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Science and Education Foundation®

Listeria monocytogenes Are Industry Practices Meeting Current and Future Challenges? Part 2

May 24th, 2016

GMA SCIENCE AND EDUCATION FOUNDATION (SEF)

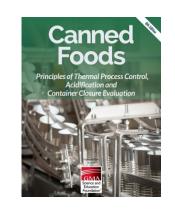
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- Training BPCS, CCFS, HACCP, Food Safety Culture, Need-based training
- Research Support projects, funding agency



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GMA SEF LEADERSHIP CIRCLE



SPEAKER INTRODUCTION

Dr. Jennifer McEntire

VP, Science Operation, Grocery Manufacturers Association

Dr. Tim Jackson

Director, Food Safety, Nestle North America

Dr. Reid Ivy

Senior Manager Food Safety, Kraft Heinz Company

Dr. Deann Akins-Lewenthal

Director of Microbiology and Food Safety, ConAgra Foods

Dr. Scott Hood

Director of Global Food Safety, General Mills





Representing the Makers of the World's Favorite Food, Beverage and Consumer Products

Industry Challenges in the Management of *Listeria*

Jennifer McEntire, Ph.D.

VP Science Operations

Grocery Manufacturers Association

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L. monocytogenes

- Recognized foodborne pathogen for nearly 40 years
 - Sporadic: outbreak = 44:1
- Risk = food + facility + practices
 - Post process contamination
 - Continuous challenges
- GMA Science and Education Foundation / JIFSAN workshop June 2015; Webinar 1 December 2015



FDA Food Advisory Committee- Dec '15

- Wonderful pre-read
 - http://www.fda.gov/advisorycommittees/committeesmeetingm aterials/foodadvisorycommittee/ucm471769.htm
- Tackled
 - Ready to eat vs. not ready to eat
 - Support growth vs. not
 - Zone 1 testing
 - Industry reps are non-voting; consumer advocates get a vote
 - GMA, ALP and others submitted comment





Regulatory Standards

- Zone 1 testing for Listeria species
 - Awaiting FDA guidance
- Foods that support/ don't support growth
 - Dose response

- Whole Genome Sequencing
 - Cost \$25-100; 4-5 day turnaround





Understanding *Listeria* risk; How we manage *Listeria*

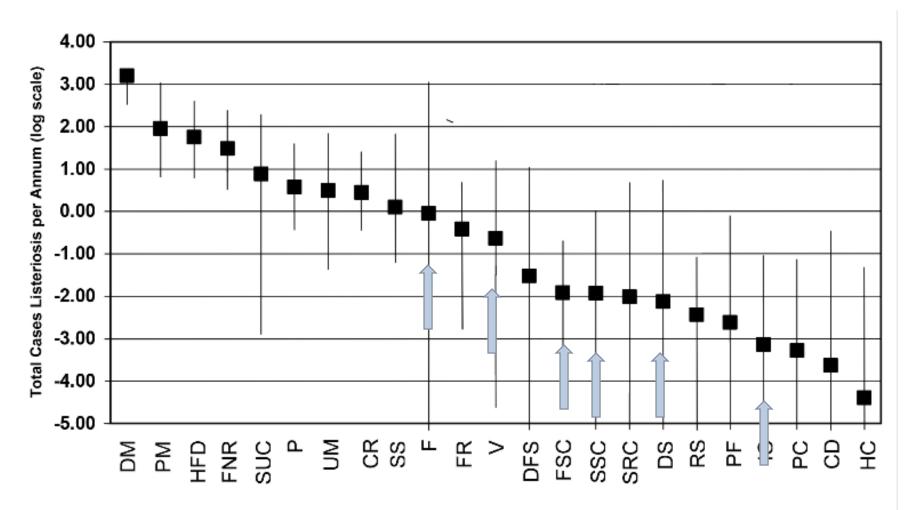
Tim Jackson, Ph.D.

Director of Food Safety

Nestlé North America



A changing risk management paradigm?



RISK CHARACTERIZATION Figure V-2. Predicted Cases of Listeriosis (log scale)
Associated with Food Categories for the Total United States Population on a per Serving
Basis (page 120 of risk assessment

http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM197330.pdf



A changing risk management paradigm?

- Reassessment of dose-response data to adjust for variation in L. monocytogenes strain virulence and host susceptibility for population subgroups.
- Most listeriosis cases are linked to the ingestion of food contaminated with medium to high concentrations of L. monocytogenes
- The model predicts the expected number of cases linked to the consumption of 10,000 cfu or less [100g at 100 CFU/g] in 55 out of 1,591 cases, i.e., 3.5% of cases.

por DOI: 10.1111/risa.12235

Listeria monocytogenes Dose Response Revisited—Incorporating Adjustments for Variability in Strain Virulence and Host Susceptibility

Régis Pouillot*, Karin Hoelzer, Yuhuan Chen, and Sherri B. Dennis

Evaluations of Listeria monocytogenes dose-response relationships are crucially important for risk assessment and risk management, but are complicated by considerable variability across population subgroups and I. monocytogenes strains. Despite difficulties associated with the collection of adequate data from outbreak investigations or sporadic cases, the limitations of currently available animal models, and the inability to conduct human volunteer studies, some of the available data now allow refinements of the well-established exponential L. monocytogenes dose response to more adequately represent extremely susceptible population subgroups and highly virulent L. monocytogenes strains. Here, a model incorporating adjustments for variability in I.. monocytogenes strain virulence and host susceptibility was derived for 11 population subgroups with similar underlying comorbidities using data from multiple sources, including human surveillance and food survey data. In light of the unique inherent properties of L. monocytogenes dose response, a lognormal-Poisson dose-response model was chosen, and proved able to reconcile dose-response relationships developed based on surveillance data with outbreak data. This model was compared to a classical beta-Poisson dose-response model, which was insufficiently flexible for modeling the specific case of L. monocytogenes dose-response relationships, especially in outbreak situations. Overall, the modeling results suggest that most listeriosis cases are linked to the ingestion of food contaminated with medium to high concentrations of L. monocytogenes. While additional data are needed to refine the derived model and to better characterize and quantify the variability in L. monocytogenes strain virulence and individual host susceptibility, the framework derived here represents a promising approach to more adequately characterize the risk of listeriosis in highly susceptible population subgroups

KEY WORDS: Dose response; Listeria monocytogenes; risk assessment

1. INTRODUCTION

Ref-Document

Listeria monocytogenes is one of the leading causes of hospitalization, fetal loss, and death due to foodborne illnesses in the United States. (1) Derivations of L. monocytogenes dose-response relationships, though crucially important for risk assessment and risk management, are impaired by the difficul-

*Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, \$100 Paint Branch Pkwy, HFS-005 MD 20740, USA; Rogis Poulliot@da.hhs.gov. ties of collecting adequate data from outbreak investigations or sporadic cases, by the lack of appropriate animal models, and by the inability to use volunteer studies due to ethical and practical concerns.^(2,2)

Two well-accepted L. monocytogenes doseresponse models have been developed by U.S. agencies⁽⁹⁾ and an international expert panel, ⁽⁹⁾ both scaled to epidemiological data. In 2003, the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services and the Food Safety and Inspection Service (FSIS) of the U.S.

0272-4332/14/0100-0001\$22.00/1 @ 2014 Society for Risk Analysis

M. Parish 12/16

Blue Bell and Jeni's Ice Cream

HOUSTON

Blue Bell, industry, flout listeria guidelines

But guidelines aimed to prevent foodborne illness ignored by many

By Mark Collette | June 21, 2015 | Updated: June 22, 2015 10:49am







The exterior of Blue Bell Creameries is shown on Tuesday, April 21, 2015, in Brenham. Blue Bell is pulling all of its products from the shelves after more ice cream samples tested positive for Listeria, following an "enhanced sampling program" that found half-gallon containers of Chocolate Chip Cookie Dough Ice Cream produced on March 17 and March 27 contained the bacteria.



Monday, June 22, 2015

25/05/2016

Data from Blue Bell sampling (Chen et al., submitted)

- "Product A", from factory A
 - 2,290 samples of Product A tested **all** but 13 samples were positive (99.4% positive)
 - Range: <0.03 MPN/g to > 208 MPN/gm
 - Highly consistent low contamination levels
 - 15% below 1 MPN/g
 - 58% below 5 MPN/g
 - 77% below 10 MPN/g
- 92% below 20 MPN/g
- 98% below 50 MPN/g
- 99.8% below 100 MPN/g
- Four samples > 100 MPN/g (max 208 MPN/g)
- Opportunities for growth?

Caramel apples (*Listeria monocytogenes* – 2014)



Q

CDC A-Z INDEX Y

Listeria (Listeriosis)



CDC > Listeria (Listeriosis) > Outbreaks

Multistate Outbreak of Listeriosis Linked to Commercially Produced, Prepackaged Caramel Apples



Highlights

- · Read the Advice to Consumers and Retailers>>
- CDC is collaborating with public health officials in several states and with the U.S. Food and Drug Administration (FDA) r
 in to investigate an outbreak of Listeria monocytogenes infections (listeriosis) linked to commercially produced, prepackaged caramel apples.
 Listeria can cause a serious, life-threatening illness.
 - People at higher risk for listeriosis include adults 65 years or older, people with weakened immune systems, and pregnant women.
- On January 6, 2015, Bidart Bros. of Bakersfield, California voluntarily recalled @ Granny Smith and Gala apples because environmental testing revealed contamination with Listeria monocytogenes at the firm's apple-packing facility.
 - On January 8, 2015, FDA laboratory analyses showed that these Listeria isolates were indistinguishable from outbreak strains by pulsed-field gel electrophoresis (PFGE).
- Listeria isolates from whole apples produced by Bidart Bros., collected along the distribution chain, were also indistinguishable from outbreak strains by PFGE.
- Consumers should not eat any recalled Granny Smith and Gala apples produced by Bidart Bros., and retailers should not sell or serve them.
- Consumers who are buying or have recently bought Granny Smith or Gala apples can
 ask their retailers if the apples came from Bidart Bros.
- Consumers should not eat commercially produced, prepackaged caramel apples that were recalled or made with Bidart Bros. apples, and retailers should not sell or serve them
- Happy Apples &, California Snack Foods &, and Merb's Candies & each announced a voluntary recall of commercially produced, prepackaged caramel apples after hearing

At a Glance:

- Case Count: 32
- States: 11
- Deaths: 7
- Hospitalizations: 31
- Recall: Yes

More Information:

- · Recall & Advice to Consumers
- Signs & Symptoms
- Key Resources

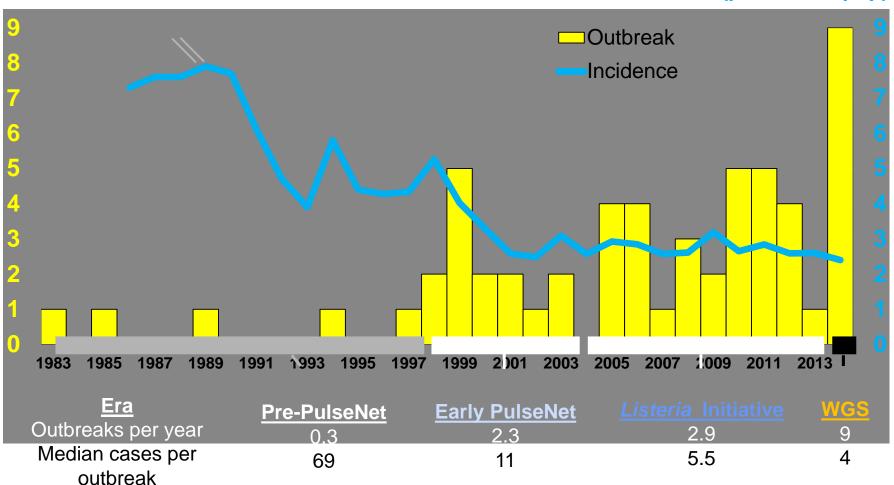


25/05/2016

CLICK TO VIEW CASE COUNT MAP.

Listeria outbreaks solved and incidence, 1983-2014





Slide: CDC via M. Wiedmann

25/05/2016



A changing risk management paradigm?





CDC A-Z INDEX ~

Listeria (Listeriosis)



CDC > Listeria (Listeriosis) > Outbreaks

Multistate Outbreak of Listeriosis Linked to Frozen Vegetables







Posted May 3, 2016 5:00 PM ET

Highlights

- Read the Recall & Advice to Consumers, Restaurants, and Retailers>>
- Since March 2016, CDC has been collaborating with public health officials in several states and the U.S. Food and Drug Administration (FDA) at to investigate a multistate outbreak of Listeria monocytogenes infections (listeriosis).
- Listeria can cause a serious, life-threatening illness.
- . Eight people infected with the outbreak strains of Listeria have been reported from three states since September 13, 2013.

At a Glance:

- Case Count: 8
- States: 3
- Deaths: 2
- Hospitalizations: 8

25/05/2016

Recall: Yes

Vay Decourage

A changing risk management paradigm?





25/05/2016

Open questions for risk managers

- What is the risk of low, sporadic Listeria in no-growth foods?
 - How is a no-growth food defined?
- Does strain variability influence risk and effectiveness of control measures?
- How do risk factors in product and consumers impact the stringency of control measures that need to be applied?
- What interventions can effectively control *Listeria* in fresh produce?
- What are appropriate criteria for Listeria monocytogenes?



Appropriate criteria for L. moncytogenes?

Codex Alimentarius Commission (2005)

Microbiological criterion for ready-to-eat foods in which growth of L. monocytogenes will not occur

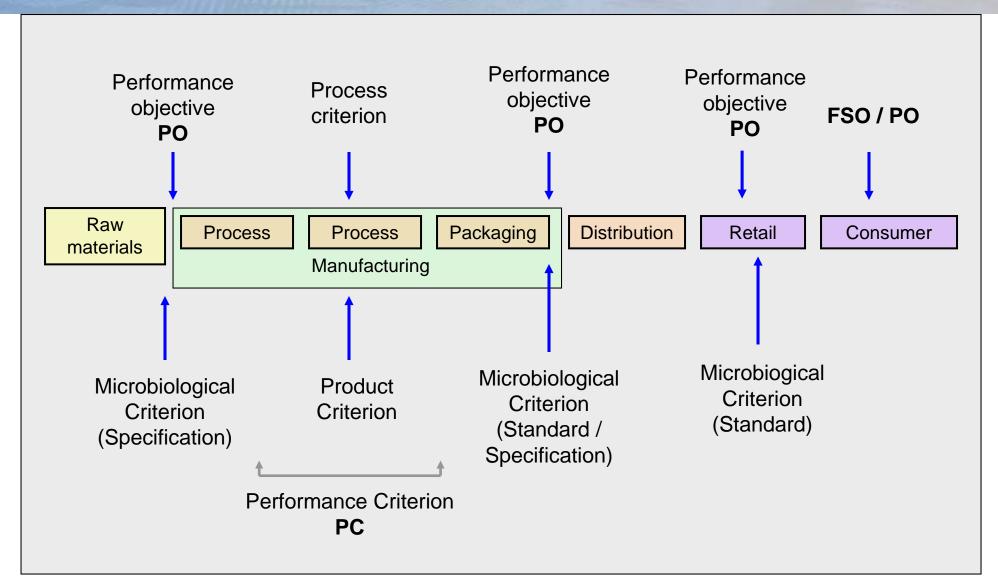
Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	monocytogenes	5 ª	0	100 cfu/g ^b	2 °

Microbiological criteria for ready-to-eat foods in which growth of L. monocytogenes can occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale		5 a	0	Absence in 25 g (< 0.04 cfu/g) b	2 °

Also other authorities: eg, Canada, EU, Australia, New Zealand

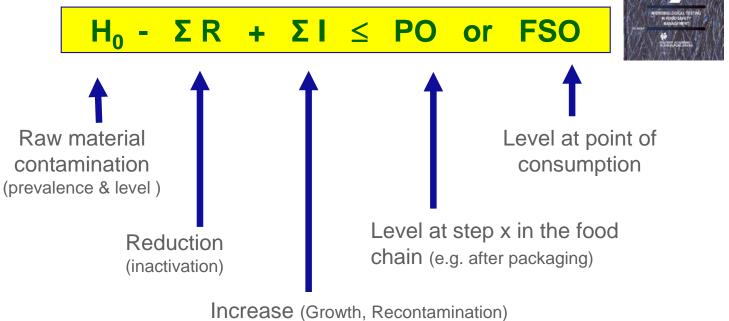
Risk based metrics



25/05/2016

Full chain approach

ICMSF's conceptual equation¹



more de la comanimation

 Σ = sum of events PO: Performance Objective FS0: Food Safety Objective

¹Microbiological testing in Food Safety Management, ICMSF (2002); Book 7



25/05/2016

A. Wong UW Madison

Listeria monocytogenes

- Listeria genus.
 - Currently eight species identified
 - L. monocytogenes pathogenic
- Sources
 - Carried by animals and humans
 - Widespread in the environment
 - Raw materials
 - Post-processing contamination
- Listeria can attach to surfaces and form biofilms
 - Surface attached communities of cells embedded in an extra-cellular polysaccharide matrix.
 - More resistant to physical and chemical agents



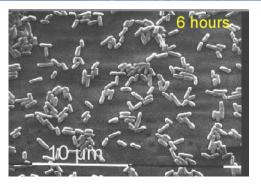
Listeria monocytogenes control

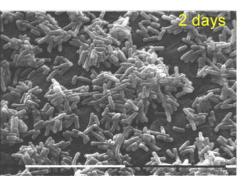
- Non-sporeforming
 - Relatively heat sensitive in high moisture products
 - Inactivated by pasteurization
- Psychrotrophic
 - Able to grow under refrigeration

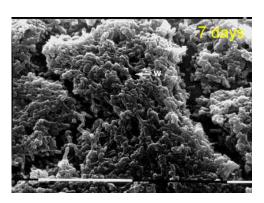
Growth and survival limits for Listeria monocytogenes				
Parameter	Minimum	Maximum	Optimal	Can survive (but no growth)
Temperature (°C)	-1.5 to +3	45	30 to 37	-18
рН	4.2 to 4.3	9.4 to 9.5	7.0	3.3 to 4.2
Water activity (a _w)	0.90 to 0.93	> 0.99	0.97	< 0.90
Salt (%)	< 0.5	12 to 16	N/A	≥ 20

Factors leading to persistence

SEM micrographs:







- Reports of strains surviving for years or decades in food plants (Ferreira et al, 2014)
- Formation of biofilms
- Existence of persister cells
 - Cells enter a persister stage after stationary phase marked by changes in cell morphology and increased resistance to heat, high pressure, sanitizer etc
- Resistance to sanitizers
 - Repeated sub-lethal exposure
- Survival in niches
- Re-introduction into the environment

Issues that may lead to contamination

Category	Issue or problem
Facility design and structure	Construction work
Facility services	Rubbish bins not being routinely emptied, maintained or cleaned / sanitized
Employees	Employees unfamiliar with business / processing procedures Employees moving between hygiene zones Cleaning of equipment parts on the processing floor Poor personal hygiene practices Inadequate training
Sanitation	Sanitation procedures during production Poor sanitation
Maintenance	Repair of equipment, floors, drain blockage, etc. Installation of new equipment

Issues that may lead to contamination

Category	Issue or problem
Equipment	Equipment failure and breakdowns
	Alteration of production lines
	Product or product debris left on equipment
	Frequent changes of packaging material and production line speeds
	Commissioning of new equipment or equipment from another facility or storage
	Raw product in cooked area / cooked product in raw area
Production	Difficulty in meeting sanitation schedules due to production schedules
	Movement or modification of a production line
	Heavy production schedules
	Using out of date stock (eg poor stock rotation)
	Frequent product changeovers
	Stagnation of product flow through processing

- Validated lethal processing steps
- Product formulation
- Identify sources of contamination

Direct	Indirect
Conveyors	Drains
Containers	Floors / Gangways
Hand tools	Walls
Protection clothing eg white coats	Ceilings
Racks used in transporting finished products	Maintenance equipment
Filling and packaging equipment	Cleaning equipment
Dicing, slicing, blending equipment	Transportation equipment (e.g. forklift)
Brines	Insulation in walls or around pipes
Packaging	Air, steam, condensation

Written sanitation program

- Effective cleaning before sanitizing critical
- Infrequent defrosting cleaning and maintenance of spiral freezers can lead to contamination

Sanitizers:

- Hot water (> 82°C) in conjunction with a sanitizer can be effective in the removal of biofilms
- Chlorine: Levels of 0.2 to 0.5 ppm
 - Efficacy influenced by temperature, contact time, pH, organic material, etc.
- lodophors: 200 ppm, 10 to 20 minutes
 - Have a reduced efficacy against L. monocytogenes at temps < 4°C
- Quaternary ammonium compounds
 - Very effective against L. monocytogenes
- Peracetic acid and peroctanoic acid

- Maintenance activities
- Personal hygiene of food workers
 - Staff working in high risk areas should receive additional training in how to avoid cross-contamination
 - Staff working with sanitation procedures
 - Managers and supervisors lead by example
- Packaging
 - Packaging kept clean and dry
 - Packaging storage at a high level of hygiene
- Storage and distribution
 - Separation into raw and ready-to-eat
 - Pallets made of plastic, kept clean and dry

- Recognize operational issues that could increase risk of crosscontamination
- Control humidity and moisture
 - Wet processing areas isolated from other areas
 - Eliminate or quickly remove areas of standing water
 - Remove water hoses from production areas before production
 - Avoid practices producing aerosols (high pressure hoses)
 - Cooling units have dehumidifying capabilities
- Control air quality and ventilation
 - Positive air pressure between raw and cooked
 - Minimize use of compressed air; filter at point of use
 - Control of air quality and ventilation should minimize condensation

Pathogen control strategy

Eliminate niche environments

Area	Example
Ancillary items	Rubbish Bins, skips
Ancillary services	Compressed air lines, hollow bump guards on bottoms of doors, plexiglass shields
Personnel hygiene	Wash basins, aprons, gloves
Plant hygiene	Cleaning equipment
Premises	Cracked walls, floors, ceilings, wet insulation, standing water, switches
Equipment	Hollow rollers on conveyors, conveyor belts, slicers, dicers, mincers, weighing scales, switches, rubber seals, open bearings, equipment motor housings, hollow frames, ice makers, damaged pipe / hoses, hollow box cutters, brine, packaging equipment, hand tools, hoppers, valves

Pathogen control strategy

- Include safe processing of rework in HACCP plan
- Inedible and condemned material
 - Segregated and clearly identified
 - Waste containers located as far as possible and physically separated from production areas
 - Appropriate insect and rodent proof containers
- Monitor effectiveness of controls through pathogen and hygiene monitoring program





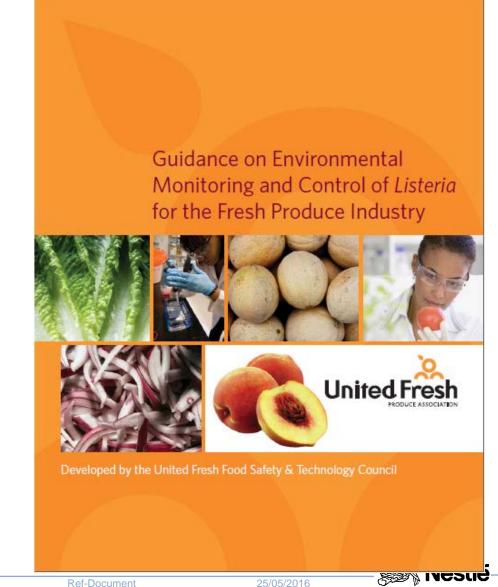






Listeria control in fresh produce

- Some control measures can inactivate Listeria:
 - Heat
 - Irradiation
 - **HPP**
 - Ohmic heating
- Control is usually a combination of control measures:
- Minimizing Listeria in the field
- Hygienic design of equipment
- Surface sanitation (1-2 log reduction)
- Cleaning and sanitation
- Zoning
- Personnel practices





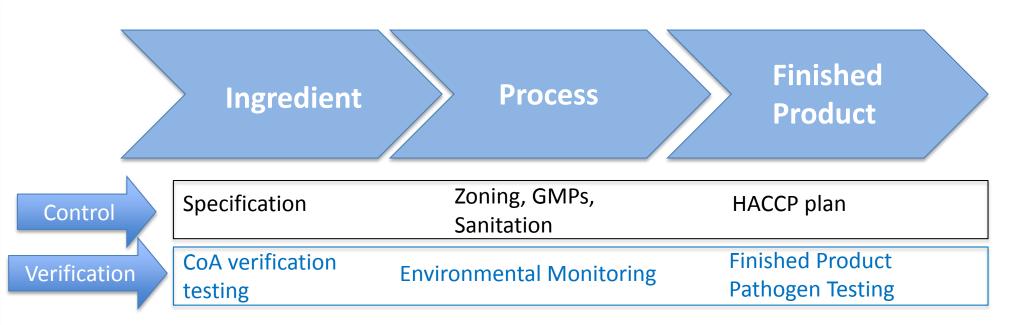
THE KRAFT HEINZ COMPANY

Managing Listeria During Cheese Production

Reid Ivy, Ph.D.
Senior Manager Food Safety
Kraft Heinz Company

Overview

Environmental monitoring and product testing are verifications that food safety controls are effective at preventing introduction of pathogens into the finished product





Risk-based Programs

- Process What is the risk of environmental cross contamination?
 - Product exposure
 - Make milk into cheese
 - Conversion size reduction (e.g. slice/shred)
- Product
 - Hot fill or cold fill?
 - Does the product support the growth of Listeria?
 - Outbreak and recall history



Program Requirements Vary by Hygienic Zone

- High level of control
 - Highly sensitive product, exposed, post-pasteurization
- Normal level of control
 - Low to medium-sensitivity product, exposed
- Raw/Limited process
 - Ingredients for further process exposed; raw ingredients
- Non-manufacturing
 - Areas in plant where manufacturing is not taking place

Hygienic Zone dictates swabbing frequency, action limits, and corrective actions



Example – Environmental Monitoring for Listeria

- Swab Zone 1
 - Direct product contact surfaces
 - Indicators at start-up and in-process; Listeria spp. (high risk cheeses)
- Swab Zone 2
 - Immediately adjacent to product contact surfaces
 - Listeria spp. weekly
- Swab Zone 3
 - Non-product contact surfaces; remote from exposed product
 - Listeria spp. weekly
- Swab Zone 4
 - Outside of processing area but could impact processing areas
 - Listeria spp. weekly/monthly



Zone 1 Swabbing

- For high risk cheeses that <u>support the growth</u> of Listeria monocytogenes
- Refrigeration is not a control for Lm
- Product contact surfaces must be monitored to ensure no cross contamination of Lm



Effective Environmental Monitoring Programs

- 'Seek and Destroy' mentality
- Effective root cause analysis
 - Cleaning and vector swabbing are not root cause analysis
- Living program
 - Periodic reanalysis
 - Site rotation
 - Investigative swabbing



Testing

Ingredients

- In some cases (e.g. cheese conversion), Certificate of Analysis is the only preventive control for biological pathogens (supplier controlled hazard)
- History has shown us that CoA alone is not an effective verification of supplier controls
- In these cases, verification activities may include testing by receiving facility

Finished product

- Verifies preventive controls are working
- Under FSMA guidelines, FPT is required where deemed appropriate



ConAgra Foods[®]

Managing *Listeria* spp. in Frozen
Products

Deann Akins-Lewenthal, Ph.D.

Managing *Listeria* spp.

- Supplier program
- Cleaning and sanitation
- Product and process criteria
- Hygienic Zoning

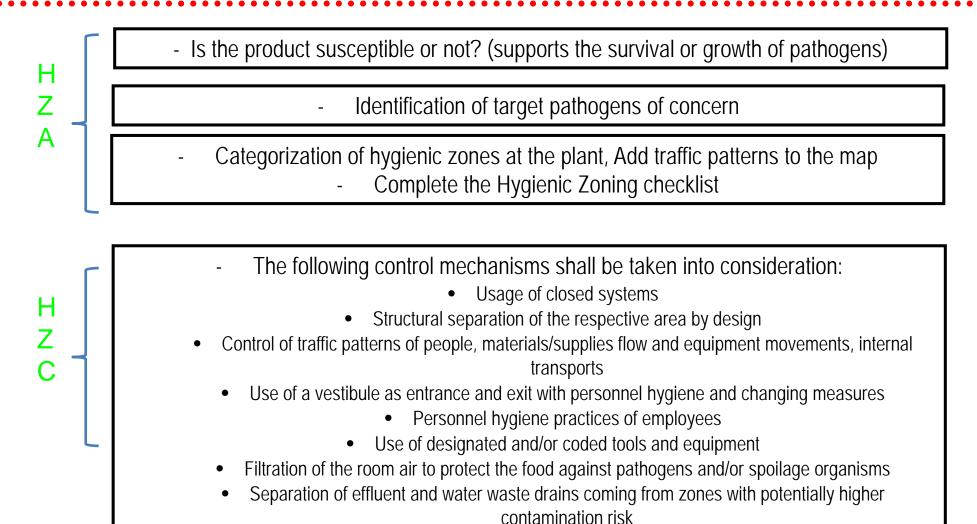
Hygienic Zoning

- Why do we need hygienic zoning?
 - Prevent microbial cross contamination of RTE products
 - Assure food safety of finished product
- What is Hygienic Zoning?
 - Identify and differentiate areas within the manufacturing facility based on microbiological risk
 - Scope: receipt, storage, processing and packaging of products
 - Consider personnel and materials traffic, air handling, equipment, effluent, drains, waste systems, locker rooms, or other situations that could result in transfer of microorganisms

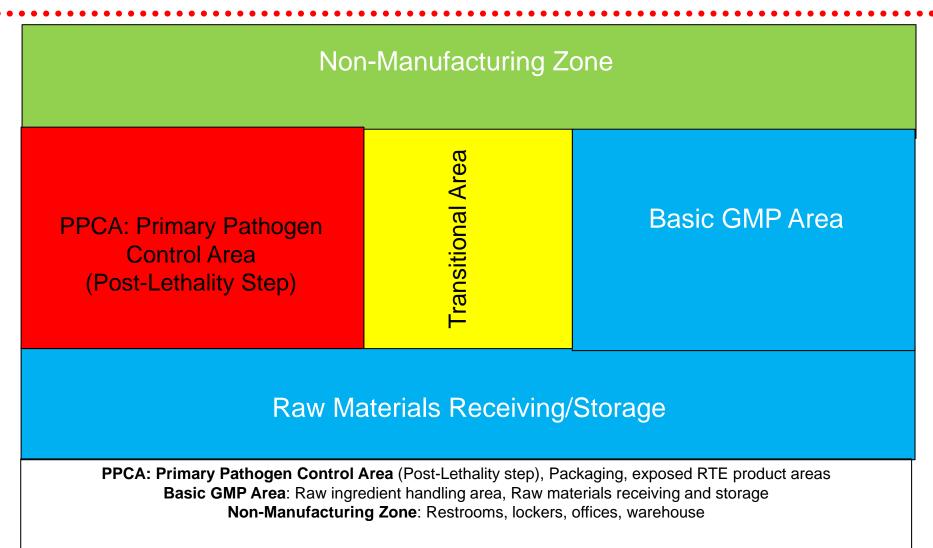
Hygienic Zoning

- Program will vary based on
 - Product type
 - Design of manufacturing processes
 - Process flow

Hygienic Zoning Assessment vs Hygienic Zoning Controls

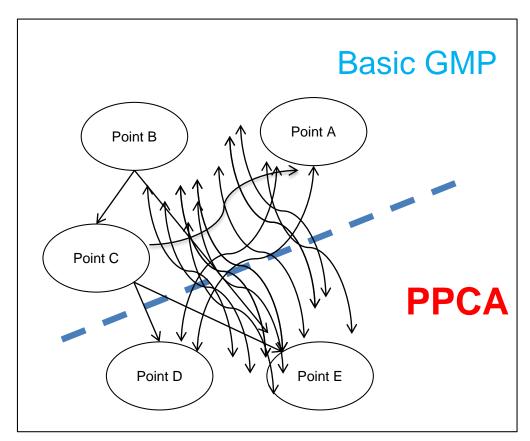


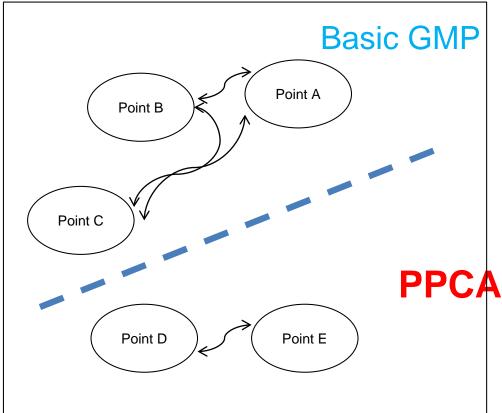
Levels of Hygienic Zoning



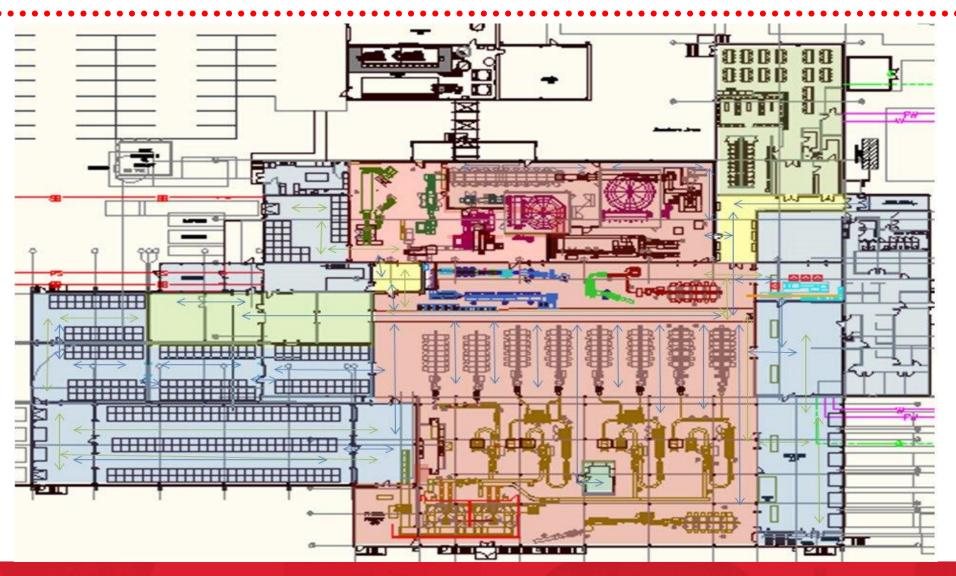
Consider Employee/Equipment Traffic Patterns

Path A Path B





Hygienic Zoning Map



Verification

The following tools can be used:

- Routine pre-operational and operational inspections
- GMP audits
- Assurance of Sanitation Effectiveness Program
- Environmental Monitoring for Pathogen Control Program
- Environmental Air Monitoring Program





Managing Listeria for Dry Products

Dry products can have wet environments

Scott Hood

WHY

Presence = Recall



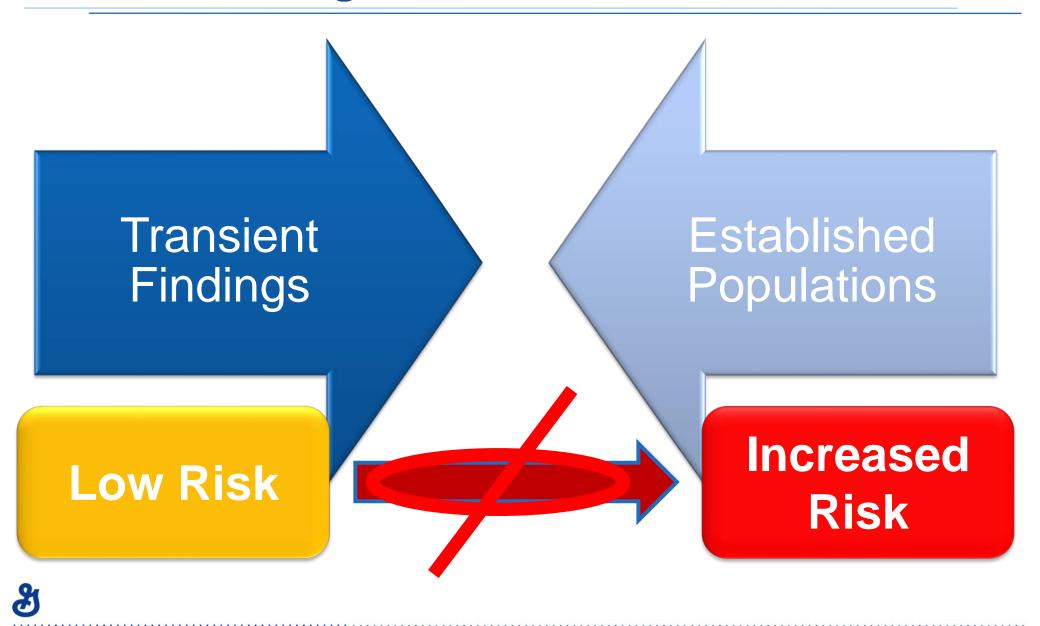
Better to know and act than to have someone else find the issue

Find It, Fix It

Seek and Destroy



Microorganisms in the Environment

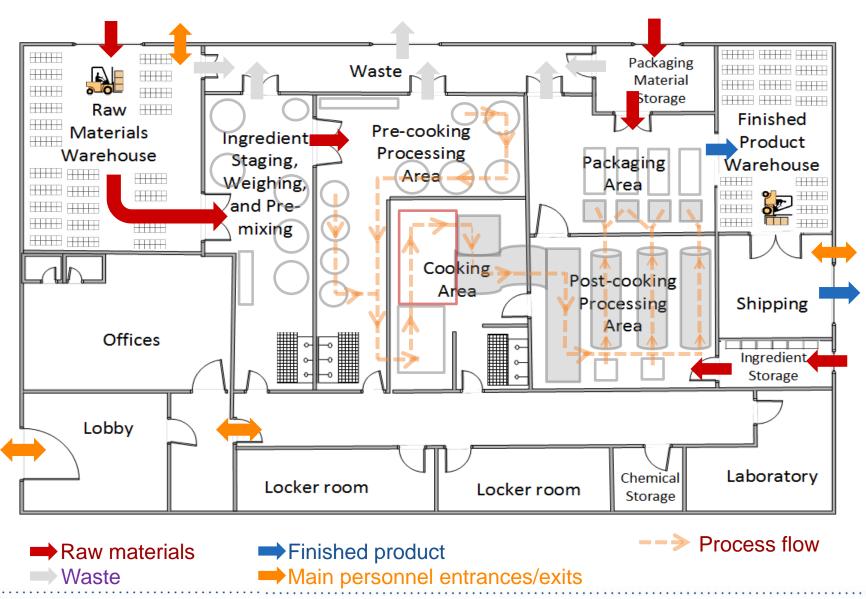


Practical Approach

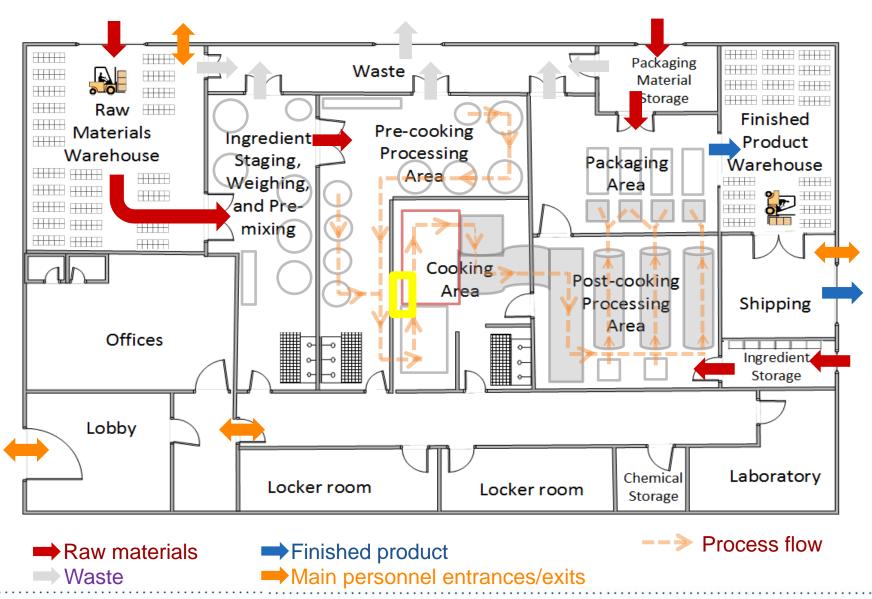
- Policy Requirement
 - In mostly dry areas, Salmonella should be emphasized. If there are specific locations that get wet, then also sample for Listeria species.



Plant Scenario



Plant Scenario



Escalation

Is *L. monocytogenes* present?

Is there an established population *L. monocytogenes*

What will be needed to eliminate *L. monocytognes*



Resources

- U.S. Food and Drug Administration (1998). Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables https://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProducendPlanProducts/UCM169112.pdf
- Codex Alimentarius Commission (2007). Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in ready-to-eat foods – CAC/GL 61-2007 http://www.codexalimentarius.net/download/standards/10740/CXG_061e.pdf (2007)
- Food Safety Authority of Ireland (2005). The Control and Management of *Listeria monocytogenes* contamination of Food.
- Listeria, Listeriosis and Food Safety (2007). 3rd Edition. Ryser and Marth (eds) CRC Press
- U.S. Food and Drug Administration (2008). Draft Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods.
 www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm
- Health Canada (2011). Policy on *Listeria monocytogenes* in ready-to-eat foods
- U.S. Department of Agriculture (2012). FSIS Compliance Guideline: Controlling Listeria monocytogenes
 in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products.
 http://www.fsis.usda.gov/shared/PDF/Controlling_LM_RTE_guideline_0912.pdf
- United Fresh Produce Association (2013). Guidance on environmental monitoring and control of Listeria for the fresh produce industry.

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Conclusions

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GMA SEF/ JIFSAN meeting research needs

- Growth / no-growth
 - Highest growth and dose, strain persistence, micro ecology/ niches
- Virulence
 - animal models, co-infection, multiple exposures
- Risk assessments
 - Dose response, subpopulations, getting right info to the right people
- Other
 - Cross training between industries, broadening the participants in the conversation



Next Steps

Anxiously awaiting FDA guidance







In the meantime, industry must take prudent steps to evaluate the risk of *L. monocytogenes* and control for this pathogen



Thank you!

Questions???

(Please identify if you would like the question addressed by a specific presenter)

For questions after the webinar contact Akhila Vasan, Ph.D., avasan@gmaonline.org

