

# Pathogen Environmental Monitoring Tools for Produce Processors

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> North Central Region FSMA Annual Conference March 1, 2022





## VISION:

To become a leading food safety research and outreach lab that fosters scientific curiosity and rigor in Nebraska and beyond.

## **MISSION**:

To provide robust, credible science-based practical solutions to mitigate the risk of microbial foodborne illness and to deliver pertinent training and technical assistance to improve food safety and public health in a collaborative and professional way.

### **CORE VALUES**:

Accountability, inclusive excellence, respect, teamwork, and tolerance.



### **Research and Extension**



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- 2. Preventive Controls for Food for Animals
- 3. Standards for Produce Safety
- 4. Mitigation Strategies to Protect Food Against Intentional Adulteration
- 5. Sanitary Transportation of Human and Animal Food
- 6. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
- 7. Accredited Third-Party Certification



## **FSMA – Preventive Controls**

- FSMA Preventive Controls for Human Food
- Facilities that manufacture, process, pack, or hold foods are required to establish and implement a food safety system.
- Food Safety Plan:
  - Hazard Analysis
  - Preventive Controls (PC)
    - Process PC
    - Sanitation PC
    - Food Allergen PC
    - Supply Chain Controls
    - Recall Plan





### **FDA-inspected facilities**





Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-

based Preventive Controls For Human Food

- Subpart B cGMP
- Subpart C Hazard analysis and risk-based preventive controls
- Subpart G Supply chain program
- 21 CFR 117.135 (3) Sanitation Controls:
- Procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as **environmental pathogens**, biological hazards due to employee handling, and food allergen hazards.





- If during the course of a hazard analysis, a manufacturer determines that an environmental pathogen is reasonably foreseeable to occur, then a sanitation preventive control for that hazard must be implemented.
- The manufacturer is required to conduct environmental monitoring to verify that the preventive control is consistently implemented and effectively and significantly minimizing or preventing the hazard.
- Environmental pathogens:
  - Listeria monocytogenes (Lm) •
  - Salmonella
- Zero Tolerance







- An environmental pathogen is reasonably foreseeable if:
- The product is RTE. 1.
- The product is exposed to the environment prior to packaging. 2.
- The product does not receive a lethal heat treatment or other control measure 3. (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen in the final product.





## **Contamination Routes**







**Figure Potential route of transmission of** *L. monocytogenes* Food Microbiology: An Introduction, 5th Ed. 2017. ASM Press

# Listeria monocytogenes

- associated with earliest outbreaks
- contamination





### **Outbreaks and Food Vehicles**

# **EM Programs**







### **Engineering Food Safety Controls**





## The Pathogen Control Equation





# **Hygienic Zoning**

- Zone 1 Product contact surfaces, the highest level of risk
- Zone 2 Non-product contact sites directly adjacent to product contact surfaces: Control buttons, equipment framework, mechanics' tools
- Zone 3 Within the post-processing areas Floors, walls, drains, floor mats, forklifts, pallets and air handling units.
- Zone 4 Post-processing areas, but if unchecked, can lead to crosscontamination of Zones 1, 2 and 3: Hallways, loading docks, warehouses, coolers, bathrooms, locker rooms and break rooms



# **EM Programs**

- Essential component of the QA/QC system
  - Control of microorganisms in air, compressed air, water, personnel, and surfaces.
- Verification tool, NOT a control measure
  - Minimize risk of cross contamination or reservoir for environmental pathogens.
- Must be written and be statistically sound
  - Experimental design and sampling
  - EXPERIENCE
- The results may be used to demonstrate that the environment is under control.
- Data must be analyzed at a pre-determined frequency to identify transmission routes and bacterial niches.



# Listeria spp. vs. LM

- Listeria spp. is an index organism for the presence of Lm.
- If *Listeria* is present, *Lm* may be present as well.
- Lm is one of 19-ish Listeria species.
  - Some share ecological niches.
- Usually present at very low quantitative levels. • Do you need to enumerate?
- Testing for *Listeria* spp. provides a higher probability of finding a positive sample.



# Listeria spp. vs. LM (cont.)

- It is recommendable to test for *Listeria* spp.
  - If positive, then the environment is suitable for *Lm*.
  - Identification of sites that require additional control
- If testing for *Lm*, collect samples of surfaces in direct contact, segregate the product, and maintain it under control until a negative result is received.
- In general, you can only approximate the presence of Lm using Listeria spp. if you follow exceptional sanitation practices.



### **Positive** *Listeria* Results

- Scenarios for *Listeria* transmission
  - *Listeria* transient
  - Listeria spread from a focal point
  - Listeria plant resident in a niche (biofilm or other)
- How do you gain control back from each of those scenarios?





- Regulatory agencies expect occasional positive results.
- A positive result must be accompanied by a corrective action adequately implemented and by a root cause analysis that will help prevent reoccurrence of the default.
- Sporadic positive results demonstrate that the monitoring system works, assuming the design is sound.
  - Positive results may be the symptom for a serious disease!





# Packinghouses vs. Fresh Cut

What's Riskier?





# Off season vs. Peak Season

What's Riskier?





# **Risk Factors**

Listeria contamination





# Where to sample?

## Listeria contamination





# How often to sample?

Listeria contamination





# THANK YOU!







