and maintained
  – Correct and report problems with harvest containers or equipment
  – Not distribute dropped covered produce
Equipment, Tools, and Sanitation

- Must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained.
- Must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.
- Must maintain and clean all non-food contact surfaces or equipment and tools used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.
Recirculated and Batch Water

- Must have no detectable generic *E. coli* in 100 mL sample at the beginning of use and maintain safe and adequate sanitary quality throughout use
- Treatment is not required but can be used to maintain water quality and reduce cross-contamination risks
- Any antimicrobial product used in the water must be labeled for use with fruits and vegetables
- A schedule must be established for changing batch water or a process in place for minimizing the build-up of organic material in the water
Packing Area Maintenance

• Regularly inspect and maintain equipment to avoid:
  – Cracked hoses, torn rubber door seals
  – Standing water
  – Dirty conveyor belts, brushes, and rusty equipment
  – Condensation: Especially from walls, ceilings, cooling equipment, and pipes over packing lines and in storage areas

• All workers must be trained so they know how to identify and reduce risks
Cold Storage Areas

• Inspect regularly to ensure the area is clean and the cooling equipment is functioning properly
  – No condensation or dripping on produce
  – Door and window seals are intact
• A cleaning and pest management program should be established for all storage areas
• Cooling is not required, but if used, do it properly (i.e., be sure thermometers are calibrated and temps are appropriate for commodity)!
Final Thoughts

• Regardless of regulatory status, practices can be implemented in ALL facilities to help address produce safety risks
• Even if you are exempt from the Produce Safety Rule, your packinghouse/farm may not be exempt from buyer requirements or other industry standards
• Best way to be prepared is to:
  – Gain as much knowledge as possible
  – Develop a food safety plan
    (if you don’t already have one)
  – Ask questions!
• We’re here to help!
For more information visit: producesafetyalliance.cornell.edu

Join the PSA Listserv

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Watch us on YouTube
FSMA Preventive Controls Rule: environmental monitoring

Alexandra Belias
amb629@cornell.edu
October 8th, 2019
Key FSMA requirements for food safety systems

• Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls.

• Requirements include:
  – Hazard analysis
  – Preventive controls
  – Oversight and management of preventive controls
PC rule and environmental monitoring

- 21 CFR 117.130 Hazard analysis
- 21 CFR 117.135 Preventive controls
- 21 CFR 117.150 Corrective actions and corrections
- 21 CFR 117.165 Verification of implementation and effectiveness
- 21 CFR 117.180(a) Requirements applicable to a preventative controls qualified individual and a qualified auditor
PC rule and environmental monitoring

PART 117 -- CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart C--Hazard Analysis and Risk-Based Preventive Controls

Sec. 117.165 Verification of implementation and effectiveness.

(a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);

(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and
(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by 117.150(a)(1).
Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry

*Draft Guidance*
Draft Guidance

• Released in addition to FSMA to give more specific recommendations on how to control Listeria within processing plants
• Gives suggestions on what should be included in an environmental monitoring program and potential corrective actions for positive results
Listeria 101: Basic Microbiology & Impacts to Produce Packing and Processing

Alexandra Belias
amb629@cornell.edu
October 8th, 2019
Illness, hospitalizations, and deaths

• Each year, foodborne *L. monocytogenes* in the United States is estimated to cause:
  – Approx. 1,600 illnesses
  – Approx. 1,400 hospitalizations
  – Approx. 250 deaths

• *L. monocytogenes* is the third leading cause of death in the United States

Top five pathogens contributing to domestically acquired foodborne illnesses resulting in death:

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Estimated Number of Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Salmonella</em>, nontyphoidal</td>
<td>378</td>
</tr>
<tr>
<td><em>Toxoplasma gondii</em></td>
<td>327</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>255</td>
</tr>
<tr>
<td>Norovirus</td>
<td>149</td>
</tr>
<tr>
<td><em>Campylobacter</em> spp.</td>
<td>76</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Norovirus</td>
<td>5,461,731</td>
</tr>
<tr>
<td><em>Salmonella</em>, nontyphoidal</td>
<td>1,027,561</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em></td>
<td>965,958</td>
</tr>
<tr>
<td><em>Campylobacter</em> spp.</td>
<td>845,024</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>241,148</td>
</tr>
</tbody>
</table>

L. monocytogenes illness

- Can have up to an incubation period of up to 3 months
- Can range from mild gastroenteritis (nausea, vomiting, aches, fever) to more severe infections (listerialiosis)
- Listeriosis is a systemic infection:
  - Can cross the placental barrier to cause spontaneous abortions
  - Can cross the blood-brain barrier to cause meningitis

https://www.cdc.gov/listeria/index.html
Who is most at risk?

<table>
<thead>
<tr>
<th>YOPIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young</td>
</tr>
<tr>
<td>Old</td>
</tr>
<tr>
<td>Pregnant</td>
</tr>
<tr>
<td>Immunocompromised</td>
</tr>
</tbody>
</table>
Listeria monocytogenes and produce outbreaks

- 1981: Outbreak in Canada linked to coleslaw
- 2009: Outbreak linked to sprouts
- 2010: Outbreak linked to diced celery in Texas (10 cases)
  - FDA investigation of facility included >200 environmental and 19 product samples; outbreak strains was detected in environmental and product samples
- 2011: Outbreak linked to cantaloupe: 147 illnesses, 33 deaths, and 1 miscarriage (28 states)
- 2013-2016: Outbreak linked to Frozen Vegetables. 9 cases, 3 deaths.
- 2014: Listeria found in fresh stone fruits, resulting in recall. Isolates subsequently linked to two clinical cases.
- 2014-2015: Outbreak linked to Commercially Produced, Prepackaged Caramel Apples. 35 cases, 7 deaths. 11 illnesses were pregnancy-related. Tied to apple packing facility.
- 2016-2016: Outbreak linked to Packaged Salads. 19 cases, 1 death.
- 2018: Outbreak linked to Australian Rockmelons (cantaloupe). 20 cases, 7 deaths, one miscarriage.
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Multistate outbreak of Listeriosis linked to cantaloupes

- 147 illnesses
- 143 hospitalization
- 33 deaths

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2016 Packaged Salad Outbreak

People infected with the outbreak strain of *Listeria monocytogenes*, by state of residence, as of March 25, 2016 (n=19)

- 19 illnesses, 19 hospitalizations, 1 death in the US (CDC, 2016)
- 14 illnesses in Canada (Public Health Agency of Canada, 2016)
- All packaged salads were linked to a single facility
Listeria Outbreaks and Incidence, 1983-2014

<table>
<thead>
<tr>
<th>Era</th>
<th>Pre-PulseNet</th>
<th>Early PulseNet</th>
<th>Listeria Initiative</th>
<th>WGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outbreaks per year</td>
<td>0.3</td>
<td>2.3</td>
<td>2.9</td>
<td>8</td>
</tr>
<tr>
<td>Median cases per outbreak</td>
<td>69</td>
<td>11</td>
<td>5.5</td>
<td>4.5</td>
</tr>
</tbody>
</table>

No. outbreaks

<table>
<thead>
<tr>
<th>Year</th>
<th>Outbreaks</th>
<th>Incidence (per million pop)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1983</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>1986</td>
<td>1</td>
<td>2.3</td>
</tr>
<tr>
<td>1989</td>
<td>1</td>
<td>2.3</td>
</tr>
<tr>
<td>1992</td>
<td>2</td>
<td>2.3</td>
</tr>
<tr>
<td>1995</td>
<td>3</td>
<td>2.3</td>
</tr>
<tr>
<td>1998</td>
<td>3</td>
<td>2.3</td>
</tr>
<tr>
<td>2001</td>
<td>2</td>
<td>2.9</td>
</tr>
<tr>
<td>2004</td>
<td>1</td>
<td>2.9</td>
</tr>
<tr>
<td>2007</td>
<td>2</td>
<td>2.9</td>
</tr>
<tr>
<td>2010</td>
<td>3</td>
<td>2.9</td>
</tr>
<tr>
<td>2013</td>
<td>4</td>
<td>2.9</td>
</tr>
</tbody>
</table>

Data are preliminary and subject to change

Provided by Peter Gerner-Smidt
Subtyping

• Tools which allow sensitive differentiation of bacterial subtypes
  – Detection of contamination sources
• Strain differentiation methods commonly applied include serotyping, ribotyping, Pulsed Field Gel Electrophoresis (PFGE), whole genome sequencing (WGS)
• These methods are used to detect foodborne disease outbreak and identify pathogen sources throughout the food chain
Pulsed field gel electrophoresis (PFGE)
Whole genome sequencing
**L. monocytogenes and Listeria testing**

- *Listeria* spp. used as “index” organisms that reveal conditions where *L. monocytogenes* could reside
  - Often used for testing of environmental samples
- *L. monocytogenes* testing typically performed on finished products
Listeria spp. vs. Listeria monocytogenes

- As of 2016, there are a total of 17 species of Listeria (Orsi et al., 2016).
  - Two are pathogenic: *Listeria monocytogenes* and *Listeria ivanovii*
  - Remainder are non-pathogenic: *L. seeligeri*, *L. welshimeri*, *L. innocua*, *L. marthii*, *L. grayi*, *L. fleischmannii*, *L. floridensis*, *L. aquatica*, *L. newyorkensis*, *L. cornellensis*, *L. rocourtiae*, *L. weihenstephanensis*, *L. grandensis*, *L. riparia*, and *L. booriae*
- Two additional species were identified in 2018: *L. costaricensis* sp. nov. and *L. goaensis* sp. nov.
Characteristics of Listeria

• Facultative anaerobe
• Soil microbe
• Generally associated with ready to eat foods (e.g., soft cheeses, lunch meats)
• Killed by pasteurization
• Can grow at refrigeration temperatures
  – However, optimal temperature range is 30 to 37°C (86 to 98.6F)
• Typically prefers wet environments
• Can survive stressful conditions (e.g., high salt)
• Can persist in environments for >10 years
L. monocytogenes prevalence

- Natural environments: 1.3% to 8% (NYS data)
- Urban environments: 7.3% (NYS data)
- Ruminant farms
  - Bovine farms with listeriosis cases: 24.3% (n=616)
  - Bovine farms without listeriosis cases: 20.1% (n=643)
  - Small ruminant farms with listeriosis: 32.9% (n=322)
  - Small ruminant farms without listeriosis: 5.9% (n=475)
- Food processing environments: <0.5% to 30% or more
Distribution of *Listeria* across the US

- **1,004** soil samples from 203 sampling areas across the continental US
- **311** samples positive for *Listeria* (31.0%)  
  - 693 negative samples

- **1,854** *Listeria* isolates (252 sigB ATs)  
  - 602 isolates selected for WGS

- These strains are banked and provide a nationwide collection for future research;
- WGS of 602 isolates is almost completed.
Learned - Distribution of Listeria
Learned - Distribution of *L. monocytogenes*
**Listeria and packing/processing**

- *Listeria* spp. and *L. monocytogenes* are commonly tracked into facilities with soil, produce, or from employees.
- Standing water and organic material in the facilities allows for its outgrowth.
- Movement of equipment and employees can transfer *Listeria* throughout the processing environment.
- *Listeria* can get into harborage sites in the facility and within equipment (e.g., in brushes), which protect it against sanitizers.
- During processing, equipment vibrations can free *Listeria* cells and allow it to contaminate product.
Listeriosis outbreak from 2015 to 2018

Listeria monocytogenes: update on foodborne outbreak

Frozen corn and possibly other frozen vegetables are the likely source of an outbreak of Listeria monocytogenes that has been affecting Austria, Denmark, Finland, Sweden, and the United Kingdom since 2015.

- 47 illnesses; 9 deaths
- Recalled over 2 years worth of product

European Food Safety Authority, 2018
Listeria Equation

(environmental pathogen and spoilage equation)

Listeria Control

(environmental pathogen and spoilage control)
Control Strategies

• Control strategies need to focus on minimizing *Listeria* that enters the facility and preventing contamination in packing houses/processing facilities
  – Sanitary equipment design
  – Environmental testing
  – Appropriately designed and implemented SSOPs (sanitation standard operating procedures)
Take home messages

• *L. monocytogenes* is a hardy organism with a high case-fatality rate.
• *L. monocytogenes* and *Listeria* spp. are commonly found in many environments.
• DNA fingerprinting of *L. monocytogenes* will have a major impact on industry:
  – Increased detection of outbreaks
  – Improved traceback to sources
• Urgent need for improved *Listeria* control by industry
Questions?