

Public Meeting:

Listeria monocytogenes

Prevention Strategies

Day 1

Listeria monocytogenes Prevention Strategies Day 1

- Wi-fi: FDA-Guest
- Press concerns:
FDAPressTeam@fda.hhs.gov
- Docket for questions/comments:
FDA-2026-N-7914-0001

Welcome and Introduction

- Don Prater, DVM, FDA
- Tressa Bennett, JD, STOP Foodborne Illness
- Conrad Choiniere, Ph.D., FDA/OMFS

Session 1 - Advances in the Understanding and Control of *Listeria monocytogenes*



Session Lead – Tim Jackson, Ph.D.

- Martin Wiedmann, Ph.D., Cornell University
- Jovana Kovacevic, Ph.D., Oregon State University
- Haley Oliver-Jischke, Ph.D., Purdue University

Panel questions

***Listeria* intro: epidemiology, pathogenesis, and taxonomy**

Martin Wiedmann

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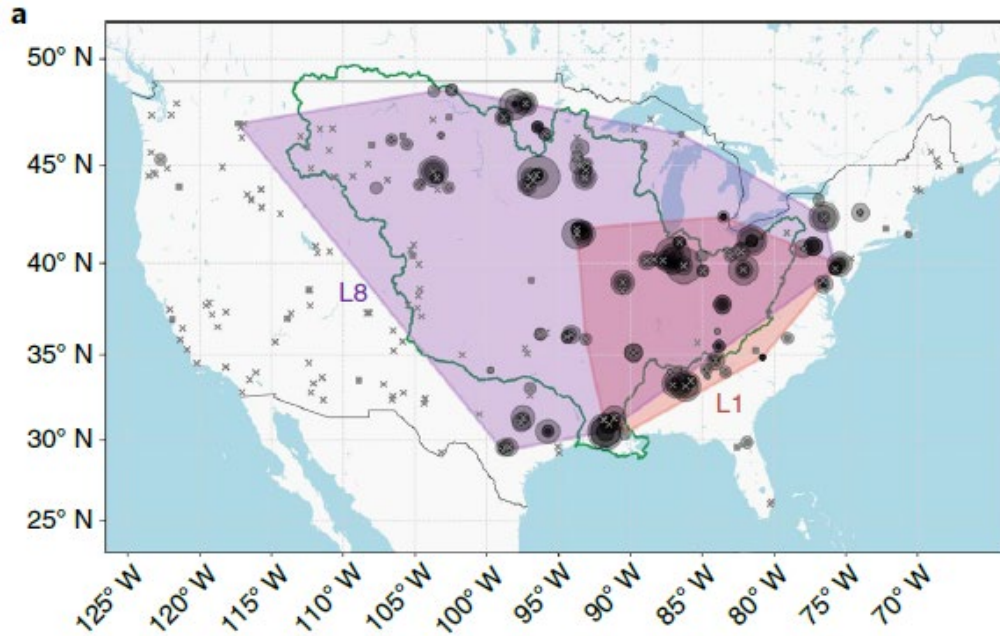


Take-home messages

- *Listeria monocytogenes*
 - Is commonly found in many environments
 - Causes severe disease, but disease cases are generally linked to exposure to very high *L. monocytogenes* levels
 - Shows tremendous ability to survive for extended time periods in food processing and food associated facilities and environments
- While some members of the genus *Listeria* are good index organisms, others are not
 - *Listeria* testing needs to focus on the correct *Listeria* (“sensu lato”)
- Listeriosis outbreaks are essentially always linked to *L. monocytogenes* persistence
 - Control strategies need to focus on reducing persistence

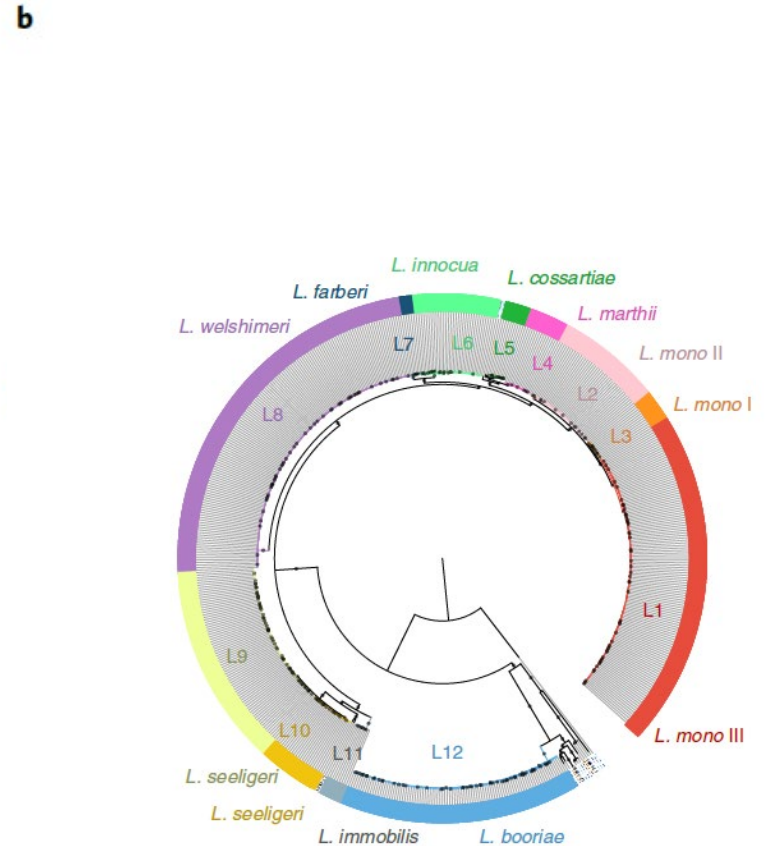
Listeria monocytogenes

- Isolated first in 1924 (1926?); outbreaks in infants first identified in 1949; first outbreak linked to foods reported in 1983
- Causes septicemia, abortion and encephalitis in humans
 - Approx. 1,300 human cases/year and 255 deaths/year in the US
- Common in many environments (hence high risk of introduction)
 - Natural environments: 1.3% prevalence in New York state; approx. 8% prevalence in a US-wide national study
 - Urban environments: 7.3% prevalence in New York state
 - Ruminant farms: Prevalence can be 20 to 30%
 - Food processing environments: from <0.1% to 30% or more
- Control strategies need to focus on (i) preventing re-contamination in processing plants (after kill step); and (ii) preventing persistence in processing plants
 - Over-reaction to sporadic positives and positives in low-risk areas may distract resources from high-risk areas



Biogeographic structure of *Listeria*. Among the 1,004 soil samples collected across the USA, 311 samples were positive for *Listeria*, yielding a nationwide prevalence of 31% (Supplementary Table 1).

Liao et al. 2021. Nature Micro



Processing facilities

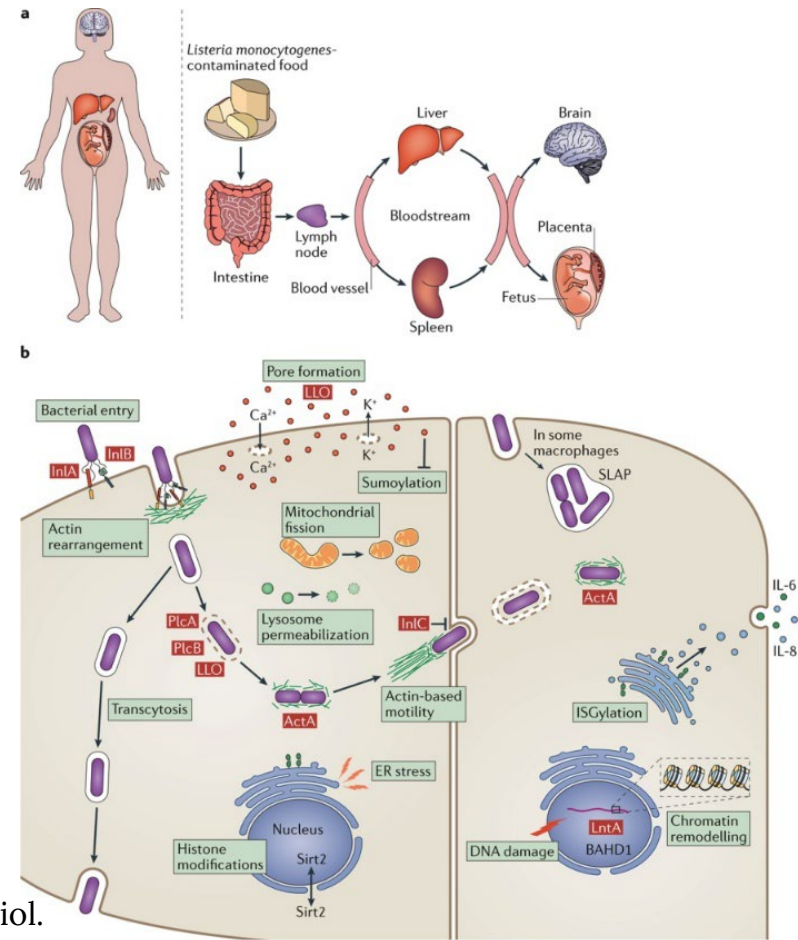
Plant ID	Listeria Prevalence (1 year routine program)	Prevalence from independent “Swabathon”
A	5.1% (34/664)	1.3% (2/150)
E	11% (88/795)	10% (6/60)
F	<0.3% (0/334)	6.0% (3/50)
G	9.1% (19/209)	2.4% (2/85)
H	23% (24/106)	4% (2/50)
I	0.4% (1/222)	<2.0% (0/50)
J	0.9% (1/106)	14% (7/50)



Lm virulence

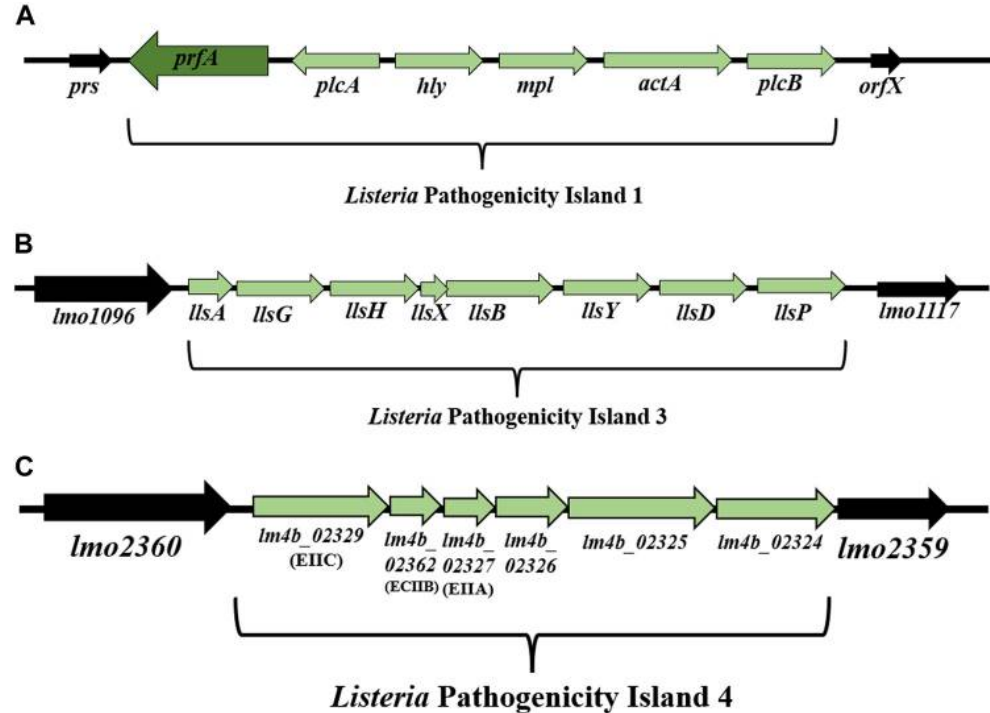
- *Lm* invades intestinal epithelial cells using the internalin A (InlA) protein
- Inside the eukaryotic cell, *Lm* life cycle includes
 - escaping of a single-membrane vacuole using listeriolysin O (LLO) and phospholipases (PlcA and PlcB),
 - moving towards the cytoplasmatic membrane through actin polymerization using ActA,
 - crossing to a neighboring cell,
 - escaping a double membrane and
 - re-initiating the cycle
- Eventually, *Lm* crosses to the lymphatic system and becomes systemic
- All major virulence genes under the positive control of PrfA

Radoshevich & Cossart, 2017. Nat. Microbiol.



Listeria pathogenicity islands (LIPI)

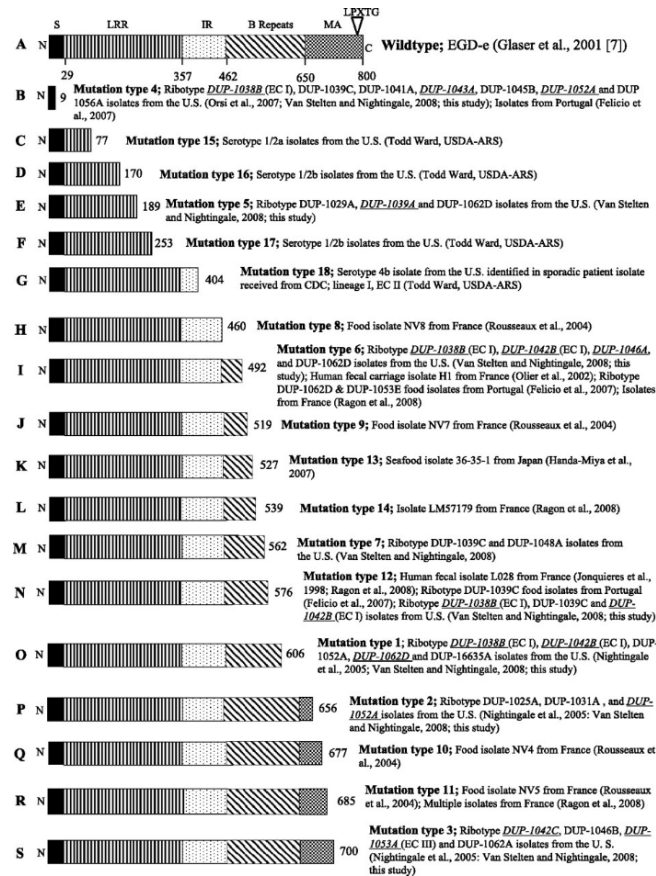
- LIPI-1
 - Six genes present in all *Lm*
 - Required for virulence
- LIPI-2
 - Only found in *Listeria ivanovii*
- LIPI-3
 - Eight genes; associated with certain subtypes
- LIPI-4
 - Six genes encoding a cellobiose-family phosphotransferase system (PTS); associated with certain subtypes (mainly Clonal Complex 4; CC4)



Wiktorczyk-Kapischke et al., 2023. Front. Mol. Biosc.

Loci associated with hypovirulence

- Premature stop codons (PMSC) in:
 - *inlA* (at least 20 different PMSC reported)
 - Most common
 - *prfA*
 - Rare
 - *hly*
 - Rare



Select *Listeria monocytogenes* Subtypes Commonly Found in Foods Carry Distinct Nonsense Mutations in *inlA*, Leading to Expression of Truncated and Secreted Internalin A, and Are Associated with a Reduced Invasion Phenotype for Human Intestinal Epithelial Cells

K. K. Nightingale,¹ K. Windham,¹ K. E. Martin,¹ M. Yeung,² and M. Wiedmann^{1*}

Variation in *Listeria monocytogenes* Dose Responses in Relation to Subtypes Encoding a Full-Length or Truncated Internalin A[∇]

Yuhuan Chen,^{1*} William H. Ross,² Richard C. Whiting,³ Anna Van Stelten,⁴ Kendra K. Nightingale,⁴ Martin Wiedmann,³ and Virginia N. Scott^{1†}



Estimated 3.4 log lower infectious dose for *inlA* PMSC strains

inlA Premature Stop Codons Are Common among *Listeria monocytogenes* Isolates from Foods and Yield Virulence-Attenuated Strains That Confer Protection against Fully Virulent Strains^{∇†}

K. K. Nightingale,^{1,2*} R. A. Ivy,¹ A. J. Ho,¹ E. D. Fortes,¹ B. L. Njaa,^{3,4} R. M. Peters,³ and M. Wiedmann¹



Confirmed virulence attenuation of *inlA* PMSC strains in guinea pigs

Revelation by Single-Nucleotide Polymorphism Genotyping That Mutations Leading to a Premature Stop Codon in *inlA* Are Common among *Listeria monocytogenes* Isolates from Ready-To-Eat Foods but Not Human Listeriosis Cases[∇]

A. Van Stelten,¹ J. M. Simpson,¹ T. J. Ward,² and K. K. Nightingale^{1*}



45% of food isolates from diverse sources in the US carry *inlA* PMSC

USDA-FDA *Listeria* risk assessment

Table IV-12. Dose-Response with Variable *Listeria monocytogenes* Strain Virulence for Three Age-Based Subpopulations

Dose (cfu/serving)	Median Mortality Rate per Serving ^a		
	Intermediate-Age	Neonatal ^b	Elderly
1	1.5×10^{-16} (1.2×10^{-146} , 1.9×10^{-13})	1.6×10^{-13} (1.2×10^{-99} , 4.0×10^{-11})	4.0×10^{-15} (6.3×10^{-124} , 1.8×10^{-12})
10^3	1.2×10^{-13} (5.4×10^{-92} , 6.8×10^{-11})	1.3×10^{-10} (4.3×10^{-56} , 1.7×10^{-8})	3.6×10^{-12} (2.2×10^{-74} , 7.2×10^{-10})
10^6	1.0×10^{-10} (1.9×10^{-50} , 3.5×10^{-8})	1.3×10^{-7} (1.2×10^{-25} , 8.6×10^{-6})	3.1×10^{-9} (5.7×10^{-38} , 3.3×10^{-7})
10^9	1.2×10^{-7} (6.0×10^{-22} , 1.9×10^{-5})	1.4×10^{-4} (1.6×10^{-8} , 5.1×10^{-3})	3.4×10^{-6} (1.3×10^{-14} , 1.9×10^{-4})
10^{10}	1.3×10^{-6} (2.5×10^{-15} , 1.5×10^{-4}) ^c	1.5×10^{-3} (3.3×10^{-6} , 2.7×10^{-2})	3.9×10^{-5} (6.0×10^{-10} , 1.7×10^{-3})
10^{12}	1.9×10^{-4} (4.9×10^{-8} , 9.2×10^{-3})	7.4×10^{-2} (7.8×10^{-4} , 2.2×10^{-1})	4.9×10^{-3} (9.8×10^{-6} , 4.8×10^{-2})

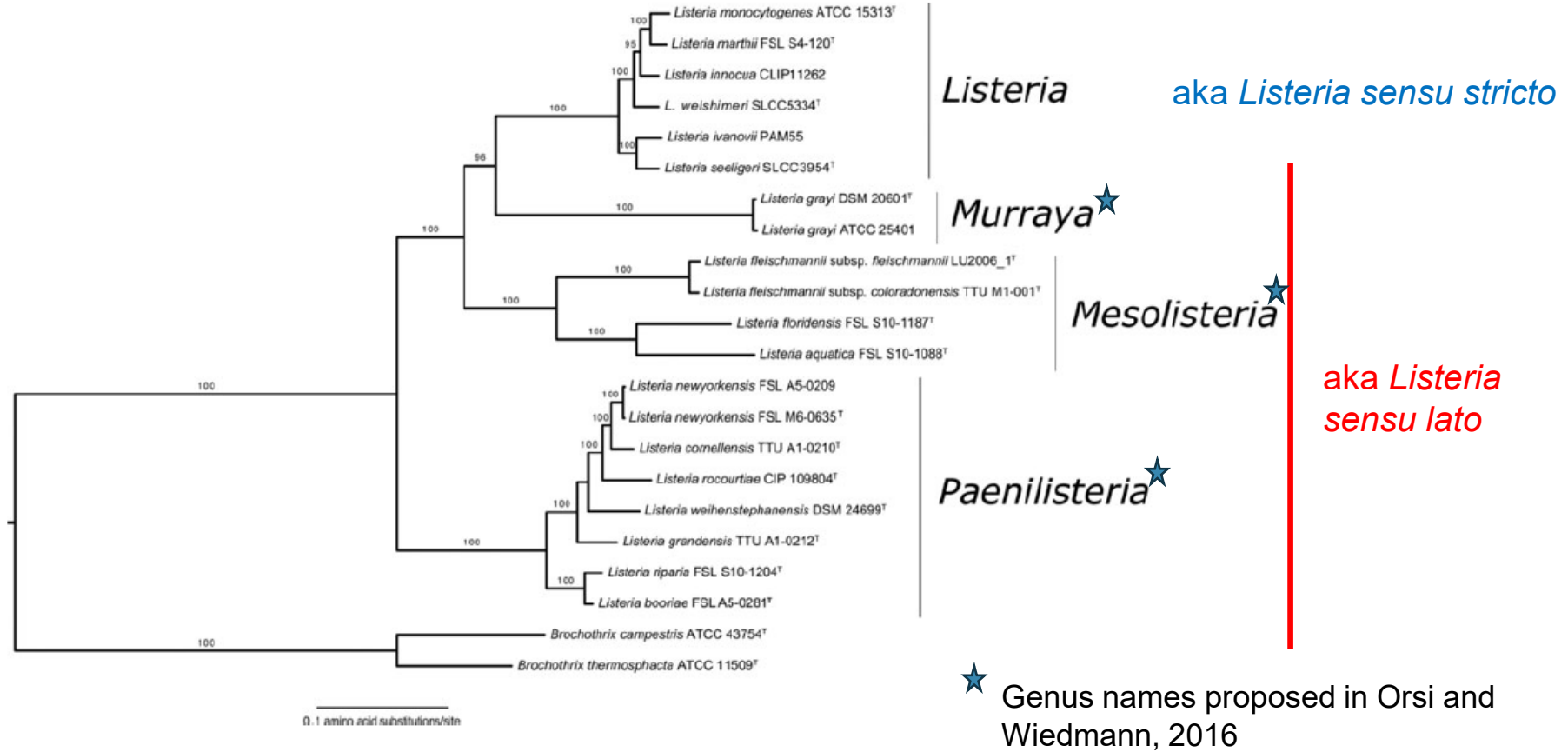
^a The 5th and 95th percentiles from the uncertainty are in parenthesis.

^b An adjustment to account for total perinatal deaths (prenatal and neonatal) is in the risk characterization section.

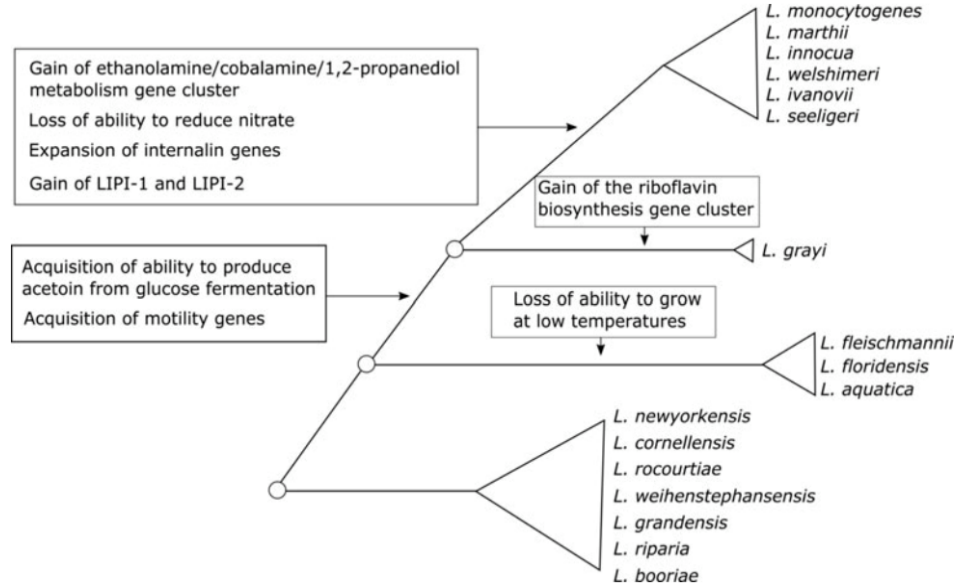
^c The median mortality rate per serving of 1.3×10^{-6} for the intermediate-age subpopulation at the 10^{10} cfu/serving dose level, corresponds to 1 death in approximately 769,231 servings ($1/1.3 \times 10^{-6}$).

Listeria*: more than *L. monocytogenes

- The genus *Listeria* includes:
 - Human and animal pathogens: *L. monocytogenes* and *L. ivanovii*
 - Non-pathogenic species: *L. innocua*, *L. seeligeri*, *L. welshimeri*, and the divergent *L. grayi*
 - >10 new non-pathogenic species described since 2010 (*L. marthii*, *L. rocourtiae*, *L. weihenstephanensis*, *L. fleischmannii*, *L. floridensis*, *L. aquatica*, *L. cornellensis*, *L. riparia*, *L. grandensis*, *L. booriae*, *L. newyorkensis*)
- *Listeria* spp. sometimes used as “indicator” or “index” organisms that reveal conditions where *L. monocytogenes* could reside



Sensu lato* species have characteristics are divergent enough they are arguably not *Listeria



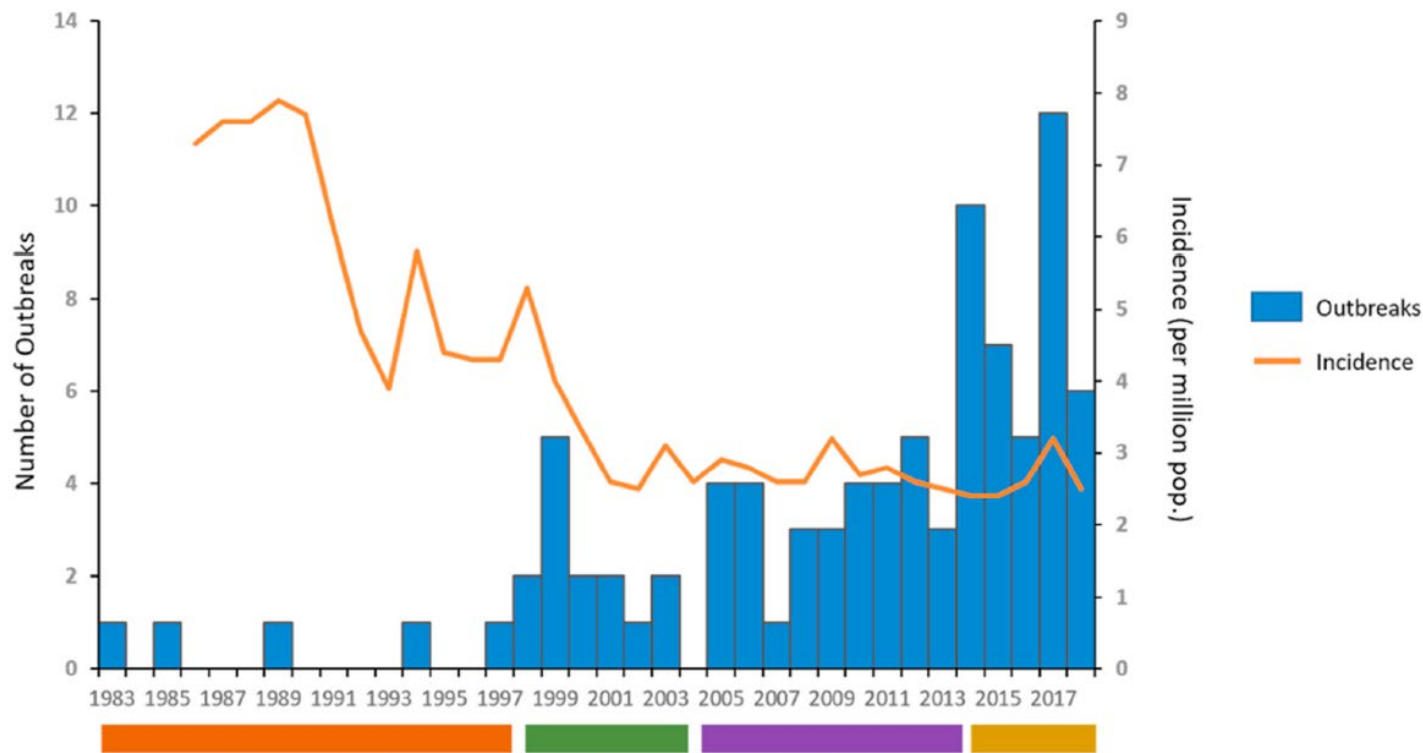
Orsi, R. and Wiedmann, M (2016)

Lm and *Listeria* in the environment

- *Listeria* is (i) considered a saprophyte, (ii) can grow at “refrigeration temperature”, and (iii) has a sophisticated repertoire of stress response systems that allow for survival under different environment and host associated stress conditions
- Speed of growth depends hugely on the **temperature**
 - *L. monocytogenes* grows much slower at 4 C (40 F) than 7 C (45 F)
 - Estimates suggested that if all refrigerated product were stored at 40 F and below, the US would have <10 listeriosis cases per year (ILSI Research Foundation/Risk Science Institute et al., 2025)

A few noteworthy *L. monocytogenes* outbreaks

- 1981: Maritime Provinces, Canada: 41 cases, 19 death, linked to Coleslaw
- 1983-87: Canton de Vaud, Switzerland: 122 cases, 31 deaths; linked to raw milk, cheese
- 1998/99: US: 108 cases, 14 deaths; linked to hot dogs and sliced deli meats
- 2007: MA: 4 (or 5) cases, 4 death. Pasteurized milk from local dairy
- 2011: US: 147 cases, 33 deaths; linked to cantaloupe
- 2023: Germany, 3 cases; sliced sausage, served in hospital

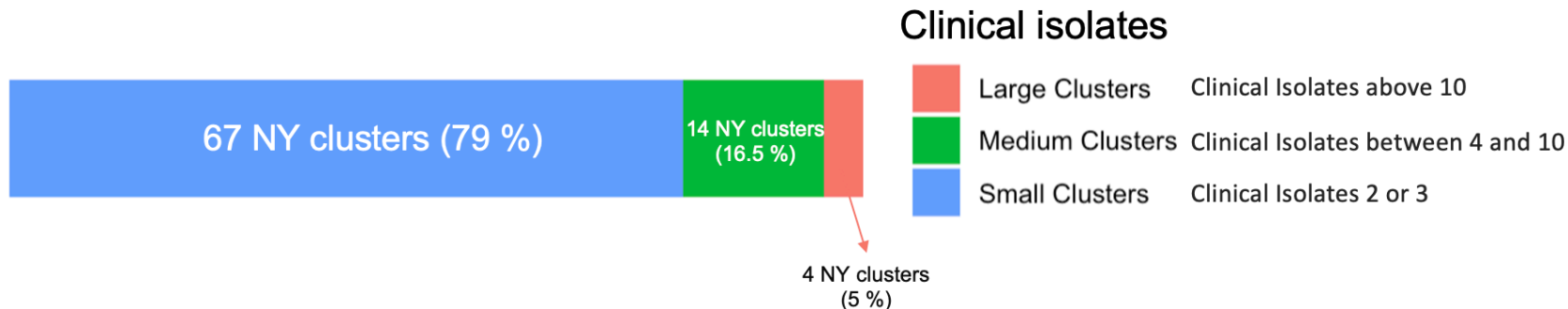


Era	Pre-PulseNet	Early PulseNet	Listeria Initiative	WGS
Outbreaks per year	0.3	2.3	3.1	8.0
Median cases per outbreak	69	11.5	6.0	5.5

Farber et al., 2021

Human listeriosis clusters are mostly small

- Analyzed 1,046 human isolates obtained in NY over 21 years



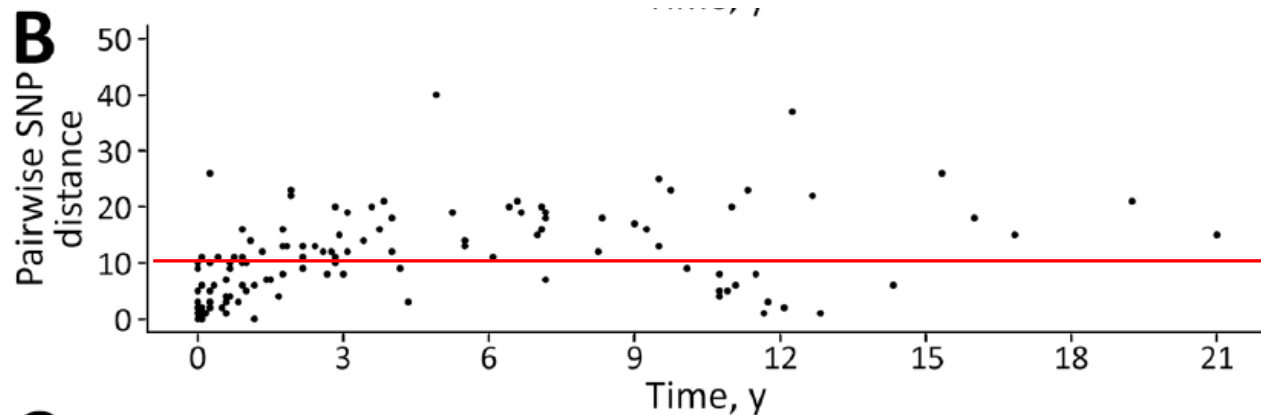
- 54%** of NY-clusters (46/85) included isolates obtained from clinical cases **> 2 years apart**, these clusters accounted for more than 70% of the clinical isolates in NY-clusters.
- 18%** of NY-clusters (15/85) included isolates obtained from clinical cases **> 10 years apart**.

Approximately 40% of the NY-clusters (34/85) included clinical isolates obtained in the same or in contiguous counties.

Retrospective Analysis of Historical *Listeria monocytogenes* Clinical Isolates, New York, USA, 2000–2021¹

Hilal Samut, Damaris V. Mendez-Vallellanes, Hannah Hoyt, Samantha E. Wirth,
Lisa Mingle, Brian D. Sauders, Gregory A. Deiulio, Alyssa W. Dickey,
Katie L. Miller, Sarah E. Hargrett-Anderson, Michael J. Tarr, David H. Walker

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 31, No. 10, October 2025



Take-home messages – zero listeriosis cases is not a goal that will drive continuous improvement

- *Listeria monocytogenes* is
 - Commonly found in many environments – we will always have Lm in foods and facilities
 - Causes severe disease, but disease cases generally linked to exposure to very high levels – reducing exposure to high levels is key
 - Shows tremendous ability to survive for extended time periods in food processing and food associated facilities and environments – focus on approaches that reduce *Listeria* persistence
- While some members of the genus *Listeria* are good index organisms other are not
 - *Listeria* testing needs to focus on the correct *Listeria* (“sensu lato”) – using *Listeria sensu lato* as index organism is not scientifically justified
- Listeriosis outbreaks are essentially always linked to *L. monocytogenes* persistence – and so are many “sporadic cases”
 - Control strategies need a focus on reducing persistence

**Be aware of unintended consequences of
well-meaning efforts**



Oregon State University
Food Innovation Center

***Listeria* in produce: from the growing environment to the packinghouse**

What outbreak investigations and produce research have taught us

Jovana Kovacevic, Ph.D.

jovana.kovacevic@oregonstate.edu | 503-872-6621

FDA Public Meeting on *Listeria monocytogenes* Prevention
College Park, MD · August 18, 2026

Where *Listeria* spp. come from



Soil and decaying vegetation

- The organism's normal habitat; survival measured in months

Vivant et al., 2013



Surface and irrigation water

- Moves it across landscapes and applies it directly to crops

Weller et al., 2015



Wildlife and livestock

- Shedding amplifies and redistributes it through the farm/fields

Nightingale et al., 2004

Produce and *Listeria* spp.

The commodity

What it means for *Listeria*

No kill step

Contamination is not corrected downstream.

Grown outdoors

The crop is raised in the organism's habitat.

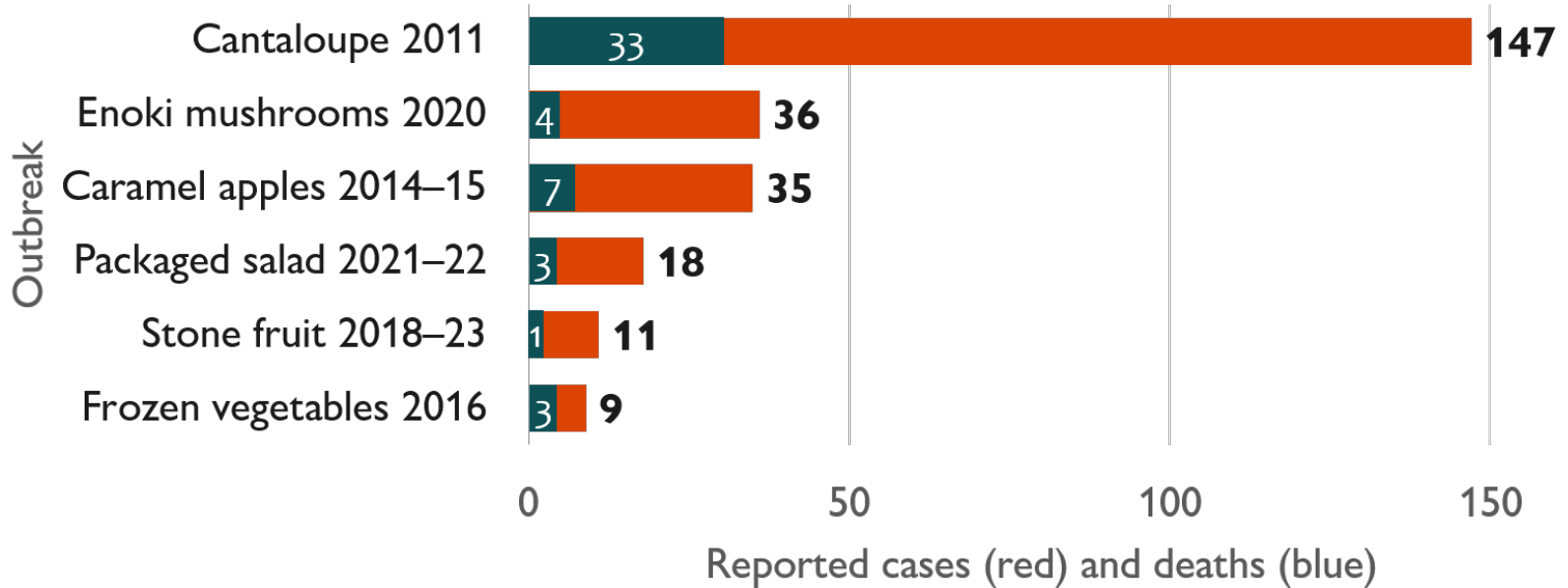
Handled repeatedly

Every dump, wash, sort and pack step can transfer it.

Often wet conditions

Wash and flume water can carry it between lots.
Pooled water on the floors can harbor it.

Listeriosis outbreaks linked to produce, 2011-2023



CDC and FDA outbreak investigation reports, 2011–2024. Case counts as reported at investigation close.

Small case counts, high severity, and long investigation windows.



Cantaloupe listeriosis outbreak in 2011



147 cases, 28 states; the first outbreak linked to whole cantaloupe

None

of the growing field samples tested positive

13 of 39

swabs in the packing facility were positive

5 of 10

cantaloupes in cold storage were positive

FDA Environmental Swabs Positive Results

Processing Line	9 positive samples from the grading belt Swabs 21, 22, 23, 24, 26, 27, 29, 30 & 33
	2 positive samples from the conveyor Swabs 20 & 28
	1 positive sample from the felt rollers Swab 13
Packing Area	1 positive sample from the conveyor belt Swab 34

FDA Product Sample Results

1 Cantaloupe Sample collected from cold storage
5 subs tested positive
(10 whole cantaloupes or "Subs")

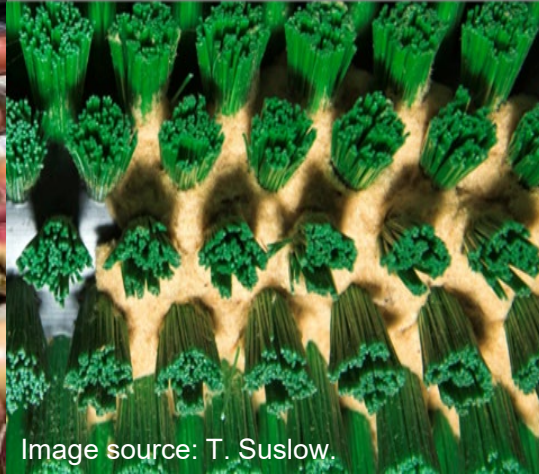
Many factors contributed to this outbreak, including no pre-cooling, pooling water, repurposed hard-to-clean equipment, and unchlorinated wash water.

FDA Environmental Assessment, 2011. · CDC final outbreak summary, 2012.

Caramel apples in 2014-2015



- 35 cases in 12 states; 7 deaths.
- Whole apples had not been linked to listeriosis outbreak before.
- 7 environmental samples from apple-packing facility matched the outbreak strain: polishing brushes, conveyor, wooden bin, drain.



Angelo et al. 2017. Epidemiol. Infect. 145:848. · Chen et al. 2017. J. Clin. Microbiol. 55:931.

Two packaged salads outbreaks investigated in 2021



OUTBREAK A

Firm X

20

cases

13

states

17

hospitalized

3

deaths

OUTBREAK B

Firm Z

10

cases

8

states

10

hospitalized

1

death

Two packaged salads outbreaks investigated in 2021



OUTBREAK A

Firm X

20

cases

13

states

17

hospitalized

3

deaths



Outbreak investigated 3 times over 8 years.



Outbreak investigations were aided by routine (Georgia) and epidemiologically directed state sampling (Michigan).



2 samples produced 7 weeks apart at **different facilities**, from iceberg grown in **different regions**, carried the same strain.



60 FDA samples across four facilities found no *L. monocytogenes*.



The firm's root cause identified one shared harvester; swabs of the harvester yielded the outbreak strain. Harvester permanently decommissioned.



Isolates from a USDA study of water-sediment related within 35 alleles by wgMLST to the outbreak strain.

Two packaged salads outbreaks investigated in 2021



OUTBREAK B

Firm Z

10

cases

8

states

10

hospitalized

1

death



Clinical isolates closely related to watershed isolates from a 2014 USDA survey of the California Central Coast. ST639 is rare; documented propensity for water.

Epi data were inconclusive at the time.



FDA conducted an environmental investigation at firm Z's facility. 100 swabs were collected; all were negative for *Listeria* spp.



Michigan routine retail sampling, 45 samples collected and 1 came back positive from Firm Z, closely related to the outbreak strain.

The source was never confirmed.

1 of 4 identified fields in the same county as watershed isolates.



Investigation pointed to 3 growers and their 4 respective fields but because of comingling at firm Z's facility, products from each of those fields were used to manufacture the positive sample collected during Michigan retail sampling.

Produce Production

Diversity of harvesting practices and food contact surfaces



Image source: T. Suslow.



Image source: T. Suslow.



Image source: T. Suslow.



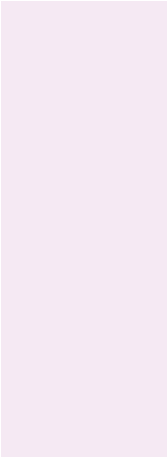
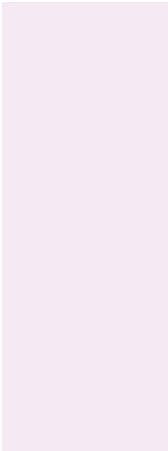
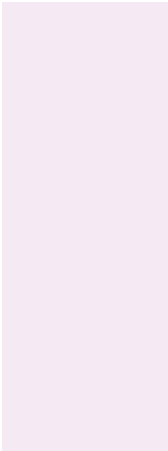
Image source: Kovacevic Lab.

- How you harvest produce influences the risks and hazards associated with those practices.
- Harvesting equipment may be difficult to clean and sanitize. It may also move between fields, farms, seasons.

Measuring Cross-Contamination During Mechanical Blueberry Harvest and the Impact of Cleaning and Sanitizing

Kilgore, Waite-Cusic, Kovacevic. 2025. Unpublished.

E. coli (Log CFU/Swab)



Standing water, soil, debris are common during production



Farm settings pose unique challenges

▶ Open environments

Harvesting happens outdoors where *Listeria* naturally lives.

▶ Equipment and personnel move

Harvesters and people move between fields, equipment cleaned and often stored outside.

▶ Seasonality

Crews and equipment may turn over every season.

▶ Design constraints

Equipment, brushes and rollers difficult to clean.

▶ Scale and cost

Many are small; capital replacement is slow.

Most guidance is written for processing facilities and assumes conditions that farms and packinghouses lack.



What we need to agree on

The contamination pathway is continuous.

The challenges	Understood from the grower's side, not just processor's.
What prevention is	In open sheds, on mobile equipment, seasonal crews.
What control is	Lowering load and removing harborage.
A positive result	How to interpret and act on positive findings. Allowing room for interpretation and decision-making for environmental positives. Incentive for testing.

***Listeria* does not know where the farm (part 112) ends and the plant (part 117) begins.**

8/7/2026

ASAC Executive Session

Ecology and Risk Factors in the Processing Environment

Listeria monocytogenes

Haley Oliver-Jischke

150th Anniversary Professor of Food Science



Food Processing Environment

Non-produce facilities where food is further processed, produced, and sold

Ready-to-eat meat & poultry — deli meats, sliced/sliced-to-order products, precooked chicken

Dairy & cheese — soft/semi-soft cheeses, queso fresco, cultured products

Ice cream & frozen desserts — soft-serve mix, novelty production lines

Low-moisture foods — dry-processing areas where water can't be used to clean

Frozen vegetables — post-blanch handling and packaging lines

Retail deli & foodservice commissaries — same principles, smaller scale

An Organism Built to Persist

Environmental traits that make elimination unrealistic — exclusion is the real goal

PSYCHROTROPHIC

-0.4°C

Grows at refrigeration temperatures (31.3°F) — cold storage alone does not control it

- Facultative anaerobe — grows with or without oxygen

HALOTOLERANT

10–12%

Survives high-salt environments common in cured and RTE products

- Broad pH range (~4.4–9.4) and ubiquitous in soil, water, and animal GI tracts

Sources: minimum growth temperature – Walker SJ, Archer P, Banks JG (1990), J Appl Bacteriol 68:157–162. Salt tolerance, pH range, facultative anaerobiosis – Farber JM, Peterkin PI (1991), Microbiol Rev 55(3):476–511; Bucur FI et al. (2018), Front Microbiol 9:2700.

A Decade of *Listeria* Outbreaks

Five of the largest U.S. non-produce outbreaks, 2016–2024

Outbreak	Facility Type	Span	Cases	Hosp.	Deaths	Root Cause
Boar's Head	RTE deli meat	2024	61+	60	10	Insanitary conditions in RTE room
Rizo-López Foods	Cheese / dairy	2014–2023	26	23	2*	Resident strain in dairy environment
Yu Shang Food	RTE meat & poultry	2021–2025	24	22	5**	Post-lethality contamination in plant
Tyson Foods	Precooked chicken	2021	3	3	1	Post-cook contamination at facility
CRF Frozen Foods	Frozen vegetables	2013–2016	9	9	3	Equipment harborage on process line

**includes one fetal loss **includes four infant deaths*

Sources: CDC outbreak investigation reports and USDA-FSIS / FDA investigation and recall notices — Boar's Head (2024); Rizo-López Foods (2024); Yu Shang Food (2024–2025); Tyson Foods (2021); CRF Frozen Foods (2016).

Boar's Head Deli Meats (2024)

Case study — 61 illnesses in 19 states · 10 deaths · 7M+ lb recalled · plant closed



WARNINGS IGNORED

- Jan. 2022 FSIS records cite “major deficiencies,” an “imminent threat”
- Rusted equipment, condensate dripping onto product, green mold on walls
- Plant kept operating two more years



INSPECTOR FINDINGS

- Sept. 27–Oct. 4, 2022: food residue on the liverwurst room floor
- Live beetles in a hallway; heavy product buildup on equipment
- Later records: mold at RTE handwash sinks, blood pooled on floors, insects near deli meat



A SYSTEMIC FAILURE

- 69 noncompliance records, Aug. 2023–Aug. 2024 — no enforcement action
- FSIS relied on Virginia state inspectors on site
- Production suspended July 31, 2024; plant closed that September

Rizo-López Cheese (2014–2023)

Case study — 26 cases · 2 deaths · 1 fetal loss, solved after 9.5 years



A 9.5-YEAR SPAN

- Sporadic cases from June 2014 to December 2023
- Went unlinked for nearly a decade



SOLVED BY GENOMICS

- Whole-genome sequencing matched a 2024 clinical isolate to historical cases
- Linked through PulseNet



A RESIDENT STRAIN

- Environmental samples at the plant matched the outbreak strain
- An established niche, not a one-time event

Facility & Hygienic Design

Risk factor — cells are ~0.001mm; any crack or gap is a harborage site

HYGIENIC DESIGN

Design harborage out of the plant so sanitation is not left compensating for it.

- **Cleanable** — to a microbiological level; no niches, hollow frames sealed
- **Self-draining** — no standing water or product collection
- **Accessible** — inspection, cleaning and maintenance without major disassembly
- **Chemically compatible** — materials, welds and gaskets that tolerate sanitation chemistry
- **Published guidance** — 3-A, NAMI 10 Principles, EHEDG Doc. 8, NSF/ANSI 14159-1
- *Sanitation cannot fix what design built in*

ZONING (ZONES 1–4)

Zone 2 carries the most signal in an environmental monitoring program — it is the early warning that harborage is moving toward product.

- **Zone 2** — adjacent non-contact: framework, housings, conveyor edges. Sample it hardest; it moves before Zone 1 does
- **Zone 1** — product contact: confirms failure, too late for early warning
- **Zone 3** — general RTE area: floors, drains, walls
- **Zone 4** — remote areas and warehouse
- *Breaches happen at zone junctions, not mid-zone*

Personnel & Traffic Flow

Risk factor — people and shared equipment are the primary vectors

▪ Primary Vectors

- People and shared tools/equipment moving between zones
- **Post-lethality handling** — slicing and packaging — is consistently the highest-risk step
- Published surveys show sliced RTE product with materially higher contamination rates than unsliced product

▪ Controls That Work

- Physical barriers between zones, not just floor tape
 - Color-coded tools, uniforms, and footwear by zone
 - Footbaths / foamers at every zone transition, zero equipment crossover
 - Same principles apply at retail deli counters and foodservice commissaries, just at smaller scale
-

Biofilms & Persistence

A weak biofilm former alone — a resilient one in company

LISTERIA ALONE	+ PSEUDOMONAS	MIXED-SPECIES MATRIX	DESICCATION SURVIVAL	SPORADIC CONTAMINATION
 A comparatively weak biofilm former on its own.	 Common in wet zones; often structurally dominates a mixed-species matrix.	 Shields embedded <i>Listeria</i>; measurably raises tolerance to BAC and PAA sanitizers.	 The biofilm dries, survives, then rehydrates and sheds cells when conditions change.	 Intermittent positives with no obvious process change — hard to root-cause.

Key Takeaways

What this means for our program

Exclusion, not elimination is the realistic goal — *Listeria*'s cold/salt/pH tolerance and environmental ubiquity mean it cannot be kept out of raw inputs entirely.

Known, controllable risk factors — not novel science — explain the decade's largest non-produce outbreaks: sanitation execution, equipment design, zoning, and monitoring response failing together.

Sporadic, hard-to-solve contamination usually signals an entrenched mixed-species biofilm reservoir, not a one-off lapse.

Layered controls — facility design, sanitation execution, EMP response, and biofilm-aware validation — are what prevent the next Boar's Head or Rizo-López.

HYPOTHESIS: Workforce/Generational turn-over is limiting longitudinal progress

PANEL QUESTIONS



Session 1, moderated by Dr. Tim Jackson

Advances in the Understanding and Control of *Listeria monocytogenes*

Panelists:

Dr. Martin Wiedmann

Dr. Jovana Kovacevic

Dr. Haley Oliver-Jischke

Session 2 - Best Practices in *Listeria monocytogenes* prevention



Session Lead – Annemarie Buchholz, Ph.D., OMFS

- Joe Stout, Commercial Food Sanitation
- Staci Richardson, Schreiber Foods
- Eric Stevens, Ph.D., IFPA
- Sanjay Gummalla, Ph.D., AFFI

Panel questions

The Listeria Control Equation

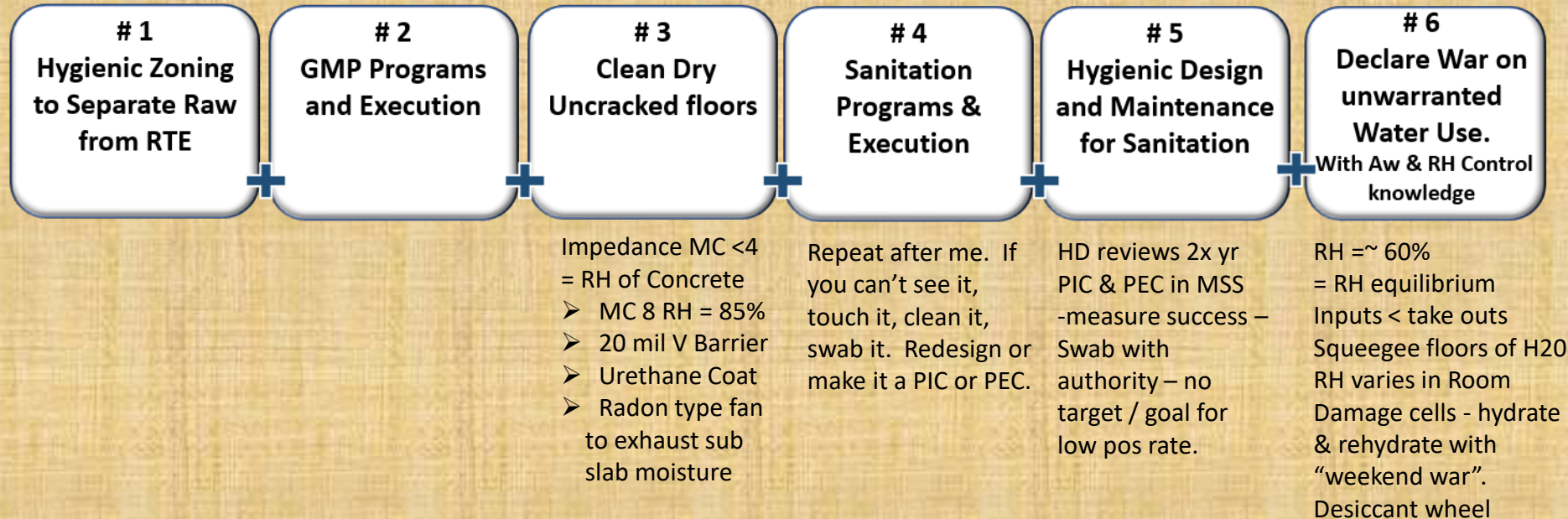
Courtesy: Joseph Stout 1999



Refreshed *Listeria* Control Equation

Courtesy: Joseph Stout 2026

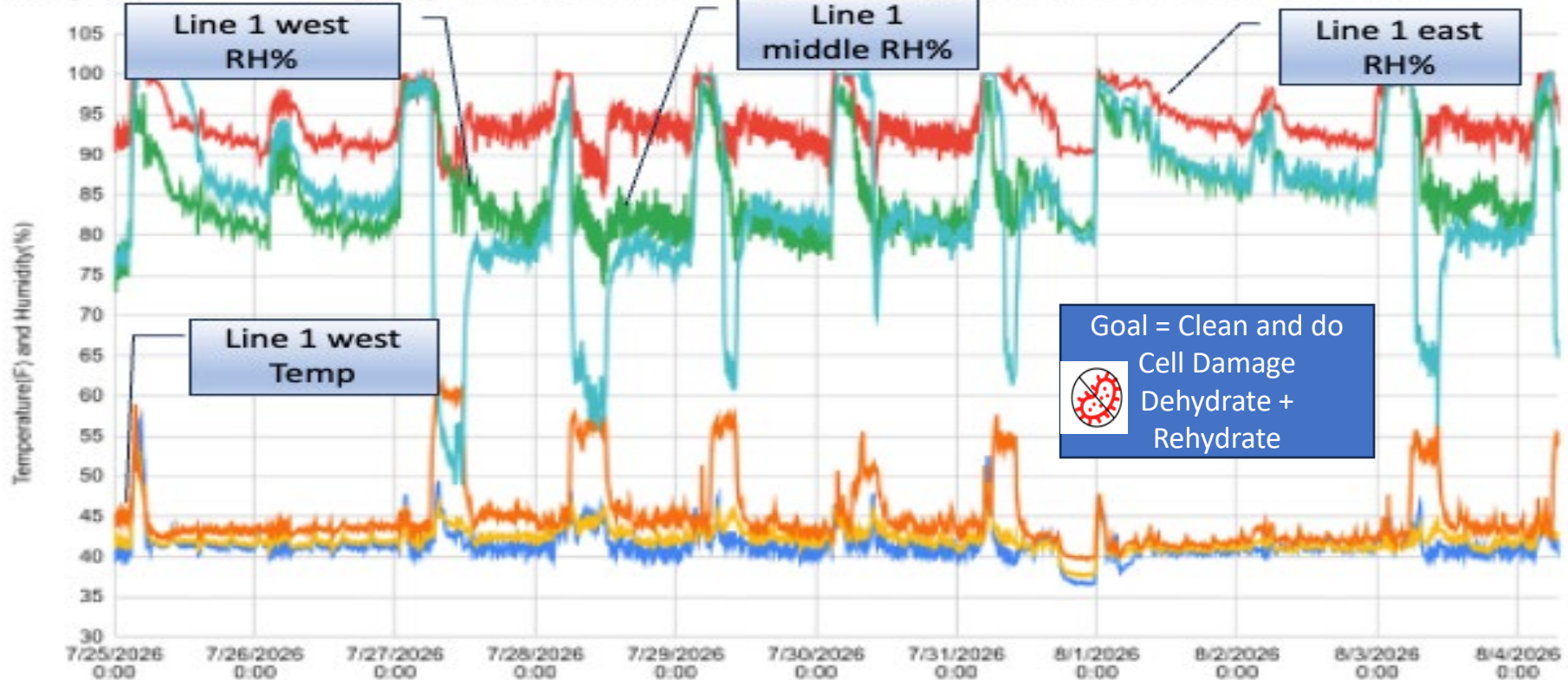
Aw
Safe Food <.85
Listeria Ctr < .92
Undisputed Science
Target RH ~ 60%



= Unparalleled *Listeria* Control

Key Message – get to know microbial growth cycles in your production rooms.

Temp (F) and Humidity (%) Trend for Line 1, 7/25/26 at 12:00 a.m. to 8/4/26 at 6:56 a.m.



Step #1 Clean, Sanitize, Increase RH + Temp (Hydrate), Step 2 Reduce Temp and RH (Dehydrate)

Aw
Safe Food <.85
Listeria Ctr < .92
Target RH ~ 60%

Summary

Prosecute the War
on Water

Irrigate to Grow Corn But Not Bacteria



YES



No



Yes - Desert Dry

If I was a Listeria Farmer this year, it would have been a bonus year.



The War on Water (Why)

Corn Farmers in Iowa call good rain in July a “million-dollar” rain because it causes rapid corn growth and elevates yields. **We are not *Listeria* Farmers – let’s stop wet & high RH conditions that support *Listeria* growth, million-dollar losses, close plants, and potentially kill people.**

Impact of RH on Humans and *Listeria*

RH	Human impact	<i>Listeria</i>	Human Outcomes	Plant FS <i>listeria</i> impact
Low ~ 30%	Skin loses moisture	Cell replication stops	Skin cracks, Eczema	Zero positives, niches negative
Med ~ 50%	Optimal balance	Cells survive	Hydration balanced	Slow growth possible
High ~ 80%	Causes tissue swelling	Rapid growth – biofilms	Acne, heat rash	Rapid growth and spread
RH Swings	Skin crack, Fungi grow	Cell envelop damaged	Discomfort	Positive rate drops
RH over all	16 B spent on lotions	Survives – kills humans	~ 225 deaths / year	~ 30 plants close to fix issues

- Rapid loss of water creates severe osmotic stress rupturing cell membranes. Sanitation cycles with RH swings are terminal to *Listeria*.
- *Listeria* will not replicate when with target $A_w < @.91$. A_w is driven by room RH, driven by water in production room with a lack RH control.
- RH below 50% will lift water off surfaces and out of niches.

Dos and Don'ts

Do these for success

Identify, eliminate or clean harborage points

- An at-risk design is one you can't see, touch, reach, clean, or sample.
- Do hygienic design reviews 2x yr to Identify *PICs & PECs
- Place PICs & PECs in MSS report. Tally % complete monthly.

Declare **WAR on Water** – Listeria will not survive or multiply w/o water

- Keep floors dry Dry, dryer and dryer yet floors ($A_w < .91$)
- Use foot Powder (Alkaline peroxide) on floors
- A dry floor is an antimicrobial environment
- Measure and control RH (target -60%)

Follow the Listeria Equation – it works

Swab Aggressively with authority

*PIC Periodic Infrastructure Cleaning

*PEC Periodic Equipment Cleaning

Aw

Safe Food $< .85$

Listeria Ctr $< .92$

Undisputed Science

Target RH ~ 60%

Don'ts for Moisture Control

- Any idle or running water in a RTE room.
- Hot water use for other than liquifying grease
- High pressure water
- Sponge floor squeegees (like a listeria swab on a stick)
- Foot Baths and boot scrubbers in production areas
- Wet Floors / trench drains



Dry is Good – Desert Dry is BEST

Aw
Safe Food <.85
Listeria Ctr < .92
Target RH ~ 60%

The War on Water Details

Every Drop of Water introduced in a production room is lifted and spread in the production room in the form of RH which increases Aw needed for *Listeria* growth

For a 45000 sq foot food plant with 20 ft ceilings at 70F

- A water hose delivers 22 gallons a minute.
- Saturated air can hold 103 gallons of water.
- To reduce RH from 100% to 70% cooling units must remove 30 gallons of water.
- A wet floor @ 70 RH adds 20 (gallons of water into the air increasing RH to about 90%.
- Water on a floor has a water activity of $a_w = 1.00$. LM grows > Aw of .92.- .95)
- Fluctuating temperature and RH in a room causes Listeria cells to dehydrate and rehydrate which compromise the cell envelope.



OUR PREMISE

Environmental monitoring is a **verification tool** — not the control itself.

Swabbing finds emerging risk. It does not prevent it. Long-term control comes from managing the conditions that let pathogens enter, survive, spread, and become established.

Staci Richardson, Senior Vice President – Enterprise Quality & Food Safety

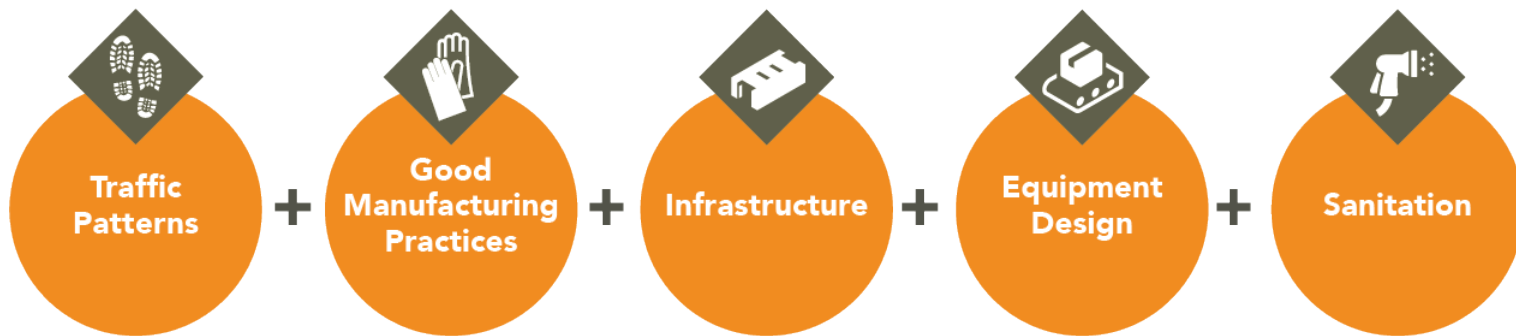
Schreiber Foods

FDA Public Meeting on *L. monocytogenes* Prevention • August 18–19, 2026

WHAT WE ACTUALLY CONTROL

Food Safety = The Big 5

FOOD SAFETY = THE BIG 5



These five foundational controls are what prevent contamination. Environmental monitoring verifies that they are working — it is the check, not the cause.

HOW WE MONITOR AND RESPOND

We Swab to Find It, Not to Pass

HOW WE MONITOR

Risk-based locations

By feature and risk, not a fixed list.

Transition zones

Catch it before food contact surfaces.

Beyond production

Zone 4 and perimeter catch ingress early.

Event-triggered

Water, construction, startup.

Zone 1	Food Contact
Zone 2	Close proximity to Food
Zone 3	Rest of RTE production room
Zone 4	Outside the RTE production room

WHEN A POSITIVE OCCURS

Reclean → Ask which of the Big 5 failed.

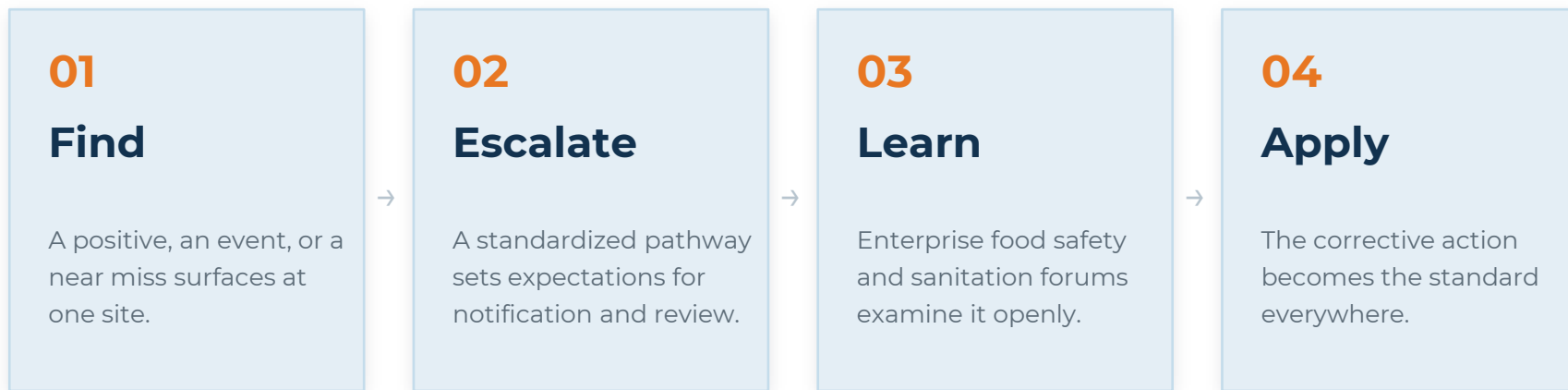
Sample more → Vector beyond adjacent sites.

Close it → Correct the condition, then verify.

We investigate the system, not the swab.

SCALING WHAT WORKS

One Plant's Lesson, Every Plant's Practice



Transparency across sites is a control, not a courtesy. One plant's learnings become another plant's playbook.

WHY INVEST UPSTREAM

The 1:10:100 Case for Prevention

George Labovitz and Yu Sang Chang introduced the 1:10:100 rule of data quality in 1992.

1

PREVENT

Hygienic design,
infrastructure, GMPs,
sanitation done right the
first time.

10

CORRECT

Investigations, deep
cleans, downtime, product
on hold, rework.

100

FAIL

Recall, illness, brand and
public-health cost that no
budget recovers.

*Every dollar not spent on prevention is borrowed at roughly ten times interest — and repaid at a hundred.
Every hour spent on prevention saves 10 hours of RCA & CAPA, and 100 hours of crisis management.*

The Industry Has Already Built This

Control of *Listeria monocytogenes*

Guidance for the U.S. Dairy Industry — the 2016 foundation document, focused specifically on *Listeria monocytogenes* best practices. Also published in Spanish.

Controlling Pathogens in Dairy Processing Environments

Guidance for the U.S. Dairy Industry — *Listeria monocytogenes*, *Salmonella* and *Cronobacter sakazakii*. Covers raw / RTE separation, GMPs, sanitary facility and equipment design, cleaning and sanitation, and environmental monitoring.

Supporting tools

Dairy plant food safety controls, supply chain and FSMA tools, food safety culture resources, artisan and farmstead guidance, and webinars.

Written by the dairy industry, for the dairy industry — free and publicly available at
usdairy.com/foodsafety



A Fresh Produce Perspective on *L. Monocytogenes* Control

Eric L. Stevens, PhD
Vice President – Food Safety and Regulatory Affairs



PRACTICAL GUIDANCE INDUSTRY NEEDS

FDA GUIDANCE SHOULD INCLUDE PRACTICAL EXAMPLES OF:



ROOT-CAUSE INVESTIGATION

Practical methods and examples to identify and address the true source of risk.



NICHE INVESTIGATIONS

How to thoroughly inspect and assess hard-to-clean and hard-to-see areas.



VERIFICATION OF CORRECTIVE ACTIONS

Examples of verification activities and acceptance criteria that confirm risk is controlled.



LEGACY EQUIPMENT EXPECTATIONS

Clear, risk-based expectations for existing equipment that cannot be easily redesigned.



CLEANING APPROACHES FOR INACCESSIBLE EQUIPMENT

Effective cleaning strategies, tools, and techniques for complex or enclosed areas.



DECISION TREES

Step-by-step visual tools to guide consistent and timely decisions and actions.



SMALL PROCESSOR EXAMPLES

Real-world examples and solutions that reflect the resources and realities of small and mid-sized processors.



**INDUSTRY NEEDS PRACTICAL TOOLS,
NOT JUST DESCRIPTIONS OF EXPECTATIONS.**



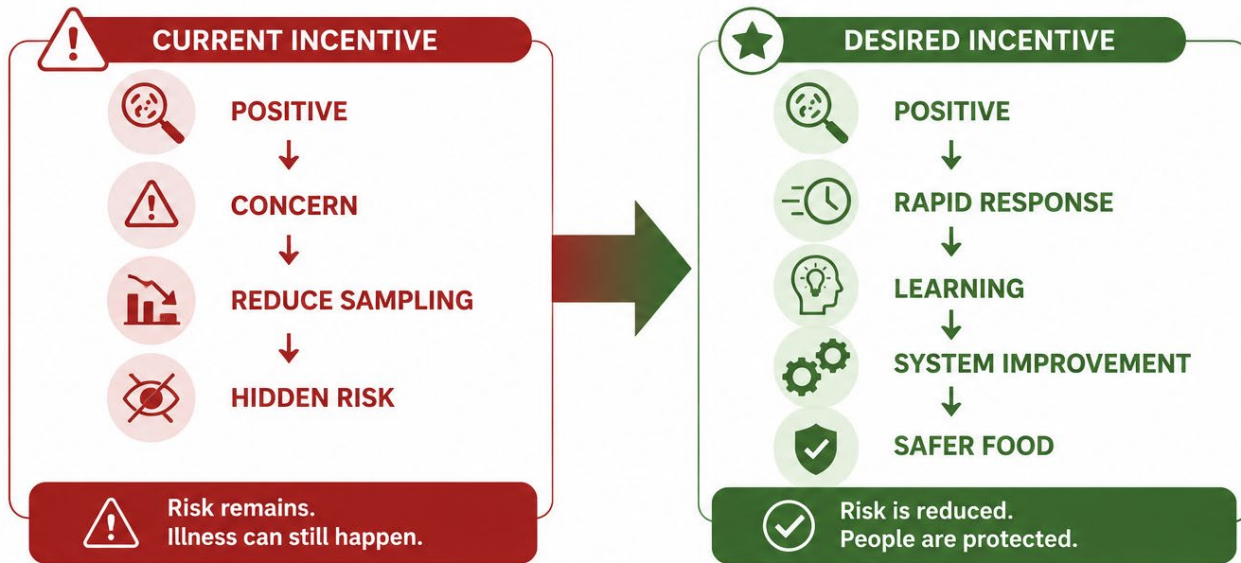
**Clear. Practical. Achievable.
Better Guidance.
Stronger Outcomes.**



FOOD SAFETY CULTURE



We should **reward** facilities that **actively look for Listeria**—not unintentionally discourage them from finding it.



A culture that encourages detection and action
prevents contamination and protects consumers.



LOOK. ACT. LEARN.
SAFER FOOD FOR ALL.



THE GOAL ISN'T ZERO POSITIVES

CURRENT PERCEPTION

POSITIVE = FAILURE



Focus shifts to avoiding findings, not eliminating risk.

VS.

DESIRED PERCEPTION

POSITIVE = OPPORTUNITY

to eliminate a harborage before it becomes a food safety event.



Focus stays on prevention and risk elimination. Safer food. Stronger systems. Better outcomes.



1. **STRONG EMPs**
SEEK—NOT AVOID—FINDINGS.



2. **EFFECTIVE CORRECTIVE ACTIONS MATTER MORE THAN TOTAL SWAB COUNTS.**



3. **TREND ANALYSIS PREDICTS RISK BEFORE CONTAMINATION OCCURS.**



FIND IT. INVESTIGATE IT. ELIMINATE IT.
THAT'S HOW WE PREVENT ILLNESS.





LEGACY EQUIPMENT IS NOT LEGACY FOOD SAFETY



NEW EQUIPMENT

-  Designed for hygienic access
-  Drainability
-  No hollow members
-  Easy inspection



EXISTING EQUIPMENT

-  Limited access
-  Older welds
-  Complex frameworks

Still capable of effective control with:

-  Enhanced cleaning
-  Targeted inspection
-  Risk-based maintenance
-  Focused EMP

VS.



PERFORMANCE—NOT AGE—
SHOULD DETERMINE COMPLIANCE EXPECTATIONS.



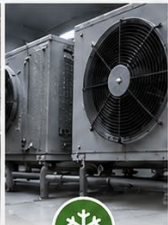
MOISTURE IS THE LEADING INDICATOR



**LISTERIA FOLLOWS MOISTURE—
NOT ORGANIZATIONAL CHARTS.**



CONDENSATION



REFRIGERATION
MAINTENANCE



FREEZER
TRANSITIONS



STANDING
WATER



WET
INSULATION



COOLING
UNITS



DRAINS &
TRAFFIC



Highlighting moisture as a preventive control can feel like *more work*—and many of these moisture issues occur and are not easily controllable.

WHERE THERE'S
MOISTURE,
THERE'S **RISK**.



NEED EXAMPLES



Guidance and practical **examples** on how to manage moisture as a **preventive control** would be very helpful.



CONTROL MOISTURE.
CONTROL **LISTERIA**.



EARLY DETECTION.
FASTER RESPONSE.



STRONGER CONTROLS.
SAFER FOOD.



BETTER TRENDS.
FEWER ILLNESSES.



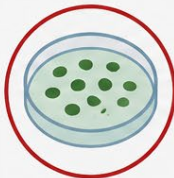
MEASURE WHAT MATTERS

OUTCOME-BASED VERIFICATION

INSTEAD OF EVALUATING



NUMBER
OF SWABS



NUMBER
OF POSITIVES



EVALUATE



TIME TO INVESTIGATION



ROOT CAUSE IDENTIFIED



CORRECTIVE ACTIONS VERIFIED



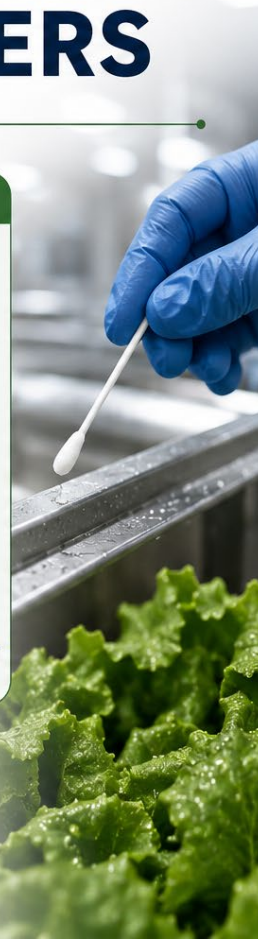
REPEAT POSITIVES ELIMINATED



LONG-TERM TREND IMPROVEMENT

“

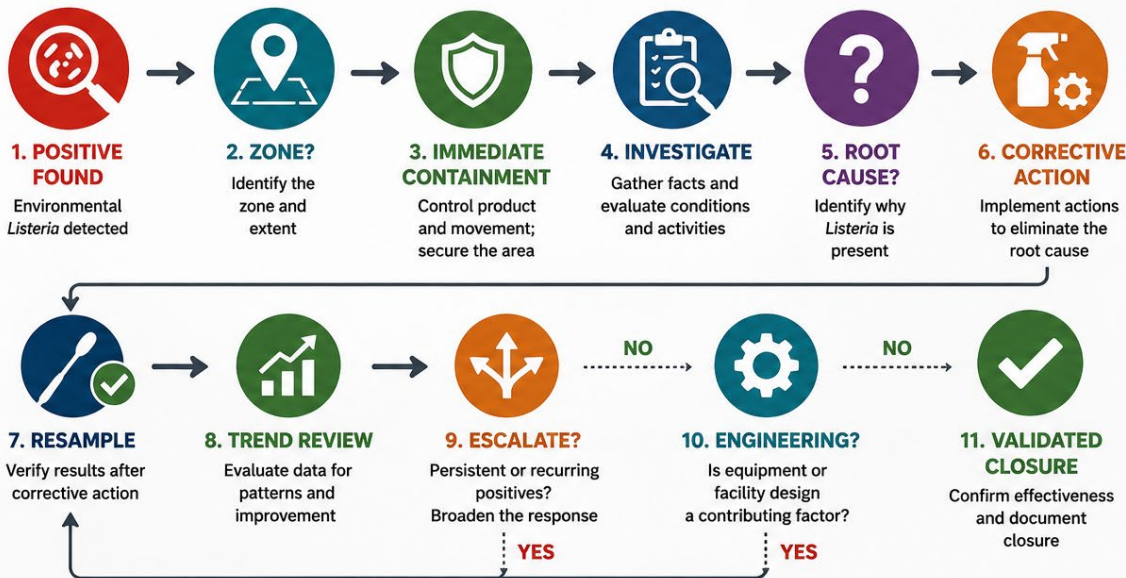
The effectiveness of an EMP should be measured by how quickly it **finds, investigates, and eliminates risk**—not by how rarely it detects *Listeria*.”





CORRECTIVE ACTION DECISION TREE

Simple. Visual. Actionable.



★
**INSTEAD OF
DOZENS OF
PAGES...**

**A SIMPLE
DECISION TREE
DRIVES FASTER
ACTIONS AND
BETTER OUTCOMES.**

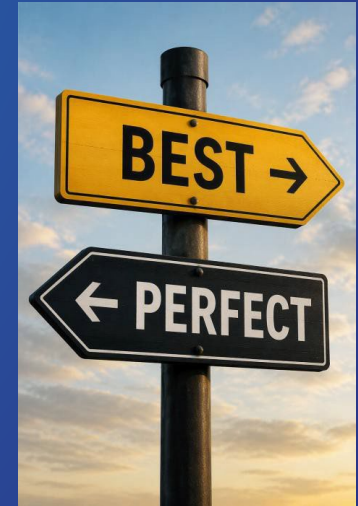


**One slide.
Everyone remembers it.**

One of FDA's biggest opportunities is providing
visual decision tools instead of lengthy
narrative guidance.

Advancing *Listeria monocytogenes* Prevention

Best Practices, Continuous Learning, and
Risk-based Approaches for Low-risk Foods



Sanjay Gummalla
August 18, 2026

Pathway to Harborage and Contamination

From environment to food

- Natural prevalence
- Avoidable & unavoidable
- Training, GMPs

- Hygienic design of infrastructure & equipment

- Cleaning & sanitation
- Training, GMPs
- Pre-requisite programs

Inadequate Verification

- Zoning & active barriers
- Training, GMPs
- Air/condensation control

Undetected Persistence

- Validated cooking instructions
- Labeling & consumer education
- Addressing vulnerable populations

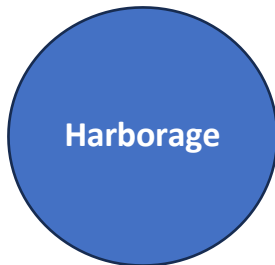
Public Health Impact



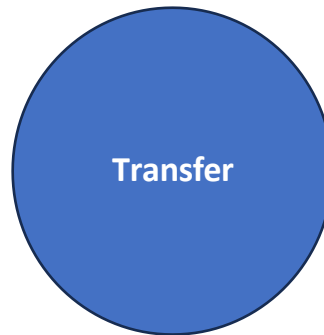
Entry



Niche



Harborage



Transfer



Product Contamination

- Raw materials
- People, shoes
- Air & moisture
- Tools & vehicles, (forklifts)
- Packaging

- **Entry +**
- Moisture
- Organic matter
- Inaccessible or Uncleanable location

- **Niche +**
- Time & Growth conditions
- No competition
- Validated PRPs
 - Frequency
 - Intensity

- **Harborage +**
- Dynamic (movement)
- Traffic: people, vehicles, tools
- Uncontrolled use of water/air

- **Harborage & Transfer ++**
- Exposed Product
- Modified exposure
- Pathogen growth to high levels



Why Data Must be the Next Frontier?

Continuous improvement

- Collect more and better data
 - Early warning signals
- Understand persistence
 - Identify investments
- Measure effectiveness
 - View tangible progress
- Understand recurrence
 - Adapt your practices
- Learn from outcomes
 - Holistic evolution of program

How, Where, When, Which, and What?

- Conditions that result in persistence
- Habits/limitations that best predict contamination?
- Interventions that are most effective?
- Corrective actions prevent recurrence?
- Practices driving largest risk reductions?



We Cannot Reduce What We are Unwilling to Find!

When mechanisms to recognize *L. monocytogenes* control are inadequate

- Persistence in facilities goes undetected
- Low-level contamination goes undetected and unresolved
- Lm is a high-dose pathogen with a vastly different dose-response
 - Very low probability of illness from a single cell
- Some foods do not support the growth of the pathogen during shelf life
 - pH, Aw, storage conditions, antimicrobials: Let's call them lower-risk foods?
- Listeriosis incidence shows: High dose = more likely to cause concerns
 - One billion servings, a single serving with 10^9 cfu = 1 illness
 - One billion servings, each with 1 cfu = may cause 1 illness (highly susceptible)



How Can We Have Effective Risk Management?

Persistence in a facility goes undetected = many servings = increased risk of exposure to vulnerable pop.

- Redirect resources to ensure hygienic process conditions
- Discovery as the motivation of a stringent and robust environmental monitoring (EM) program
- A sporadic low-level product finding treated in the context of such an EM program
- Focus on root cause analysis to identify harborage
 - 'Seek and Destroy'
- Use data, analysis, and trends to drive continuous improvement
 - Subsequently, pursue more sophisticated tools
- **AFFI's proposed industry pilot for low-risk foods: DATA**
 - A risk-based approach to *L. monocytogenes* prevention and control

Best Practices – www.affi.org/safety



PANEL QUESTIONS



Session 2, moderated by Dr. AnneMarie Buchholz

Best Practices in *Listeria monocytogenes* prevention

Panelists:

Joseph Stout

Staci Richardson

Dr. Eric Stevens

Dr Sanjay Gummalla

Docket



Please provide any questions/comments to the docket:

FDA-2026-N-7914-0001

Docket closes November 2, 2026

