USDA

United States Department of Agriculture

One Team, One Purpose

Food Safety and Inspection Service
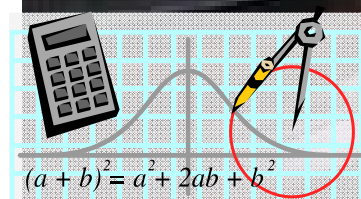### Protecting Public Health and Preventing Foodborne Illness
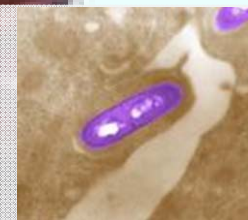
A Risk-Based Approach to Preventing Listeriosis in the U.S.

$$(a + b)^2 = a^2 + 2ab + b^2$$

Janell Kause, M.P.P., M.P.H.
Scientific Advisor for Risk Assessment
Food Safety and Inspection Service
U.S. Department of Agriculture

Food Safety and Inspection Service
Presentation Outline

Agency Mission & Operation

Listeriosis in the U.S.

Risk-informed Decisions

Emerging Issues

Part 1

Part 2

Part I:

Public Health Regulatory Context & Risk-based Decisions

Agency Mission & Operation

Food Safety and Inspection Service
Mission in Action

We are the public health agency in the USDA responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.

- Federal Meat Inspection Act (FMIA), 1906
- Agricultural Marketing Act (AMA), 1946 (select sections)
- Poultry Products Inspection Act (PPIA), 1957
- Humane Methods of Slaughter Act (HMSA), 1958
- Egg Products Inspection Act (EPIA), 1970

Food Safety and Inspection Service
One Team, One Purpose

We work **together** to accomplish our mission of **protecting** public health.

committed

skilled

motivated

More than **9,600** employees strong
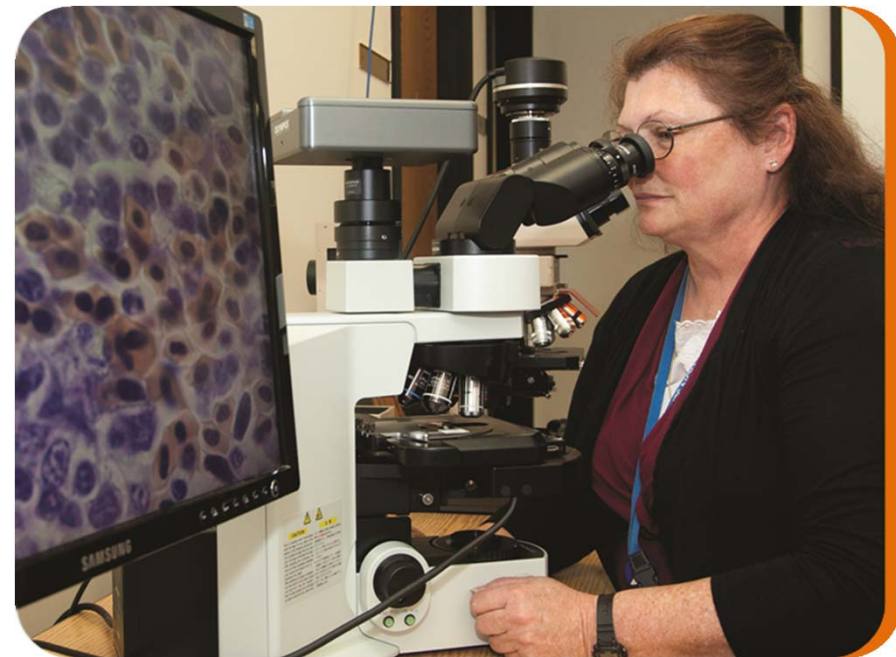
diverse

highly trained

Food Safety and Inspection Service
Modern Approach: Increased Use of Science, Data & Analytics

We implement policies based on current science and data.

We focus on preventative measures and management control rather than on prescriptive requirements.

"To improve its food safety approach, FSIS has moved to an increasingly science-based, data-driven, risk-based approach."
   – GAO 2014 Poultry Pathogens Audit Report

Food Safety and Inspection Service
Public Health Science

FSIS performs approximately 190,000 scientific analyses every year.

Public Health & Science employees:

- Assist in investigating national and international outbreaks

- Monitor current and emerging foodborne threats

- Conduct **risk assessments** and other scientific analyses to guide national food safety policies and programs

The public health community is more powerful when it speaks with a single voice and shares resources in service of a common mission.

FSIS collaborates with other Federal agencies, States, tribal communities, stakeholders, and the public, to ensure the safety of meat, poultry, and processed egg products.

Listeriosis in the U.S.

Food Safety and Inspection Service

Listeria monocytogenes: Ubiquitous, Persistent, and Foodborne

- Ubiquitous and persistent environmental contaminant along the food supply chain

  - Food animals are carriers; found in farm soil, water, and vegetation; biofilms/niches in processing plants and at retails; home refrigerators

- Grows at refrigeration temperatures & survives under a wide variety of conditions

  - Heat, salt, nitrite, acidity, and low oxygen

- Transmitted to people by food

- Destroyed by proper sanitation, pasteurization (at processing establishment), and cooking (in-home)

- Infection (listeriosis) causes severe disease, generally during vulnerable stages of life
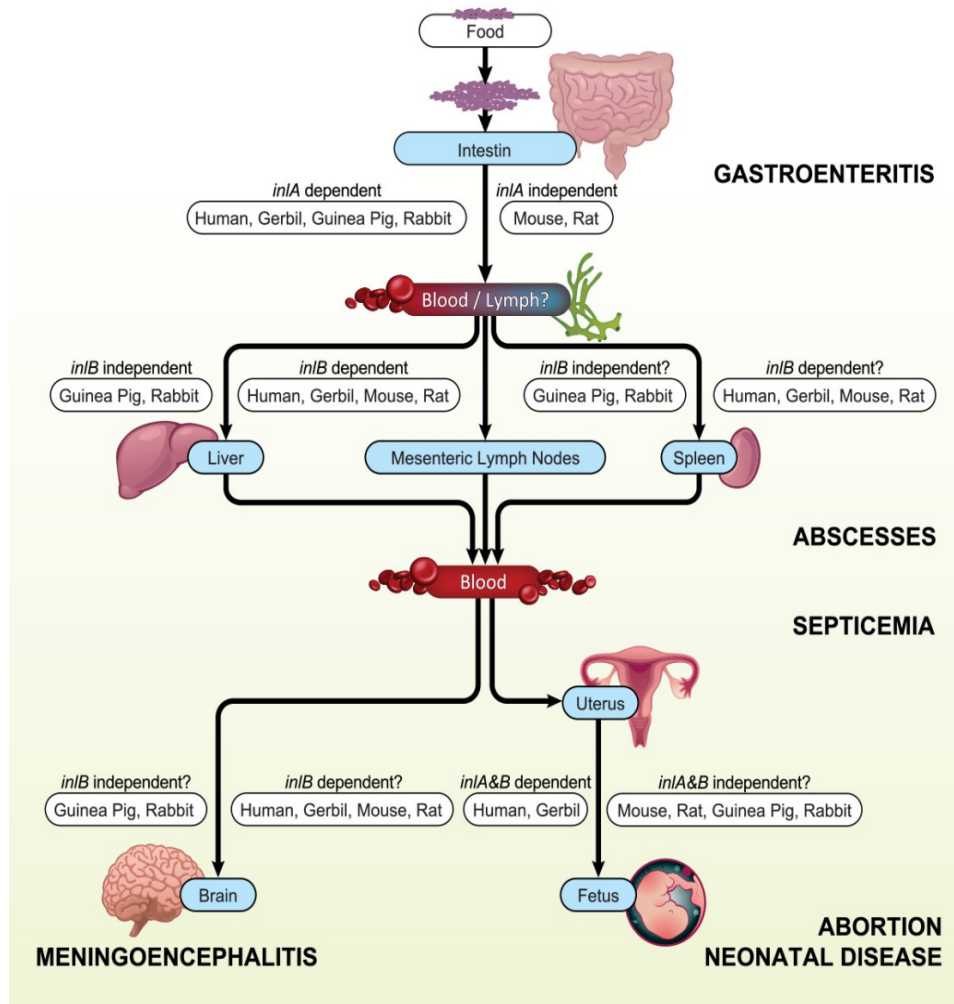
Source: Hoelzer et al., 2012. Vet. Res. 43:18)

The clinical symptoms

- **Gastroenteritis** (non-invasive disease; flu-like symptoms)

- **Septicemia**

- **Meningitis / encephalitis**

- **Stillbirth / fetal loss**

- **Other (e.g., joints, skin)**

Invasive disease

Note: Long incubation period: 7-60 days (identification of food vehicle is difficult; most cases not linked to an outbreak).

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Food Safety and Inspection Service
Risk at Vulnerable Stages – a Growing Concern

- **58%** - Older Adults (≥ 65 years old) (n=950)
  - Portion of the U.S. projected to double to 83.1 million by 2050 [U.S. Census

- **21%** - Immunocompromised (n= 351)
  - May be larger portion at risk (underlying conditions, over the counter medications, etc.)

- **14%** - Pregnancy-related (newborns, fetuses) (n=227)
  - 1 in 7 Lm cases occur during pregnancy
  - 20x more likely (compared to general population)

- **7%** - Other (healthy population) (n= 123)
  - Emerging concern: Recent outbreaks with children

Food Safety and Inspection Service
Listeriosis is Rare, but Deadly

Pathogen	Illnesses	Deaths	Case-fatality rate
*Listeria monocytogenes**	1,600	260	16-21%
Campylobacter	1,300,000	120	0.1%
Salmonella	1,230,000	450	0.5%
Shiga toxin- producing *E. coli* O157	96,000	30	0.5%

** Listeria monocytogenes (Lm) is a leading cause of food-related hospitalization, fetal loss and death in the U.S. Accounts for **19% of all food-related deaths** in the U.S. 3rd highest overall economic impact: of all major foodborne pathogens $2.8 billion annually; highest impact on a per case basis – $1.78 billion.*

Sources:
- Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis*. Jan. 2011.
- Centers for Disease Control and Prevention. 2013. Vital signs: *Listeria* illnesses, deaths, and outbreaks--United States, 2009-2011. *Morbidity and Mortality Weekly Report*, 2013, 62(22), 448-452.
- Hoffmann S., Maculloch B., and Batz M. Economic burden of major foodborne illnesses acquired in the United States. U.S. Department of Agriculture, Economic Research Service Information Bulletin No. 140. Washington, DC. May 2105.

Food Safety and Inspection Service
Relative Risk of Listeriosis
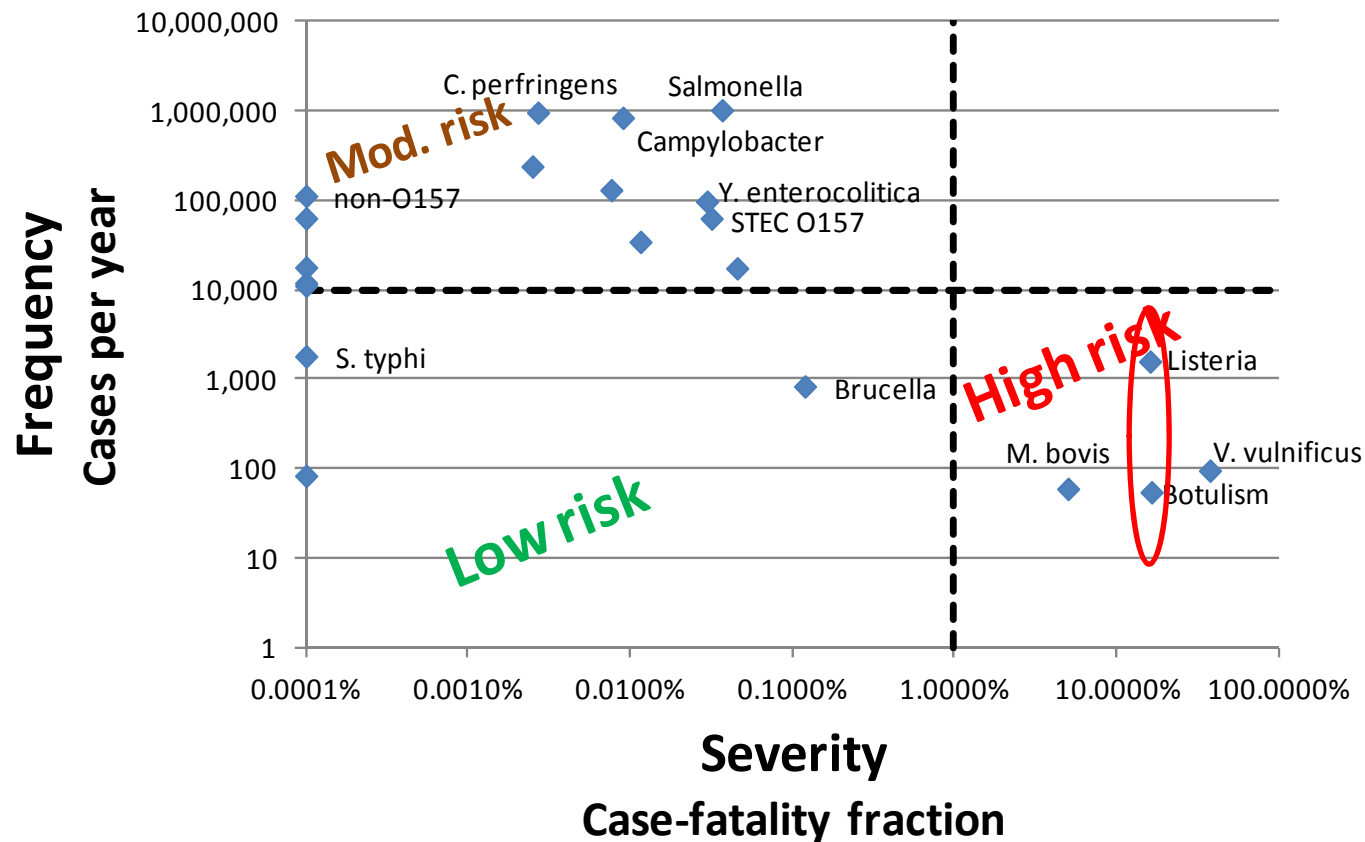
- *Lm* case-fatality rate comparable with *Clostridium* botulinum (C. bot.)

- More *Lm* cases than C. bot. (1600 vs. 55)

- Higher hospitalization rate than C. bot.: 94% vs. 83%

Food Safety and Inspection Service
Timeline of Key Events Related to *Lm*: Science-Based Prevention

Emerging Issue

Paradigm: Vulnerable Populations/Growth Lm/High Levels

Changing Risk?

1980's – *Lm* a recognized foodborne pathogen

- 1983: Pasteurized milk outbreak (449 cases; 14 deaths)
- 1985 Mexican style soft cheese outbreak (142 cases, 52 deaths)
- 1989: Listerial meningitis linked to turkey frankfurters

1990's – *Lm* outbreaks --variety of RTE foods that support *Lm* growth

- 1998-99: 3rd largest listeriosis outbreak in U.S. history – linked to frankfurters (108 cases, 14 deaths)
- 1996-98 incidence: 4.8 cases per 100,000 population

2000's – *Lm* outbreaks: Variety of RTE Foods that support *Lm* growth

- Outbreaks primarily associated with soft and Mexican-style cheeses and RTE meat and poultry products
- 2002: Large listeriosis outbreak among elderly associated with turkey deli meats in Northeastern U.S. (46 culture-confirmed cases, 7 deaths)

2010's – *Lm* outbreaks: "low risk" foods; healthy children; "low dose"

- 2011: Largest outbreak in U.S. history from cantaloupes (147 cases; 33 deaths)
- 2014: Outbreak - caramel apples; healthy children (35 cases; 7 deaths)
- 2015: Outbreak - ice cream; low *Lm* levels (10 cases, 4 deaths)

1980's – Surveillance & Focus on Prevention

- 1986: CDC begins active listeriosis surveillance at sentinel locations
- 1989: U.S. intensified *Lm* monitoring and verification sampling of RTE products; "zero tolerance" adopted

1990's – Strengthen Surveillance (FoodNet) & Inspection (HACCP)

- 1996: Active listeriosis surveillance incorporated into FoodNet
- 1996: USDA-FSIS modernizes its inspection program (1996 HACCP Rule)
- 1998: FDA & USDA-FSIS initiated 1st Listeria risk assessment to identify which RTE foods pose the greatest risk (FDA-FSIS risk ranking)

2000's – Risk-based Policies and Programs (targeted efforts at processing)

- 2001: Draft FDA- FSIS risk-ranking for RTE foods (highest risk: deli meats)
- 2003: FSIS risk assessment evaluates effectiveness of process controls and sanitation (leads to FSIS *Listeria Rule*)
- 2004: FSIS develops risk-based inspection program/targets inspection/motivate industry adoption of controls (SUCCESS)

✓ 75% decline of Lm in FSIS-tested RTE meat and poultry products   ✓ 42% decline in the incidence of listeriosis in the U.S.

2010's – Focus on Retail; Modernize Subtyping; Acknowledge Knowledge Gaps

- 2010: FSIS Comparative *Lm* risk assessment -focus on retail risk (83% of deli meat listeriosis cases)
- 2013: Interagency Retail *Lm* Risk Assessment: cross-contamination/no growth foods a risk
- Whole genome sequencing used to identify outbreaks more quickly; new food vehicles

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Risk Assessments & Decision-making

Food Safety and Inspection Service
Microbiological Risk Assessments for Foodborne Pathogens

- Applicable for assessing the risk associated with the ingestion of a foodborne pathogen

- Cornerstone of our food safety program – bridges data and decisions

- Provides an objective, structured, systematic, and transparent approach that facilitates stakeholder engagement

- Synchronized with both the National Research Council and Codex frameworks

MICROBIAL
RISK ASSESSMENT GUIDELINE

PATHOGENIC MICROORGANISMS
WITH FOCUS ON FOOD AND WATER

Prepared by the Interagency Microbiological
Risk Assessment Guideline
Workgroup
July 2012

Publication Numbers:
USDA/FSIS/2012-001
EPA/100/J12/001

USDA
Food
Safety and
Inspection
Service
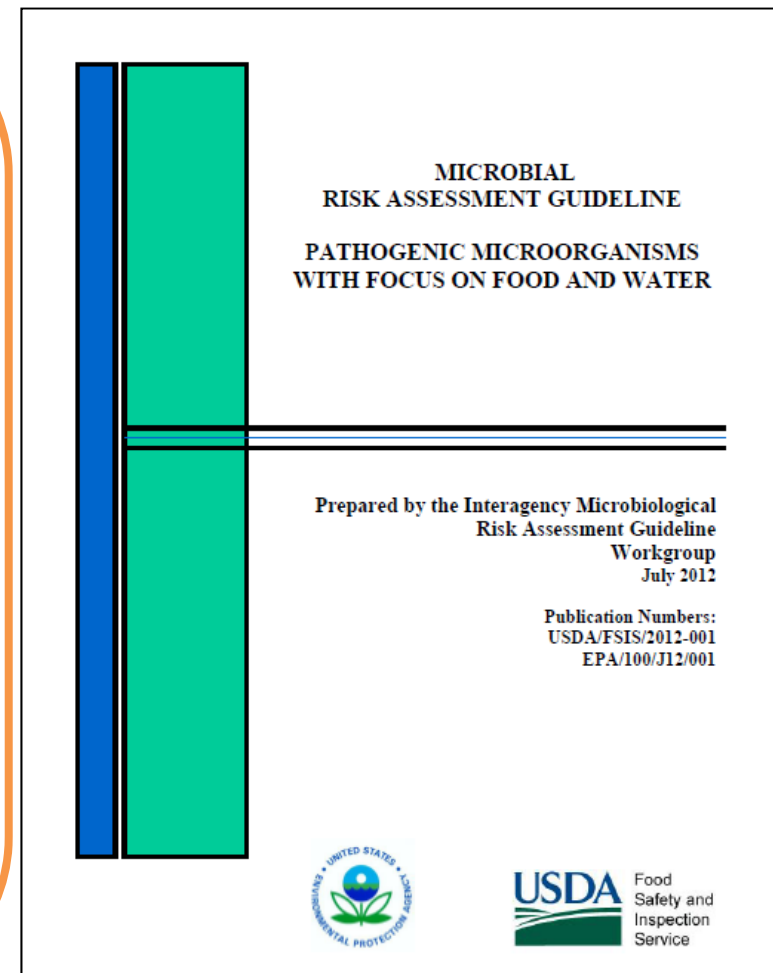
Food Safety and Inspection Service
Why Conduct Risk Assessments

o **Estimate risks from FSIS-regulated products, providing information for agency decision makers, such as:**

- Estimate the illnesses avoided by implementing a given policy
- Compare the effects of different policy options
- Rank public health risks from different types of products to focus sampling programs or other activities

o **Required for rulemaking**

- Significant regulatory action (Executive Order 12866)
- Expected to cost more than $100M (1994 Reorganization Act for Agriculture)
- International requirements (1995 WTO/SPS Agreement)

Food Safety and Inspection Service:
Achieving National Food Safety Goals for Reducing *Listeriosis*

2010 Goal: 0.25 cases per 100,000 persons
(50% decline from 1996-98 incidence)

2020 Goal: 0.20 cases per 100,000 persons
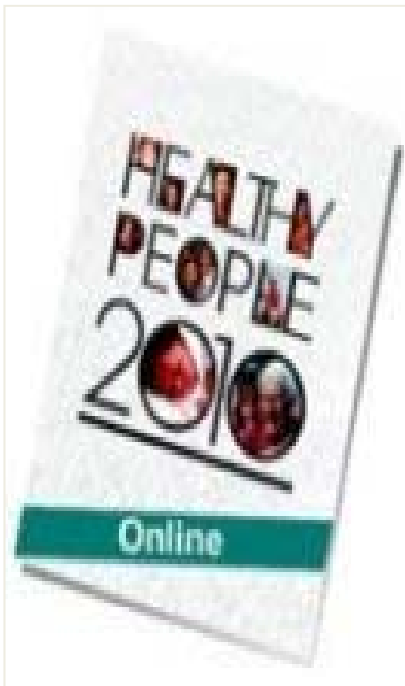
FIGURE 1. Relative rates compared with 1996–1998 baseline period of laboratory-diagnosed cases of infection with *Campylobacter*, *Escherichia coli* O157, *Listeria*, *Salmonella*, and *Vibrio*, by year — Foodborne Diseases Active Surveillance Network, United States, 1996–2004
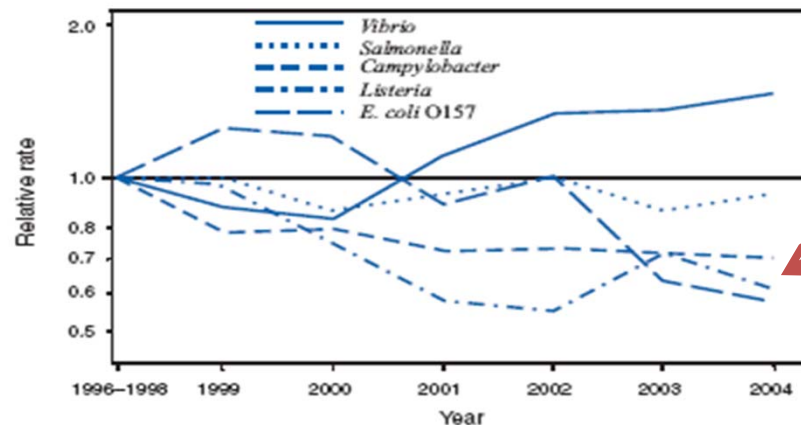
Incidence of invasive listeriosis (2003):

- 0.4 cases per 100,000 persons (general population)

- 0.7 cases per 100,000 persons (Hispanic population)

Voetsch A, et al, *Clinical Infectious Diseases, 2007*

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Food Safety and Inspection Service
Identification, Regulation & Inspection: Addressing *Listeriosis*

Systematic, sequential use of science and risk assessments to guide policies and inspection to prevent listeriosis:

- Which RTE foods pose the greatest risk of listeriosis?
  - 2001/2003 FDA-FSIS risk-ranking

- Which processing controls most effectively reduce the risk of listeriosis? How effective are they?
  - 2003 FSIS Deli Meat Risk Assessment

- How can USDA-FSIS inspection resources be effectively utilized across manufacturers?
  - 2005 FSIS Risk-based *Lm* Verification Sampling

- What others areas along the supply chain should efforts be focused?
  - 2010 FSIS Comparative *Lm* Risk Assessment for Deli Meats (Endrikat *et al.*, 2010)

- How much do various retail practices and conditions contribute to the risk of listeriosis?
  - 2013 Interagency Retail *Lm* Risk Assessment (Pouillot *et al.*, 2015)

Food Safety and Inspection Service
Which RTE Foods Pose the Greatest Risk of Listeriosis?

- Risk Assessment: 2003 FDA/FSIS *Listeria* Risk Assessment (draft presented in 2001)

- Estimated the relative risks of serious illness and death associated with consumption of different types of RTE foods

- Estimates exposure among three age-based categories and the total U.S. population; used a single dose-response relationship

- Probabilistic **retail-to-table** exposure assessments
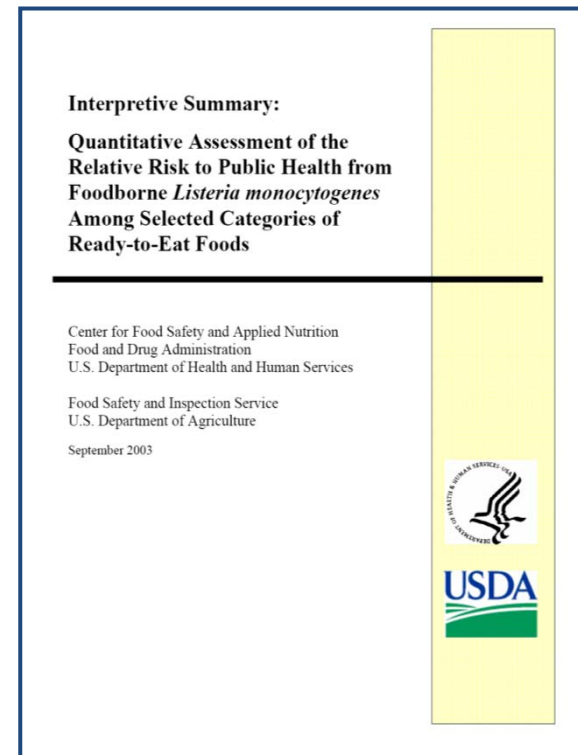
Interpretive Summary:

Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods

Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services

Food Safety and Inspection Service
U.S. Department of Agriculture

September 2003

USDA

Available at:
http://www.fda.gov/downloads/food/scienceresearch/researchareas/
riskassessmentsafetyassessment/ucm197330.pdf)

*Carried out in a manner consistent with the guidelines established by Codex Alimentarius, ICMSF, and the U.S. for the conduct of a microbial risk assessment: 1) transparency; 2) broad scientific and stakeholder input; and 3) extensive peer review.

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Food Safety and Inspection Service
Approach Used for the 2003 FDA-FSIS Risk Ranking

Compared risk of listeriosis from 23 categories of RTE foods:
- e.g., seafood, milk, cheese, produce, meat, deli salads.

Compared risk for different stages of life:
- Age-based subgroups (perinatal, intermediate & >60 years).
- The total population.

Separate exposure assessments for each food category.

Dose-response calibrated ("anchored") to national listeriosis surveillance health statistics (CDC, FoodNet).
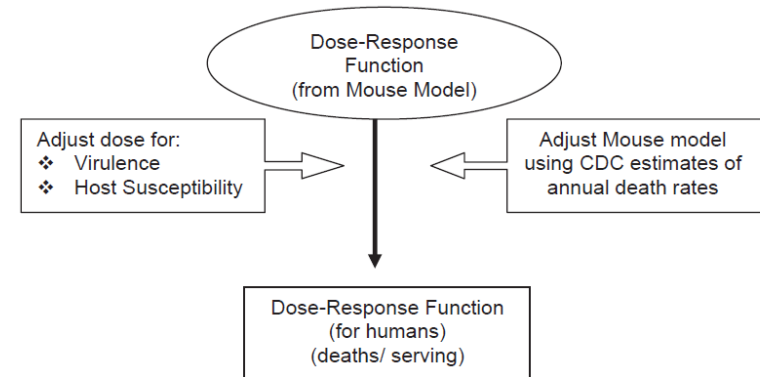

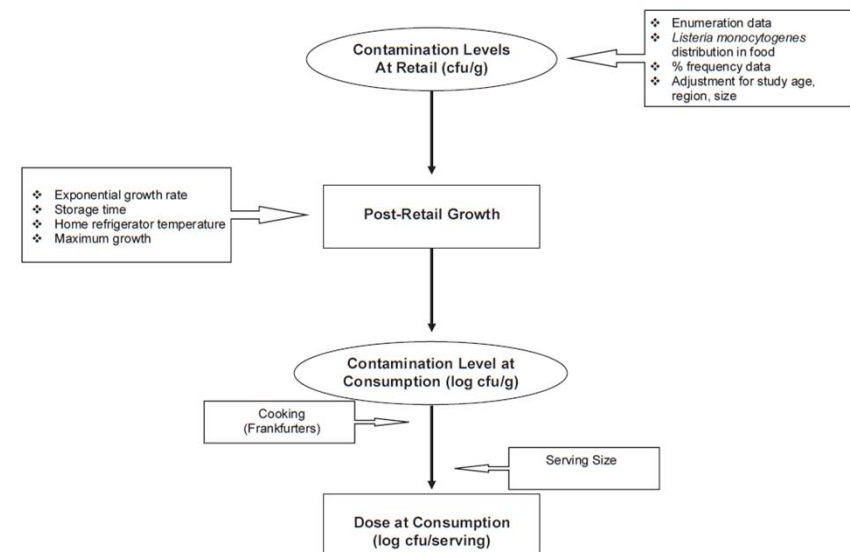Figure IV-1. Components of the Dose-Response Model

Figure III-1. Components of the Exposure Assessment Model

Food Safety and Inspection Service:
Types of Data & Sources for 2003 FDA/FSIS Risk Ranking

Exposure Assessment:

- Consumption Survey (CSFII, NHANES)

- Contamination data (testing – processing/retail)

- Growth, Survival, & thermal inactivation data – refrigeration, storage, and reheating

- Scientific, published literature, government survey, industry data

- Exposure assessment examined almost 500,000 data points

Dose-Response:

- Animal models – shape of curve

- Surveillance data – shift curve

- No threshold

- High uncertainty (several-fold)

Pouillot, Hoelzer, Chen and Dennis. *Risk Analysis, 35(1):90-108, 2015*

"Using the model and assumptions discussed above led to the conclusion that, while most of the cases are linked to a medium to high exposure doses to *L. monocytogenes*, those at greatest risk of developing listeriosis are also at a measurable risk of illness when consuming food contaminated with relatively low doses of *L. monocytogenes,* especially if highly virulent bacterial strains are involved."
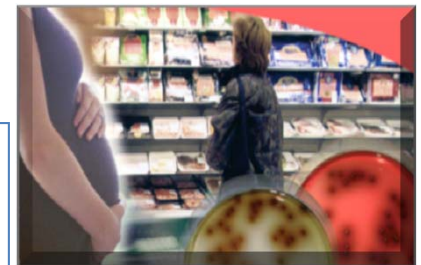
Food Safety and Inspection Service
Findings: 2003 FDA-FSIS Risk Ranking

Table V-6. Relative Risk Ranking and Predicted Median Cases of Listeriosis for the Total United States Population on a per Serving and Per Annum Basis

| Relative Risk Ranking	Predicted Median Cases of Listeriosis for 23 Food Categories					
	Per Serving Basis[a]			Per Annum Basis[b]		
		Food	Cases		Food	Cases
1	High Risk	Deli Meats	7.7×10^{-8}	Very High	Deli Meats	1598.7
2		Frankfurters, not reheated	6.5×10^{-8}	High Risk	Pasteurized Fluid Milk	90.8
3		Pâté and Meat Spreads	3.2×10^{-8}		High Fat and Other Dairy Products	56.4
4		Unpasteurized Fluid Milk	7.1×10^{-9}		Frankfurters, not reheated	30.5
5		Smoked Seafood	6.2×10^{-9}		Soft Unripened Cheese	7.7
6		Cooked Ready-to-Eat Crustaceans	5.1×10^{-9}	Moderate Risk	Pâté and Meat Spreads	3.8
7	Moderate Risk	High Fat and Other Dairy Products	2.7×10^{-9}		Unpasteurized Fluid Milk	3.1
8		Soft Unripened Cheese	1.8×10^{-9}		Cooked Ready-to-Eat Crustaceans	2.8
9		Pasteurized Fluid Milk	1.0×10^{-9}		Smoked Seafood	1.3
10	Low Risk	Fresh Soft Cheese	1.7×10^{-10}	Low Risk	Fruits	0.9
11		Frankfurters, reheated	6.3×10^{-11}		Frankfurters, reheated	0.4
12		Preserved Fish	2.3×10^{-11}		Vegetables	0.2
13		Raw Seafood	2.0×10^{-11}		Dry/Semi-dry Fermented Sausages	<0.1
14		Fruits	1.9×10^{-11}		Fresh Soft Cheese	<0.1
15		Dry/Semi-dry Fermented Sausages	1.7×10^{-11}		Semi-Soft Cheese	<0.1
16		Semi-soft Cheese	6.5×10^{-12}		Soft Ripened Cheese	<0.1
17		Soft Ripened Cheese	5.1×10^{-12}		Deli-type Salads	<0.1
18		Vegetables	2.8×10^{-12}		Raw Seafood	<0.1
19		Deli-type Salads	5.6×10^{-13}		Preserved Fish	<0.1
20		Ice Cream and Other Frozen Dairy Products	4.9×10^{-14}		Ice Cream and Other Frozen Dairy Products	<0.1
21		Processed Cheese	4.2×10^{-14}		Processed Cheese	<0.1
22		Cultured Milk Products	3.2×10^{-14}		Cultured Milk Products	<0.1
23		Hard Cheese	4.5×10^{-15}		Hard Cheese	<0.1

[a]Food categories were classified as high risk (>5 cases per billion servings), moderate risk (<5 but >1 case per billion servings), and low risk (<1 case per billion servings).

Food commodities & risk

- Deli meats pose the highest risk (~ 67% of cases in U.S.) [foods that support *Lm* growth predicted to pose greatest risk]
- Highest incidence among older adults (> 60 years)
- Specific practices: Hispanic-style cheese
- Home refrigeration a significant contributor to risk (consumer storage time/temperature)

- Limited data for some categories resulting in higher uncertainty for some foods

- Ice cream/frozen dairy identified as "very low risk" (no *Lm* growth) (confident)

- Fruits identified as "low risk" (limited *Lm* growth expected) (less confident)

Food Safety and Inspection Service:
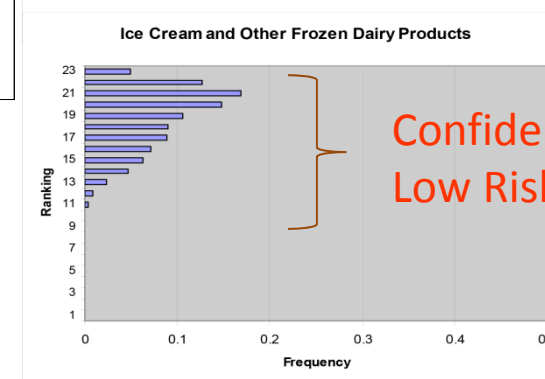## Predicted Cases of Listeriosis per Annum (Total Population): Confidence in Quantitative Risk Ranking Results
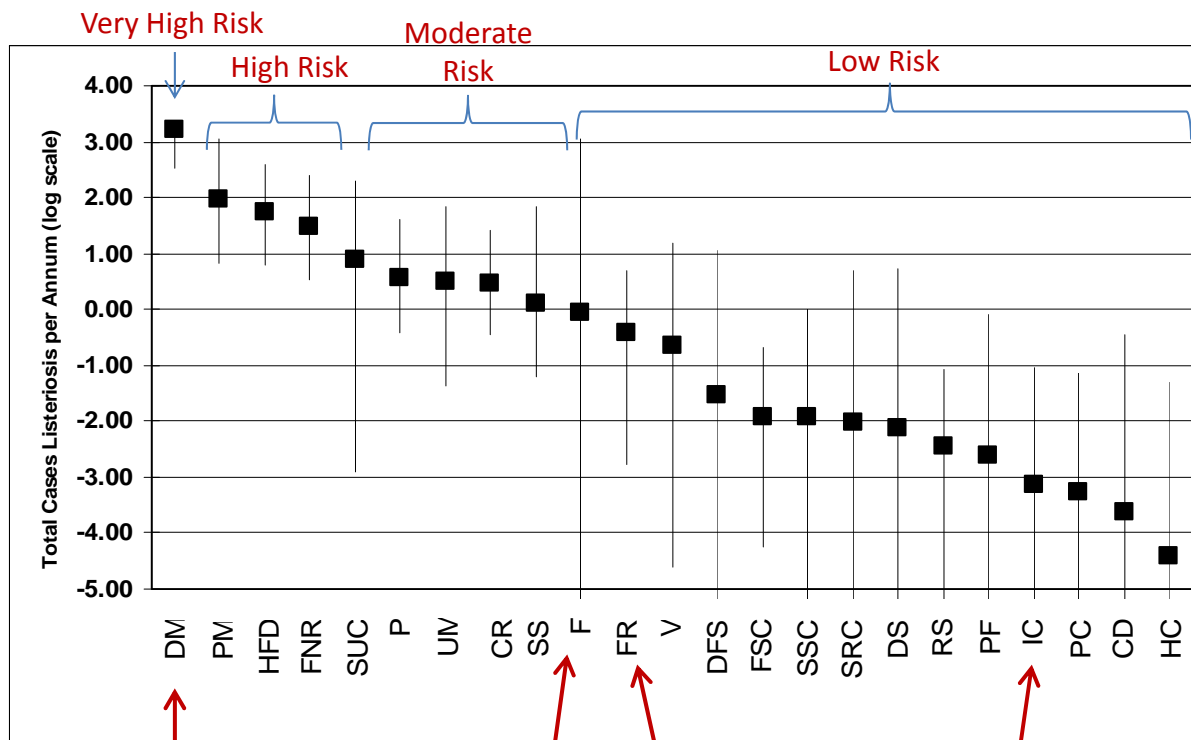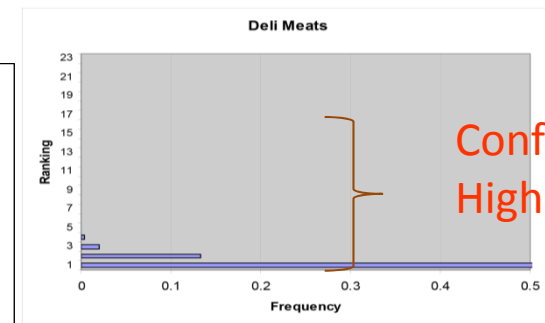
Food Safety and Inspection Service:
USDA-FSIS & FDA Decisions: Focus on Education & Outreach

2003 Listeria Action Plan (updated 2008)

1. Develop and revise guidance for processors, retailers, food service operators, and institutional establishments that manufacture or prepare RTE foods

2. Training and technical assistance

3. Consumer and health care provider information and education – older adults (>60 yrs)/pregnant women

4. Review, re-direct and revise enforcement & regulatory strategies

5. Enhance disease surveillance and outbreak response

6. Research needs

Temperatures at Which Foodborne Pathogens Live, Multiply and Die
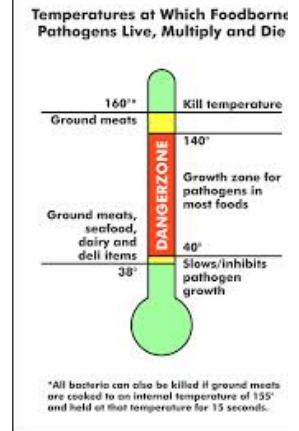
Partnership for Food Safety Education

Food Safety and Inspection Service:
2002 Listeriosis Outbreak: Turkey Deli Meat/Older Adults

- Multistate outbreak of listeriosis, primary in Northeastern U.S.
  - NY, PA, DE, MD, CO, MA, MI

- July 18 – September 30, 2002

- 46 culture-confirmed cases; 7 deaths & 3 miscarriages

- 27.4 million pounds recalled

- USDA-FSIS gathered data that indicated that some establishments were not adequately addressing the potential for bacteria contamination in their HACCP plans, SSOPs, and other control measures

Listeria monocytogenes
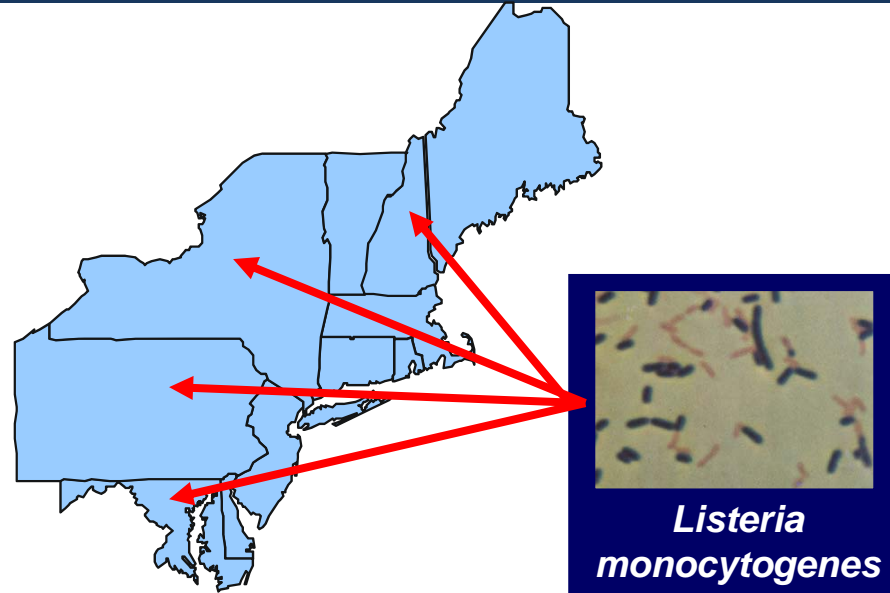
Source: CDC, MMWR 51(42);950-951 (October 25, 2002)

Food Safety and Inspection Service

Which processing controls most effectively controls *Lm*? How effective are they?

- 2003 FSIS *Listeria* Risk Assessment

- Focus on contamination of deli meats during processing (some establishments wee not adequately addressing pathogen contamination in their HACCP and SSOP control plans)

- Evaluated the number of illnesses prevented and lives saved annually based on the adoption of various interventions during manufacturing

  – Post-lethality interventions
  – Product formulation with growth inhibitors
  – Testing/Sanitation

- Built from FDA/FSIS *Listeria* risk assessment
- <u>Processor-to-table</u> risk assessment

FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats

Prepared by:

Daniel L. Gallagher
Dept. of Civil and Environmental Engineering
Virginia Polytechnic Institute and State University

Eric D. Ebel and Janell R. Kause
Risk Assessment Division
Food Safety and Inspection Service, USDA

May 2003

FSIS

Available at:
http://www.fsis.usda.gov/wps/wcm/connect/b5027918-ee69-475e-acc9-a07c642f13b6/Lm_Deli_Risk_Assess_Final_2003.pdf?MOD=AJPERES

*Carried out in a manner consistent with the guidelines established by Codex Alimentarius, ICMSF, and the U.S. for the conduct of a microbial risk assessment: 1) transparency; 2) broad scientific and stakeholder input; and 3) extensive peer review (scientific and regulatory review)
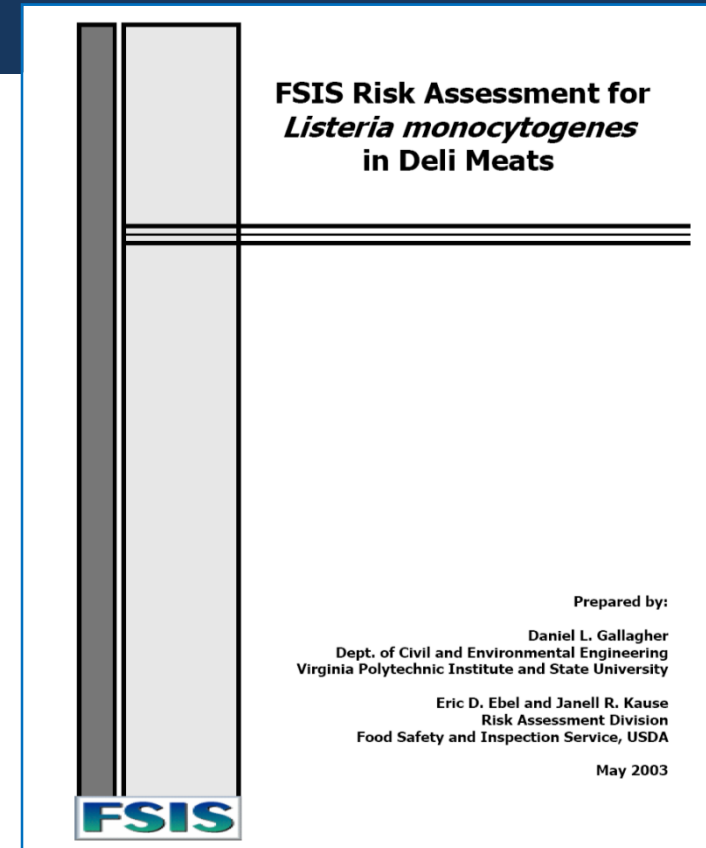
Food Safety and Inspection Service
2003 FSIS Risk Assessment: Risk Management Questions & Approach

- What is the effectiveness of testing and sanitation of food contact surfaces on mitigating product contamination and reducing the subsequent risk of illness?

- How effective are other pre- and post-packaging interventions in mitigating product contamination and reducing the subsequent risk of illness?

- What guidance can be provided on testing and sanitation of food contact surfaces for *Listeria* species?
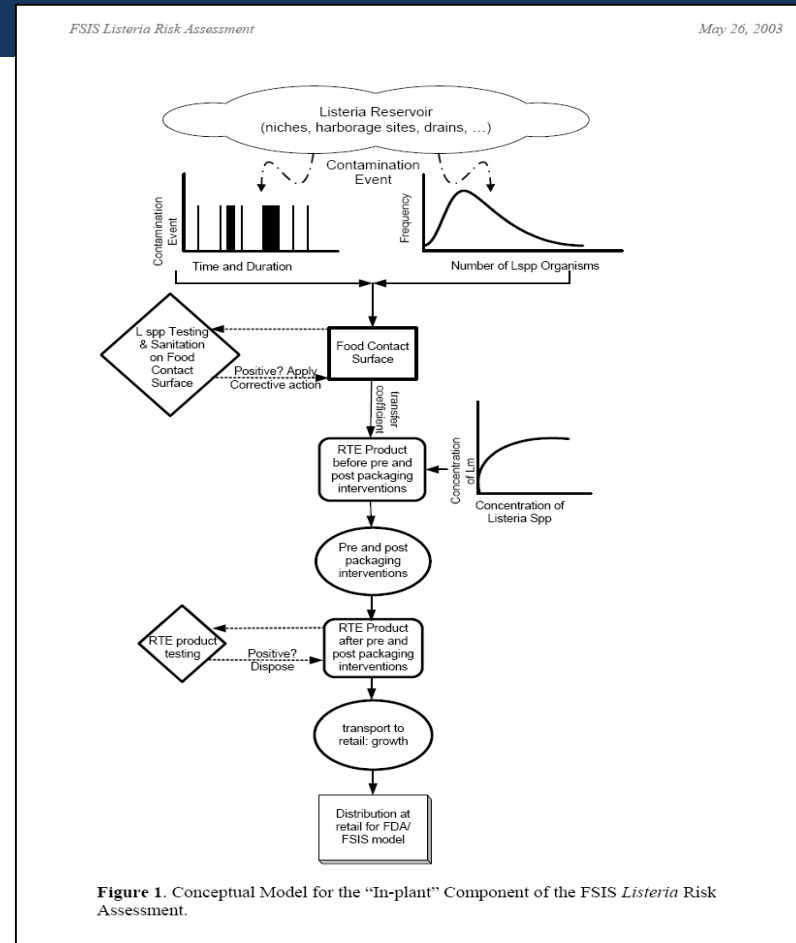
Figure 1. Conceptual Model for the "In-plant" Component of the FSIS *Listeria* Risk Assessment.

Food Safety and Inspection Service
Evaluating *Lm* Process Controls & Sanitation: Risk Assessment Scenario Analyses

Sampling Effectiveness

Process Control Effectiveness

Scenario 3: Testing/Sanitation

*Proposed mandatory testing:

4 tests/line/month

2 tests/line/month

1 test/line/month

Scenario 2a: Post lethality interventions

Scenario 2b: Growth inhibitors

Scenario 1: Growth inhibitors & Post lethality intervention

Number of annual lives saved among elderly: Median prediction

Scenario

post-lethality interventions; antimicrobial agent/processes

* Proposed testing for *Listeria monocytogenes* (66 FR 12589; 2001)

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Food Safety and Inspection Service
Risk Assessment Predictions

Scenario	Older Adults	Intermediate	Neonates	Total
4-2-1	20	4	1	25
8-4-2	30	?	?	30
10-10-10	40	?	?	40
16-8-4	30	?	?	30
32-16-8	60	?	?	60
40-20-10	70	15	4	89
60-60-60	120	27	7	154
60-60-60 RTE	120	26	7	153
PP-95%	120	26	?	146
PP-99%	173	39	10	221
GIP	110	25	?	135
PP-95% & GIP	186	41	11	238

Food Safety and Inspection Service
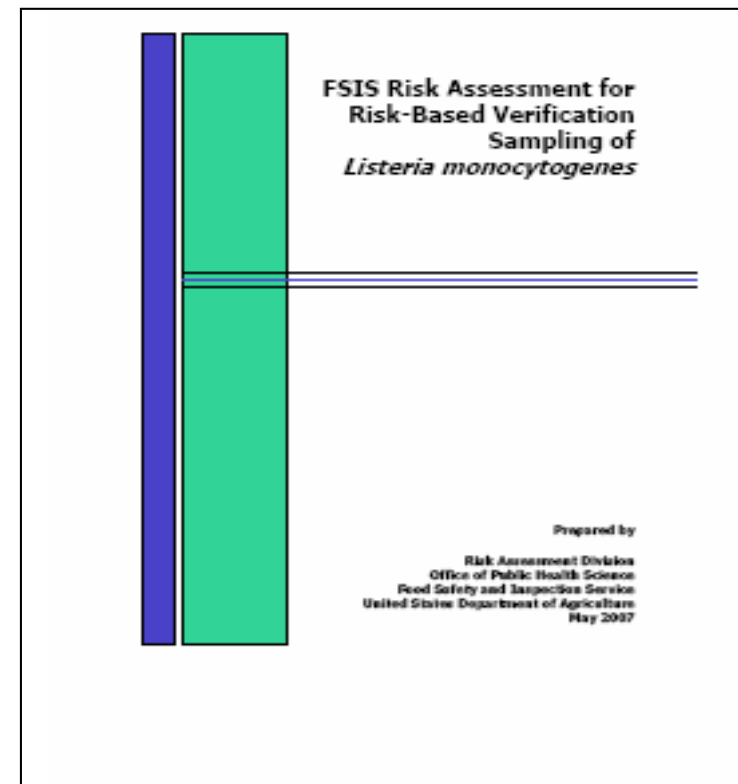## FSIS *Listeria* Rule: Control of *Lm* in Ready-to-Eat Meat and Poultry Products

- Developed directly from risk assessment information (2003 FSIS Listeria Risk Assessment & 2003 FDA/FSIS Risk Ranking)(June 6, 2003)

- Establishments producing post-lethality exposed RTE product must comply with requirements included in one of the following alternatives (9 CFR 430.4)

  Alternative 1: **Use post-lethality treatment __AND__ an antimicrobial agent or process**

  Alternative 2: (a) **Use post-lethality treatment __OR__ (b) an antimicrobial agent or process**

  Alternative 3: **Use sanitation measures __ONLY__**

- FSIS Directive 10,2401.4 (10/2/03); establish a risk-based sampling program to verify compliance with *Lm* Rule

Food Safety and Inspection Service
How can USDA-FSIS inspection resources be effectively utilized across manufacturers?

- 2005 FSIS Risk Assessment for Risk-Based Verification Sampling of *Lm* (updated 2007/2013/2014)

- Allocated USDA-FSIS inspection resources among establishments that produced RTE meat and poultry products (under 9 CFR 430.) based on public health risk

- Risk-based *Lm* verification algorithm based on prior quantitative risk assessments
    - 2003 FSIS *Listeria* Risk Assessment
    - 2001/2003 FDA-FSIS Risk-Ranking of RTE Foods

- Monthly ranking of establishments
    - Lm controls (10,240.1 – industry data/FSIS inspection)
    - Product type (deli meats highest risk)
    - FSIS *Lm* testing (6 month rolling average)
    - Production volume

FSIS Risk Assessment for
Risk-Based Verification
Sampling of
Listeria monocytogenes

Prepared by

Risk Assessment Division
Office of Public Health Science
Food Safety and Inspection Service
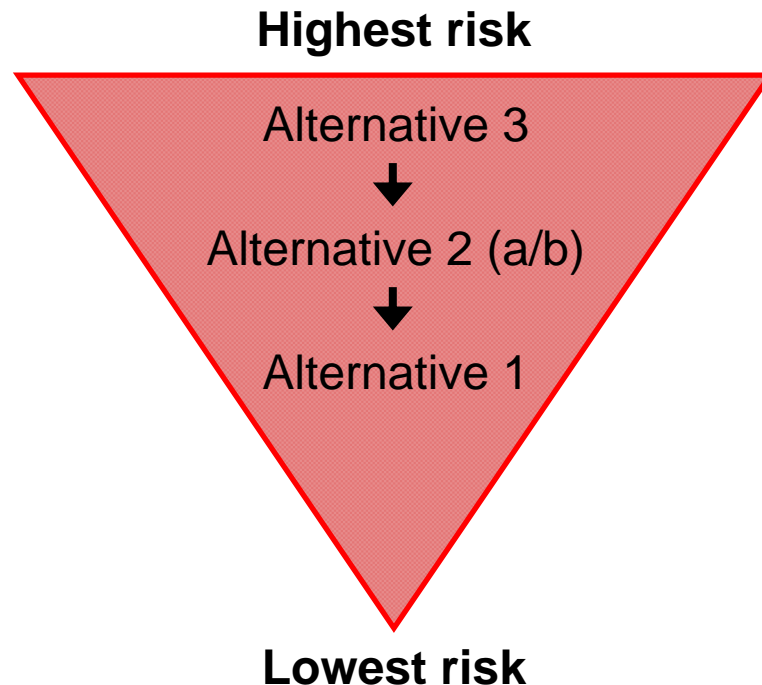United States Department of Agriculture
May 2007

Available at:
http://www.fsis.usda.gov/wps/wcm/connect/1b21901d-a6ea-42a2-b6eb-110fad3a4675/RBVS_Risk_Assess_Jun07.pdf?MOD=AJPERES

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Implementation of FSIS's Risk-Based *Lm* Testing Program

Highest risk

Alternative 3

⬇

Alternative 2 (a/b)

⬇

Alternative 1

Lowest risk

- FSIS verification sampling allocated among establishments based on public health risk (initiated: Jan. 2005)
  - ✓ Approximately 10,000 product samples annually
  - ✓ Expanded to collect environmental & food contact sample (April 2006)
  - ✓ Risk defined quantitatively for each facility

- Interim Final Rule enhanced FSIS oversight of RTE establishments, while providing *incentives* for industry to implement new preventive measures
  - ✓ Monthly ranking
  - ✓ Test & hold tested product "lot"

- FSIS compliance guidance for processors (including small/very small establishments)

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Result: Industry Adoption of more Effective *Lm* Controls

- Industry adopted more effective *Lm* control measures
  - ✓ Use of growth inhibitors
  - ✓ Post-lethality interventions
- RTE meat and poultry industry considers *Lm* it's "success story"
  - ✓ Food safety a non-competitive issue/ information sharing (best practices)
  - ✓ Paradigm change: proactively seeking to find Lm and institute controls to prevent it ("find it/fix it")
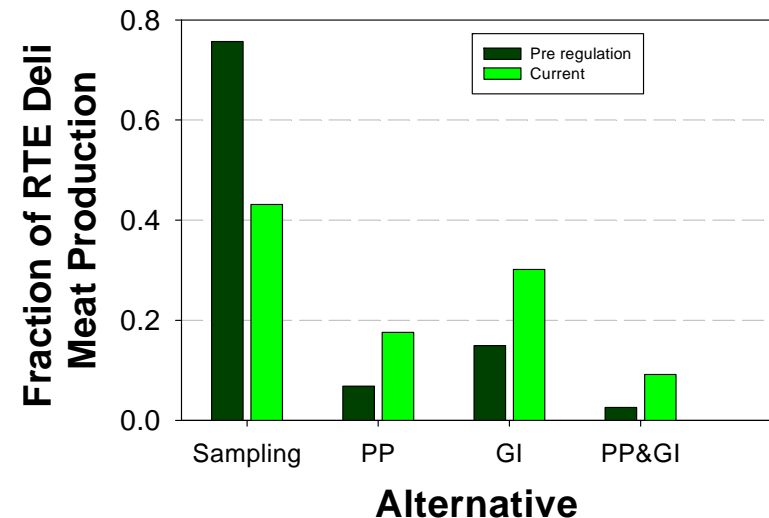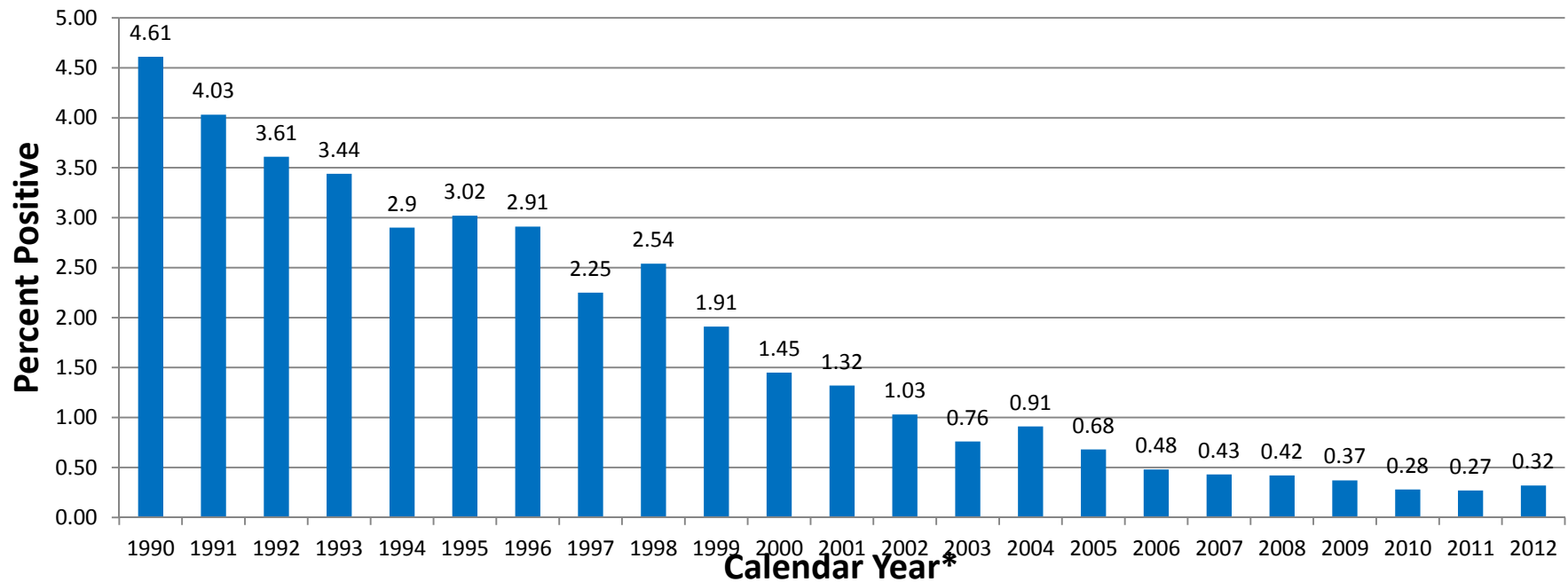

Source: http://www.fsis.usda.gov/PDF/RBVS_Risk_Assess_Jun07.pdf

Food Safety and Inspection Service
Impact of USDA-FSIS Regulation & Industry Response

Significant Reduction of *Lm* in RTE Meat & Poultry Products

Bar chart — Percent Positive by Calendar Year*:
- 1990: 4.61
- 1991: 4.03
- 1992: 3.61
- 1993: 3.44
- 1994: 2.9
- 1995: 3.02
- 1996: 2.91
- 1997: 2.25
- 1998: 2.54
- 1999: 1.91
- 2000: 1.45
- 2001: 1.32
- 2002: 1.03
- 2003: 0.76
- 2004: 0.91
- 2005: 0.68
- 2006: 0.48
- 2007: 0.43
- 2008: 0.42
- 2009: 0.37
- 2010: 0.28
- 2011: 0.27
- 2012: 0.32

- *FSIS results of routine regulatory testing of finished RTE meat and poultry products analyzed for Lm (1990-2012). Approximately 4,000-10,000 samples taken annually.*

These risk-informed federal policies and the corresponding shift in industry food safety culture focused on prevention resulted in a substantive decline in the presence of *Lm* in federally-inspected RTE meat and poultry products -- from 0.72 percent in 2005 to 0.27 percent in 2011.

Food Safety and Inspection Service
A "Plateau" Observed

Reduction of *Listeria monocytogenes* in Deli Meats From Manufacturer
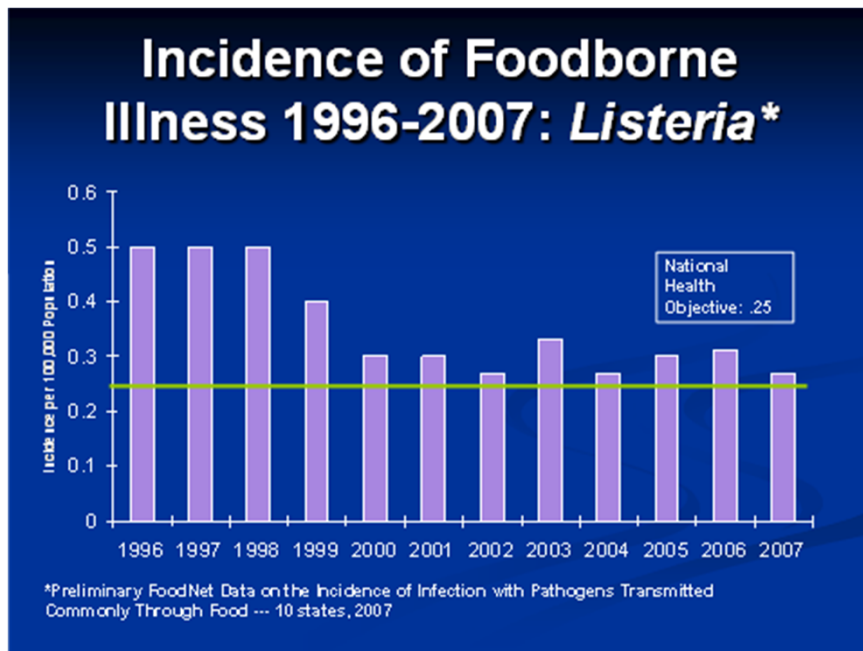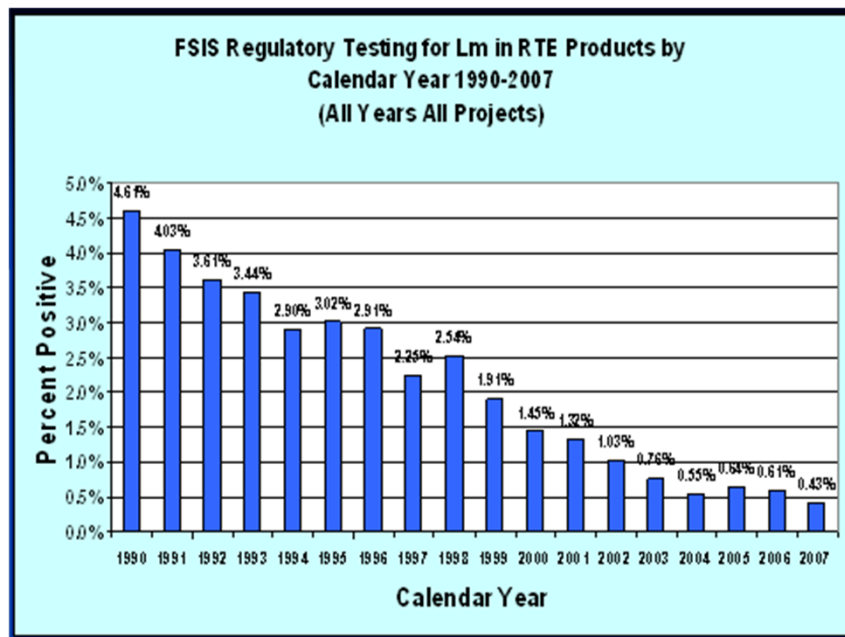
Why a plateau in listeriosis?

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Lm Prevalence in Deli Meats Product (NFPA and NAFSS Data)

Product	Prevalence	
	NFPA	NAFSS
Retail Sliced	2.7%	1.4%
Prepackaged	0.4%	0.2%
n	9199	7040
Sampling Dates	2000-2001	2005-2006
Sample size	25 g	125 g

Source: National Food Processors Association (Gombas et al. JFP 2003); National Alliance for Food Safety and Security (USDA/ARS Funded; Lead: Ann Draughon, 2006)

Food Safety and Inspection Service
What others areas along the supply chain should efforts be focused?
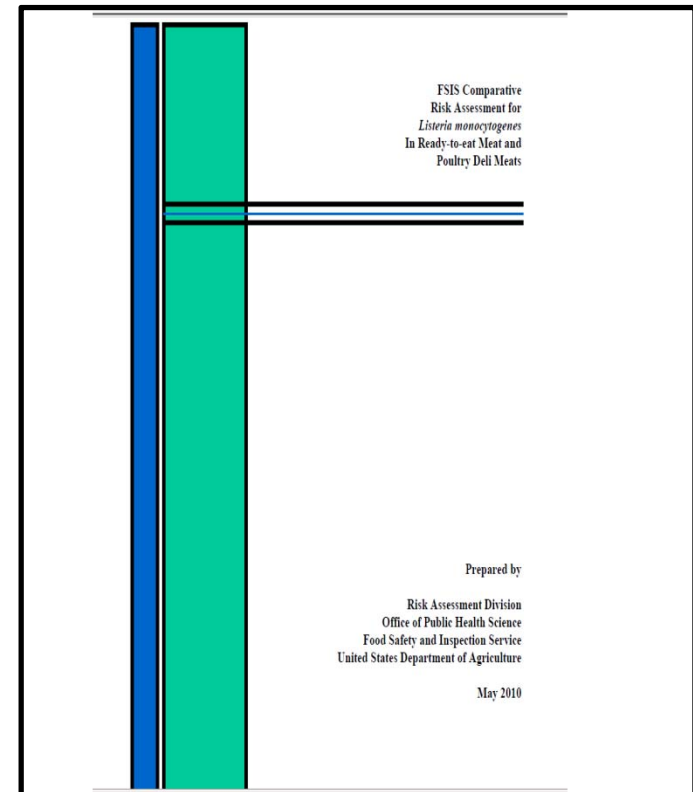
- 2010 USDA-FSIS Comparative risk assessment for *Listeria monocytogenes* in ready-to-eat meat and poultry products

- Objectives

  - Compare the prevalence and level of *Lm* in retail-sliced versus prepackaged ready-to-eat deli meats
  - Determine the comparative risk based on where the deli meats are sliced

- Based on 2003 FDA/FSIS risk assessment and retail testing of deli meat products (NAFSS, 2006)

FSIS Comparative
Risk Assessment for
Listeria monocytogenes
In Ready-to-eat Meat and
Poultry Deli Meats

Prepared by

Risk Assessment Division
Office of Public Health Science
Food Safety and Inspection Service
United States Department of Agriculture

May 2010

Available at:
http://www.fsis.usda.gov/wps/wcm/connect/b5027918-ee69-475e-acc9-a07c642f13b6/Lm_Deli_Risk_Assess_Final_2003.pdf?MOD=AJPERES

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Retail Data Collection, NAFSS

- Four states: GA, CA, MN, TN

- ~ 2000 samples each

- Cured poultry, uncured poultry, pork, beef

- ~75% large chains, 25% independent grocers

- ~50% retail-sliced, 50% prepackaged

- *L. monocytogenes* presence & enumeration
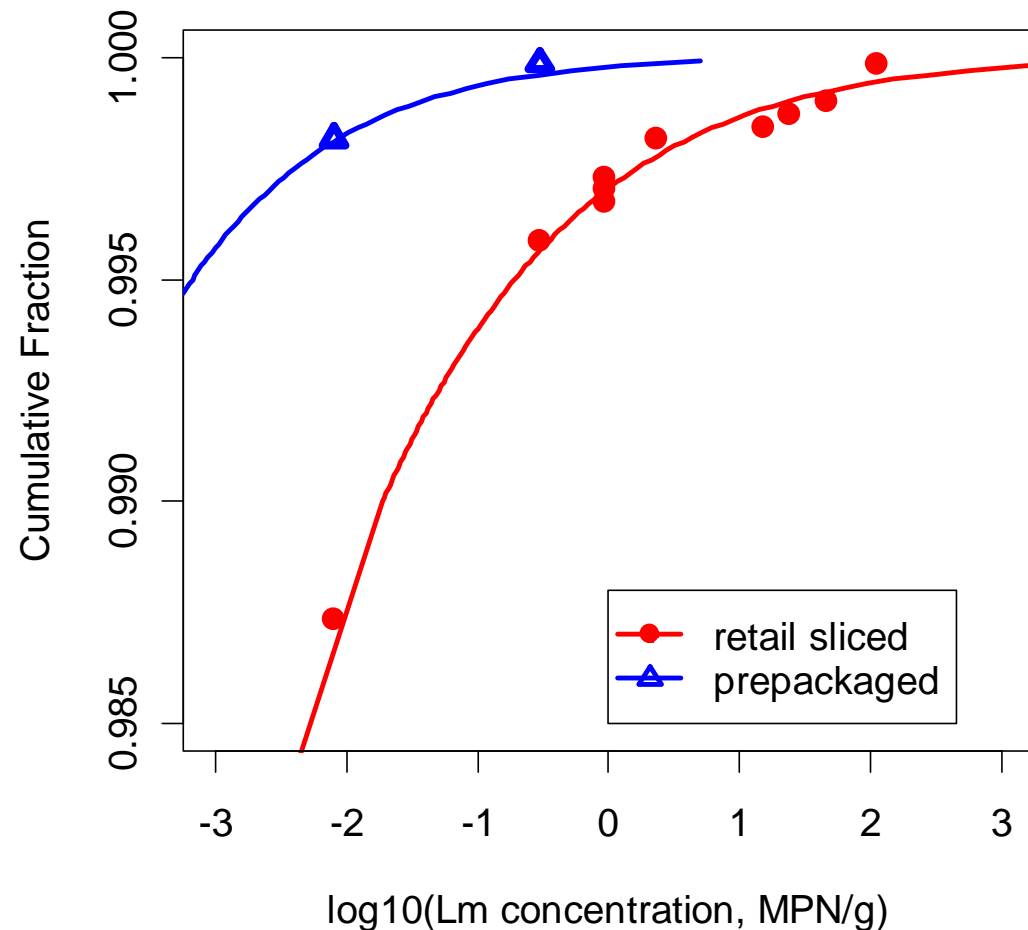
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Prevalence Results by Slicing Location and Sampling Site

Slicing Location	GA	CA	MN	TN
Retail	1.3% n = 12 / 929	1.4% n = 10 / 731	1.4% n = 12 / 841	1.5% n = 15 / 1017
Prepackaged	0.0% n = 0 / 1071	0.0% n = 0 / 629	0.5% n = 4 / 844	0.2% n = 2 / 978

Food Safety and Inspection Service
Measured *Listeria* Concentrations

- Retail-sliced product has higher concentrations of *Lm* than prepackaged product

Endikrat et al. JFP 2010
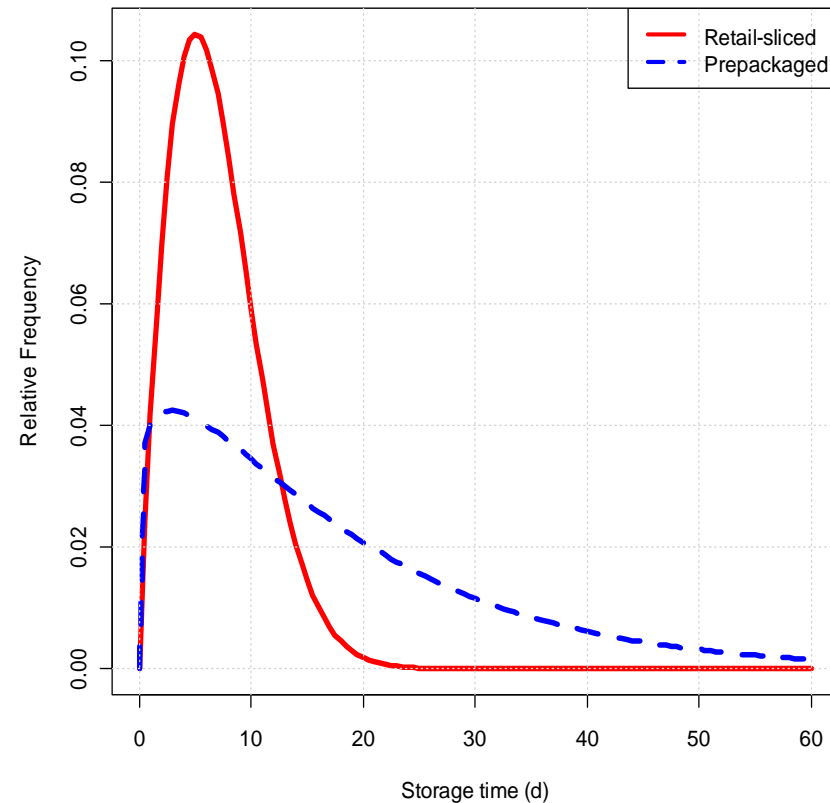
Consumers tend to use retail-sliced product more quickly than prepackaged.

This limits the amount of growth of *Lm* in retail-sliced product prior to consumption.

Data: RTI International, www.FoodRisk.org
Analysis: Regis Pouillot, FDA

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- Deli split into 4 categories
  - Plant sliced with growth inhibitor
  - Plant sliced without growth inhibitor
  - Retail sliced with growth inhibitor
  - Retail sliced without growth inhibitor
- Plant vs retail starting Lm distributions from NAFSS
- Growth inhibitor use from USDA database
  - Exponential growth rate differed for product with and without antimicrobial differed

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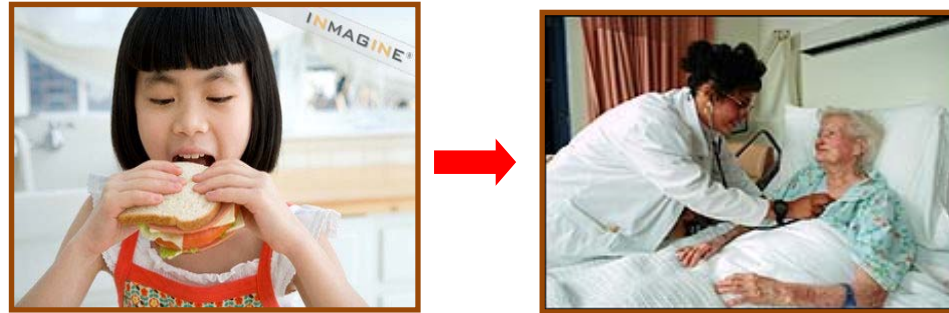
- Used existing 3 age groups: older adults (> 60 years), intermediate, perinatal

- Used same 4 deli categories from exposure assessment as additional food categories
  - Prepackaged versus retail-sliced
  - With and without growth inhibitor

- Model run in calibration mode – same total number of deaths across all food groups as original FDA/FSIS risk ranking model
  - Likely to overstate the total number of deaths

Food Safety and Inspection Service
Results: Box Plots

Endikrat et al. JFP 2010
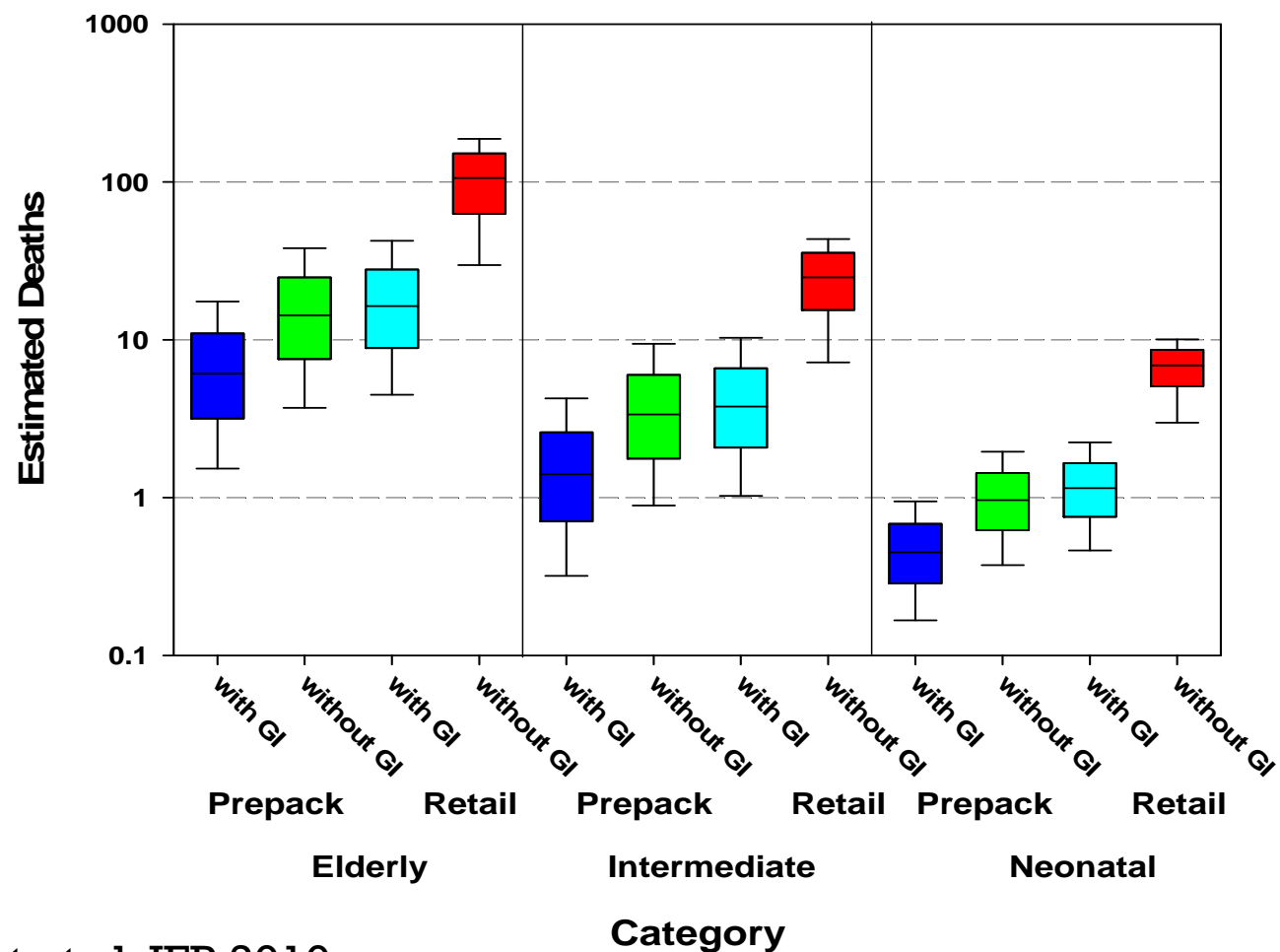
Food Safety and Inspection Service
Percent Simulated Mean Number of Deaths

Growth Inhibitor	Source		TOTAL
	Prepackaged	Retail-sliced	
With	5.2%	13.2%	18.4%
Without	11.7%	69.8%	81.5%
TOTAL	17.0%	**83.0%**	100.0%

83% of listeriosis cases associated with deli meats are from those sliced at retail (FSIS Comparative *Lm* Risk Assessment (2010))

Endikrat et al. JFP 2010

Food Safety and Inspection Service
Similar to Independent Results by Pradhan *et al.* Based on Industry Data (Gombas 2003)

Percent Simulated Median Number of Deaths

- ## Ham

Growth Inhibitor	Source		Total
	Prepack	Retail sliced	
With	5.7	27.1	32.7
Without	15.9	51.3	67.3
Total	21.6	**78.4**	100.0

- ## Turkey

Growth Inhibitor	Source		Total
	Prepack	Retail sliced	
With	3.3	29.5	32.8
Without	17.5	49.7	67.2
Total	20.8	**79.2**	100.0

Pradhan et al. JFP 2010

- How does the risk of listeriosis compare for deli meat handled at the retail level versus prepackaged deli meat?

  - Retail-sliced product has higher prevalence and level of *L. monocytogenes* than prepackaged product

  - Retail-sliced product ~5x riskier than prepackaged product

  - Retail-sliced deli meats riskier even if stored for a shorter period of time

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Part II:

Risk-based Decisions & Emerging Issues

Food Safety and Inspection Service
Why would retail sliced RTE products be more contaminated than prepackaged product?

- Major hypothesis: cross contamination at retail
    - More than one kind of product manipulated at a given time or place
        - Meat, Poultry, Vegetables, Seafood, …
    - More than one process at a given time and place
        - Slicing, Cutting, Mixing, …

- Additional consideration: potential growth of *Listeria monocytogenes* (e.g. storage time and temperature abuse)

Interagency Risk Assessment:
Listeria monocytogenes in Retail Delicatessens

Technical Report

The Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup

September 2013

USDA

- Objective: Ascertain the impact on public health of current practices and potential interventions that reduce or prevent *Lm* contamination in ready-to-eat food sliced, prepared and/or packaged in retail facilities

Listeria monocytogenes in Retail Delicatessens: An Interagency Risk Assessment—Model and Baseline Results

RÉGIS POUILLOT,[1a] DANIEL GALLAGHER,[2] JIA TANG,[2] KARIN HOELZER,[1] JANELL KAUSE,[3] AND SHERRI B. DENNIS[1]

[1]U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, Maryland 20740; [2]Civil and Environmental Engineering Department, 409 Durham Hall, Virginia Polytechnic Institute and State University, Blacksburg, Virginia 24061; and [3]Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue S.W., Washington, DC 20228, USA

MS 14-235: Received 21 May 2014/Accepted 13 August 2014

- Technical report and Interpretive Summary on FDA & FSIS websites
- Model description: *Journal of Food Protection*, 2015, 78(1), 134-145
- Scenario Analysis: Journal of Food Protection, Submitted

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Interagency Retail *Lm* Risk Assessment: Interactive Approach

- ## Partnership
  - USDA/FSIS & FDA/CFSAN

- ## Collaboration
  - Univ. of Maryland, Cornell Univ., VA Tech

- ## Engagement
  - Stakeholders early and throughout; > 56 meetings

- ## Innovation
  - 1st QMRA to quantitatively link retail practices to public health outcomes
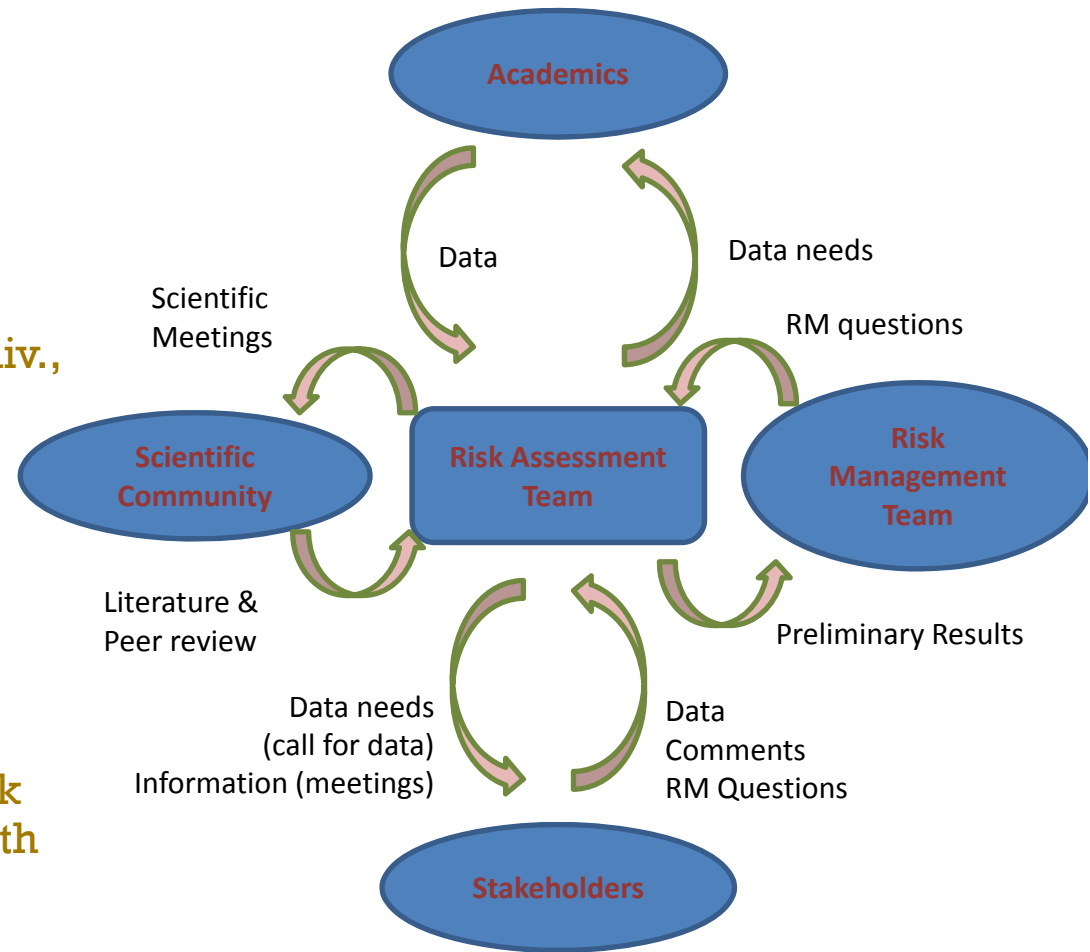
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Risk Management Questions

- "What is the exposure to *Listeria monocytogenes* from consuming ready-to-foods prepared in retail facilities?"

- "What are the key processes that increase ready-to-foods contamination at retails?"

- "How much is the relative risk per serving reduced according to specific risk management options?"

Further refined; a list of proposed 'what if' scenarios to evaluate:

Sanitation   Worker behavior

Growth inhibition   Cross contamination

Storage temperature & duration

Examples

What is the public health impact of temperature abuse in deli cases?

What would be the impact of separated slicers/counters for growth versus non-growth products?

What is the impact of the use of gloves in the retail environment?

Dynamic mass balance/
Discrete event model
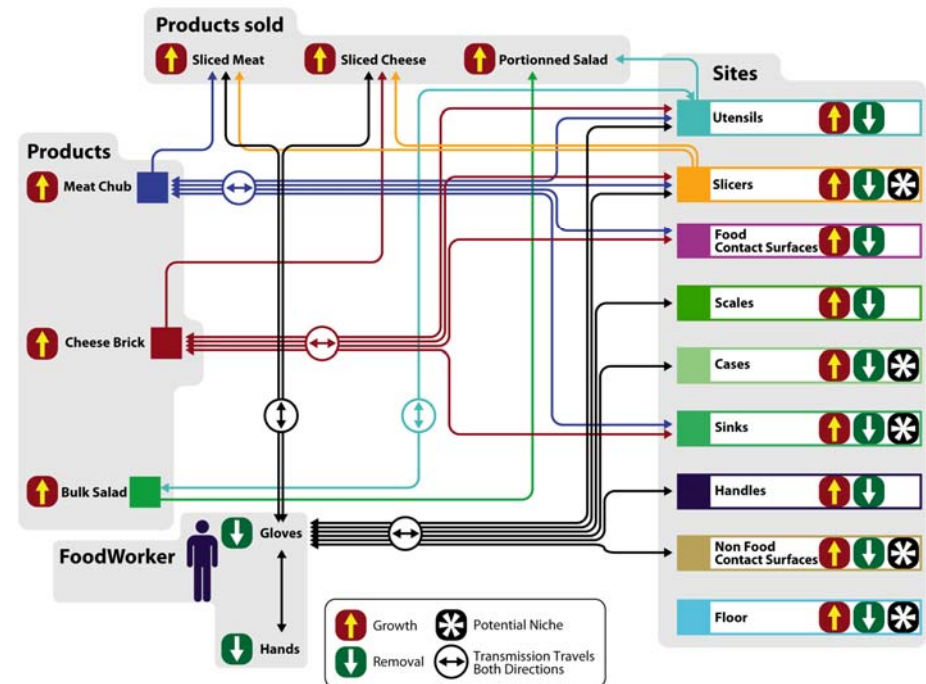
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From Retail to Risk

Contamination when sold

Home Storage (bacterial growth)

Contamination when eaten

Serving Size

Number of *Lm* ingested

Dose Response Model

Probability of Illness
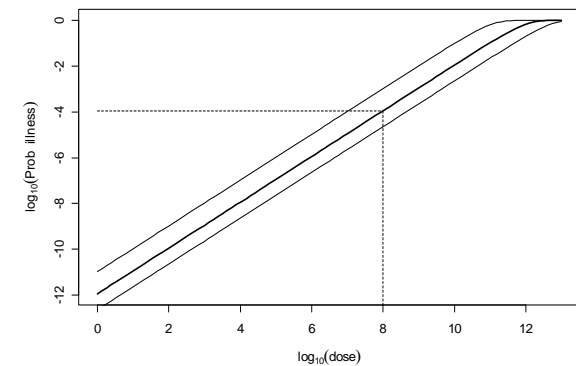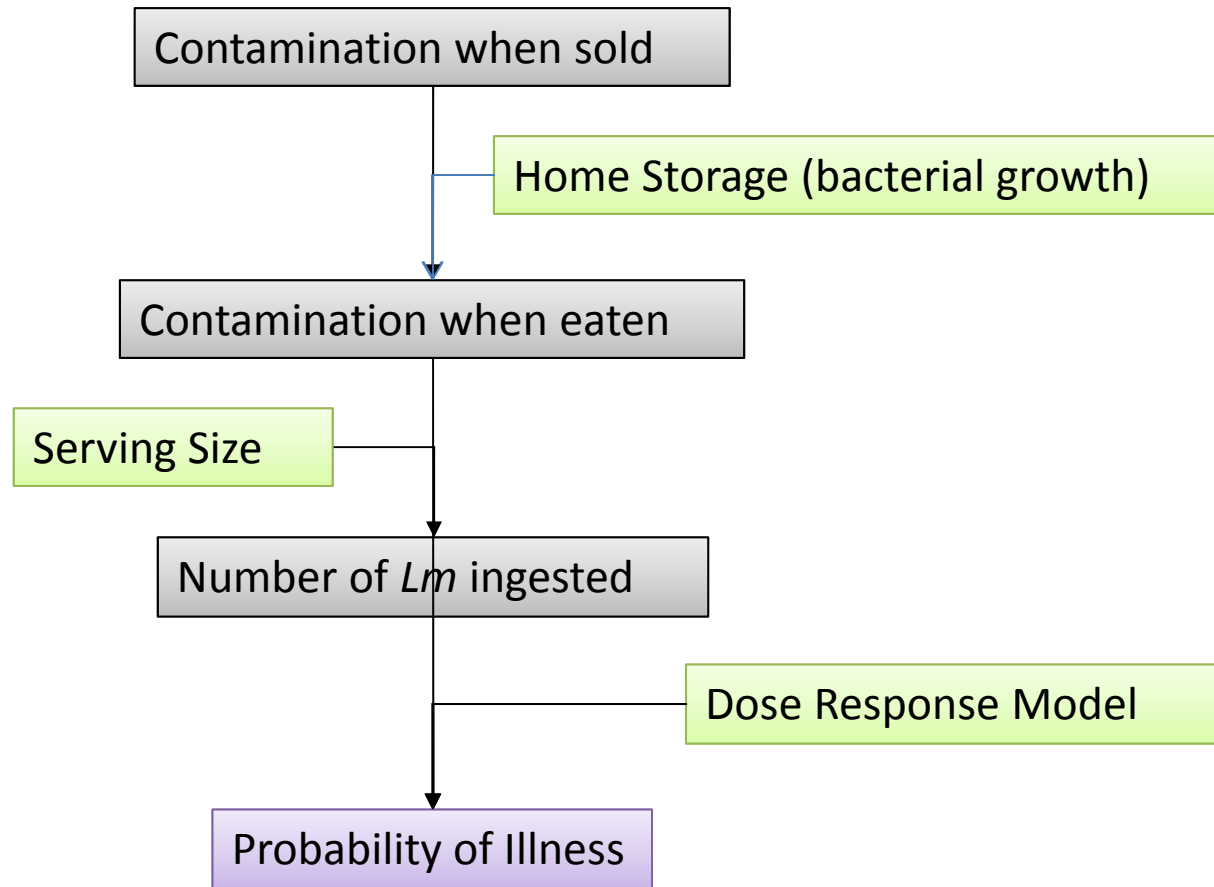
(FAO/WHO, 2004)

Food Safety and Inspection Service
Data Sources

- **Food worker behavior**
  - *Lubran MB, et al. (2010) J Food Protection, 73 (10):1849-57*

- **Transfer coefficients and Slicer**
  - *Hoelzer K, et al. (2012) International J of Food Microbiology, 157:267-77*

- **Risk mapping**
  - *Hoelzer K, et al. (2012) Risk analysis, 32(7): 1139-56*

- **Persistent strains in deli departments**
  - *Simmons, C. et al. (2014) J. Food Protection, 77(1): 1929-1939*

- **Potential transfer during specific events**
  - *Maitland J, et al. (2013) J Food Protection, 76 (2): 272-82*

- **Growth model**
  - *Mejholm and Dalgaard, 2009 J Food Protection, 72(10), 2132-2143*

- **Temperature in deli case**
  - Ecosure 2007 (www.FoodRisk .org)

- **Time/ temperature during transport and at home**
  - Ecosure 2007 (www.FoodRisk .org)

- **Consumption data**
  - NHANES study, WWEIA data, 1999-2006

- **Dose response model**
  - FAO/WHO 2004

Funded studies	Literature sources

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Verification

✓ General correspondence between the frequency of contamination *vs.* observed one (Cornell longitudinal study)

✓ Important sources of contamination considered in the model (Risk mapping, Mock Deli study)

✓ Control of the mass balance

✓ Correspondence between the simulated bacterial density distribution *vs.* the observed one (NAFSS, 2008) (this graph)
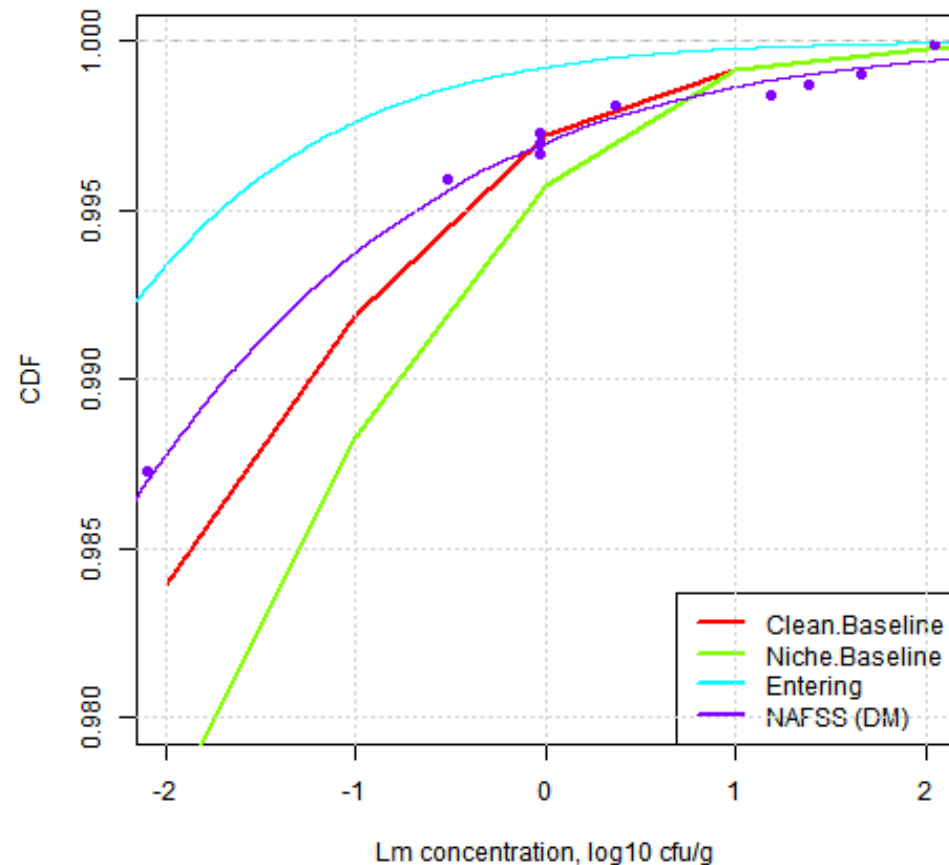
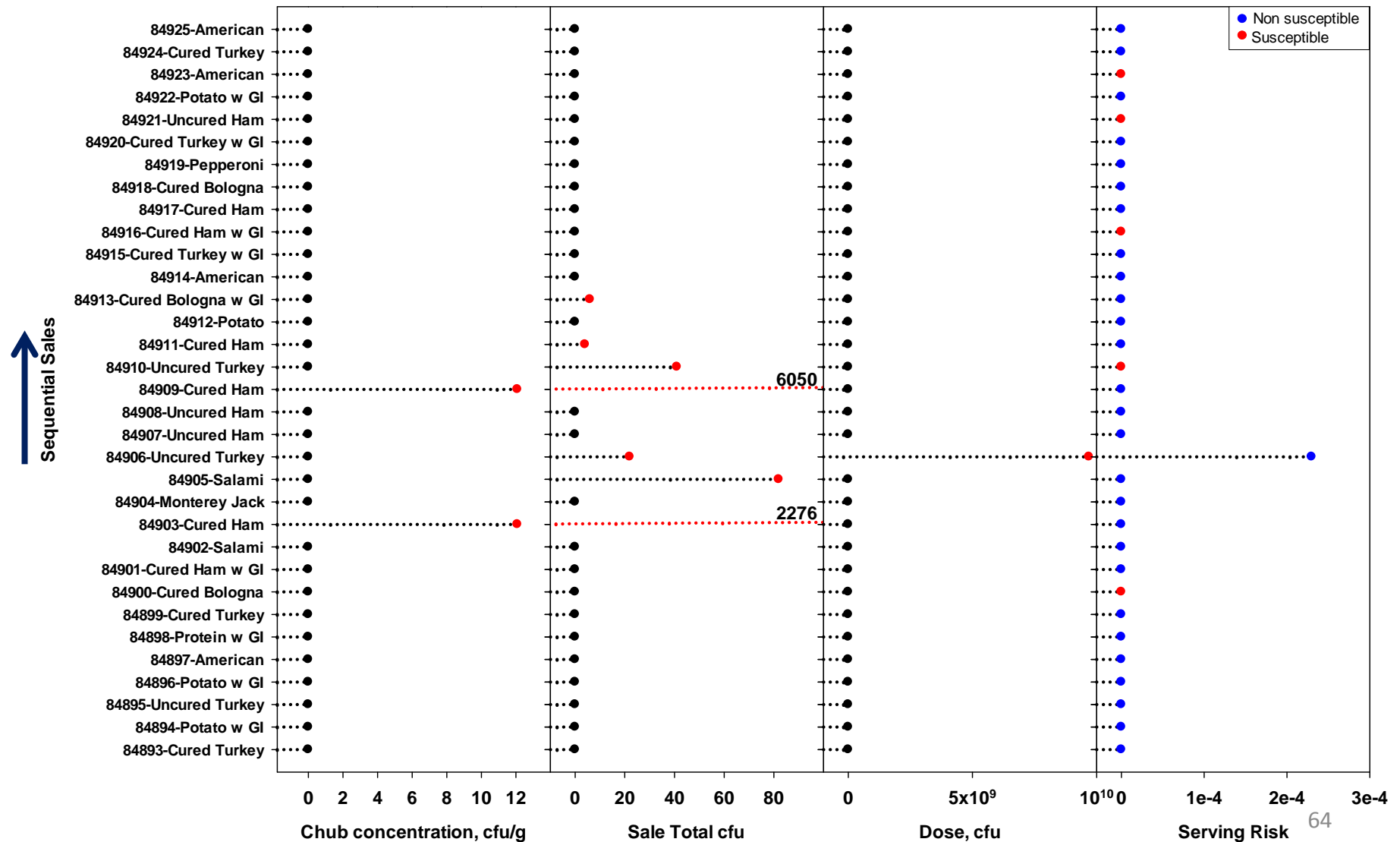# What can we learn from the virtual deli model?
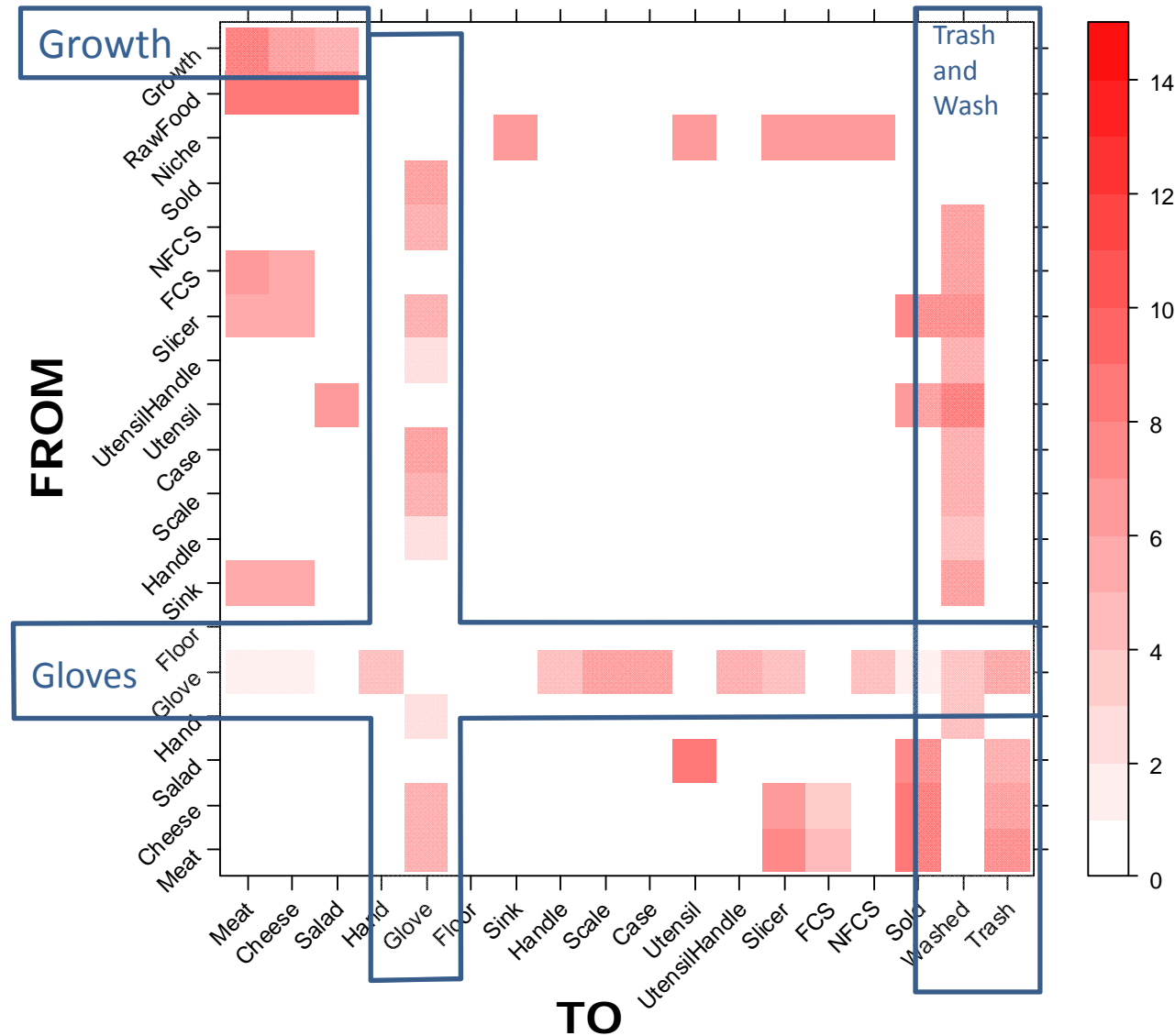
Initial contamination, growth, inactivation and transfers from sites to sites

- Large number associated with gloves/hand
- Large impact of growth
- Large number of bacteria inactivated
- Some are sold

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Most listeriosis cases predicted to occur as a result of:

- Contaminated product at time of sale (incoming or cross contamination)
- Growth supporting RTE product
- Consumer mishandling (time / temperature)
- Susceptible consumer

Recent outbreaks suggest…..

- Illness can result at **low doses** among vulnerable populations (older adults)[i.e., ice cream outbreaks (2015)]
- Illness can result among **healthy populations** possibly because of growth in product [i.e., 2014-15 caramel apple outbreak]
  - Not necessarily the result of consumer mishandling of product (time/temperature abuse)

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Scenario analysis (n=122)

"What-If" Scenarios

- **Sanitation Related Scenarios**
  - ❖ Some NFCS cleaned as frequently as FCS, Increase the effectiveness of cleaning, No sanitation, ...

- **Worker Behavior Related Scenarios**
  - ❖ No glove, No contact glove-case, Preslice products in the morning, Do not slice product on gloves

- **Growth Inhibitor Related Scenarios**
  - ❖ All products with GI, No product with GI

- **Cross contamination Related Scenarios**
  - ❖ Separate slicers, No cross contamination

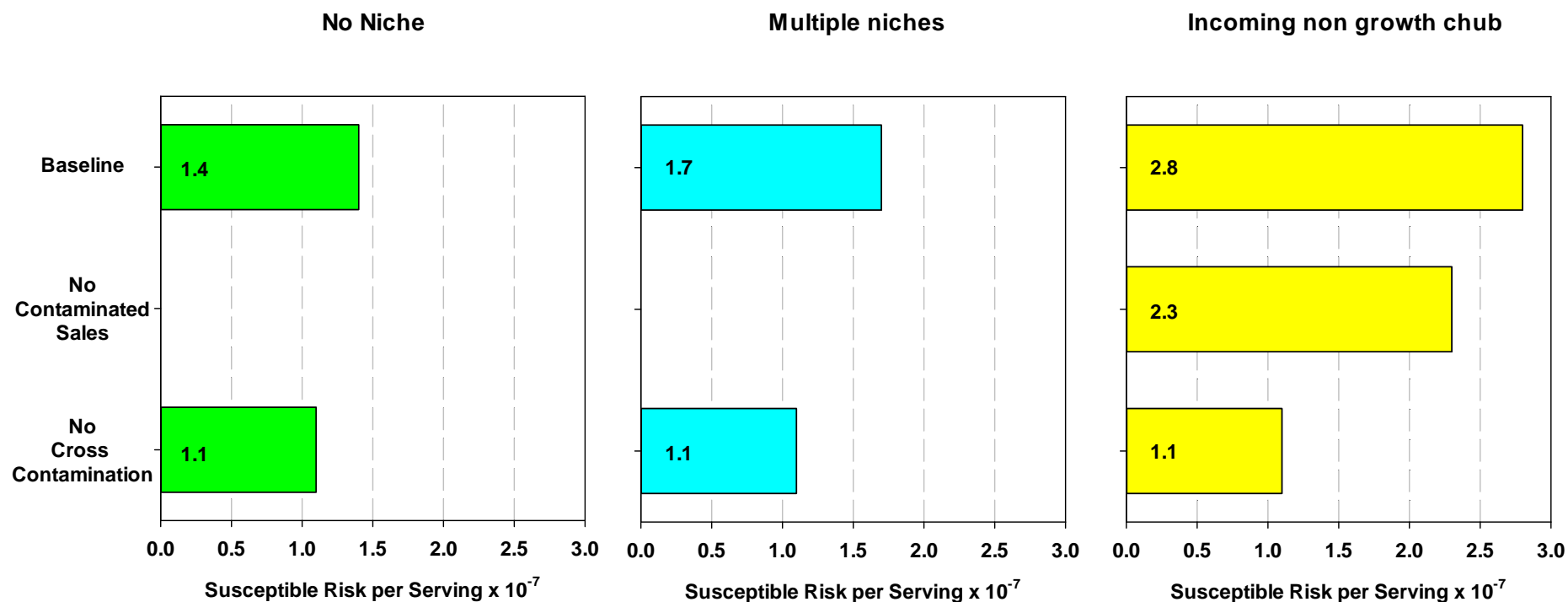- **Storage Temperature and Duration Related Scenarios**
  - ❖ Temperature in compliance with FDA food code, Temperature set so that no growth can occur

http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp

	Multiple Niche 100W	No Niche	Incoming Growth Chub	Incoming Non-growth Chub	Temp. Control
Predicted risk per serving, susceptible population[2]	1.7×10^{-7}	1.4×10^{-7}	16.6×10^{-7}	2.8×10^{-7}	1.2×10^{-7}
Sanitation Related Scenarios:	Percent Change Relative to Baseline				
Wash & Sanitize: Increase the effectiveness of cleaning from simply washing to washing and sanitizing	-1.6	1.7	-0.6	2.0	-1.3
Clean 8 Sporadic: Double the number of sites cleaned from 4 to 8	-4.2	-4.1*	-0.7	-1.9	-0.5
No Sanitation: No wiping, washing, or sanitizing	41.3*	7.9*	2.9*	23.5*	11.9*
No Sporadic Cleaning: Clean as required by the 2009 FDA Food Code, but no additional sporadic cleanings	3.0	-3.0	-0.4	1.7	1.7
NFCS As FCS: Workers clean deli NFCSs at same rate as FCSs	-3.0	0.7	-0.6	0.3	-5.4*
Worker Behavior Related Scenarios:					
No Glove: Workers do not use gloves when serving customers	5.1*	2.5	1.2	8.5*	6.0*
Gloves Every Serving: Workers change gloves before every sale	4.1	0.7	0.7	0.6	-0.2
No Contact Glove Case: Workers do not use their hands to open the deli case (e.g. if a floor switch is used)	-1.4	-3.4	-1.3	1.3	1.3
Pre-slice: Workers pre-slice RTE products in the morning, after cleaning	6.0*	24.9*	49.5*	-34.4*	19.2*
Separate Slicer: Workers use a separate slicer for RTE products that support growth of L. monocytogenes	-6.3*	-0.6	-1.7*	22.7*	-0.8
Do Not Slice On Gloves: Workers collect the slices of RTE products on tissue paper rather than on his/her gloved hand	1.9	1.0	0.2	3.8	-1.9
Growth Inhibitor Related Scenarios:					
All GI: Reformulate all RTE products sold at the retail deli that would otherwise support L. monocytogenes growth to include growth inhibitors	-96.0*	-95.2*	-97.5*	-94.5*	-94.4*
No GI: Reformulate all RTE products that support L. monocytogenes growth that are sold at the retail deli to not include GI to restrict L. monocytogenes growth	184.1*	191.5*	35.1*	190.5*	187.7*
Cross Contamination Related Scenarios:					
Transfers to 0: Cross contamination would only result from the deli slicer	-4.3	2.5	1.0	3.7	0.2
Transfers and Slicer to 0: No cross contamination in the retail deli	-33.8*	-18.6*	-9.5*	-60.8*	-19.2*
Reduce Level: Mean incoming L. monocytogenes concentration in all RTE products lowered from -9.2 to -9.5 $\log_{10}$ cfu/g	-21.6*	-24.2*	-1.1	-9.8*	-22.5*
Separate Slicer Case: Workers use a separate slicer and a separate deli case for RTE products that support the growth of L. monocytogenes.	-2.5	-1.6	-1.2	21.0*	-0.9
Lower Env Cont: Reduce transfer of L. monocytogenes among RTE products, FCSs, and NFCs (i.e., reduce transfer coefficients by 50%)	-4.5	-4.4*	-1.4	0.4	1.6
Storage Temperature and Duration Control Related Scenarios:					
Temp = 5°C: Set the retail deli case temperature to					

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Critical Finding: Risk from RTE Foods that Do Not Support *Lm* Growth

No Niche — Baseline: 1.4; No Cross Contamination: 1.1
Susceptible Risk per Serving x 10^{-7}

Multiple niches — Baseline: 1.7; No Cross Contamination: 1.1
Susceptible Risk per Serving x 10^{-7}

Incoming non growth chub — Baseline: 2.8; No Contaminated Sales: 2.3; No Cross Contamination: 1.1
Susceptible Risk per Serving x 10^{-7}

Note: RTE foods that do not support growth can cross contaminate growth-supporting foods at retail to present a risk.

Food Safety and Inspection Service
Key Findings

- Major increases in risks to consumers arise from

  - Cross-contamination at retail significant increases risk

  - Increased *Lm* entering deli department from incoming product
    - Whether they support growth of *Lm* or not (re: cross contamination to other RTE foods)
    - From environment/niches

  - Lack of adequate temperature control
    - Low-hanging fruit

  - Lack of growth inhibitor use (growth at retail and at home)
    - Use of growth inhibitors whenever possible

  - Lack of adequate sanitation
    - Importance of the slicer
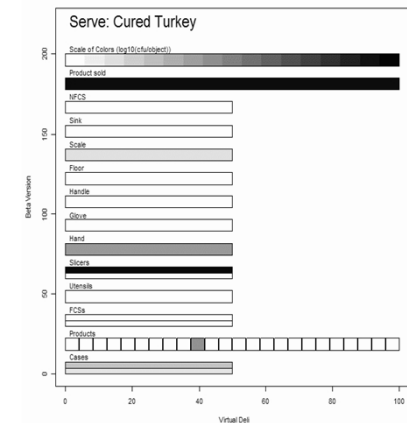
No single intervention will eliminate listeriosis risk from food sold at retail delis. Instead, there are a host of steps that deli operators and suppliers can take to reduce the risk.

Food Safety and Inspection Service
Next Steps

Retail *Lm* Compliance Guide

In April 2014 [FSIS issued the Best Practices Guidance for Controlling *Listeria monocytogenes (Lm)* in Retail Delicatessens](). This guidance document advises retailers of specific actions they can take to decrease the potential for *Lm* growth or cross-contamination in the deli area. FSIS is currently revising the guideline in response to public comments.

Surveillance at Retail

FSIS is considering in-commerce surveillance of ready-to-eat (RTE) meat and poultry products at retail delis. FSIS plans to work closely with federal partners (CDC) and the states.

Emerging Issues

Food Safety and Inspection Service
Success with Risk-based Policies & Programs: Meat Safety

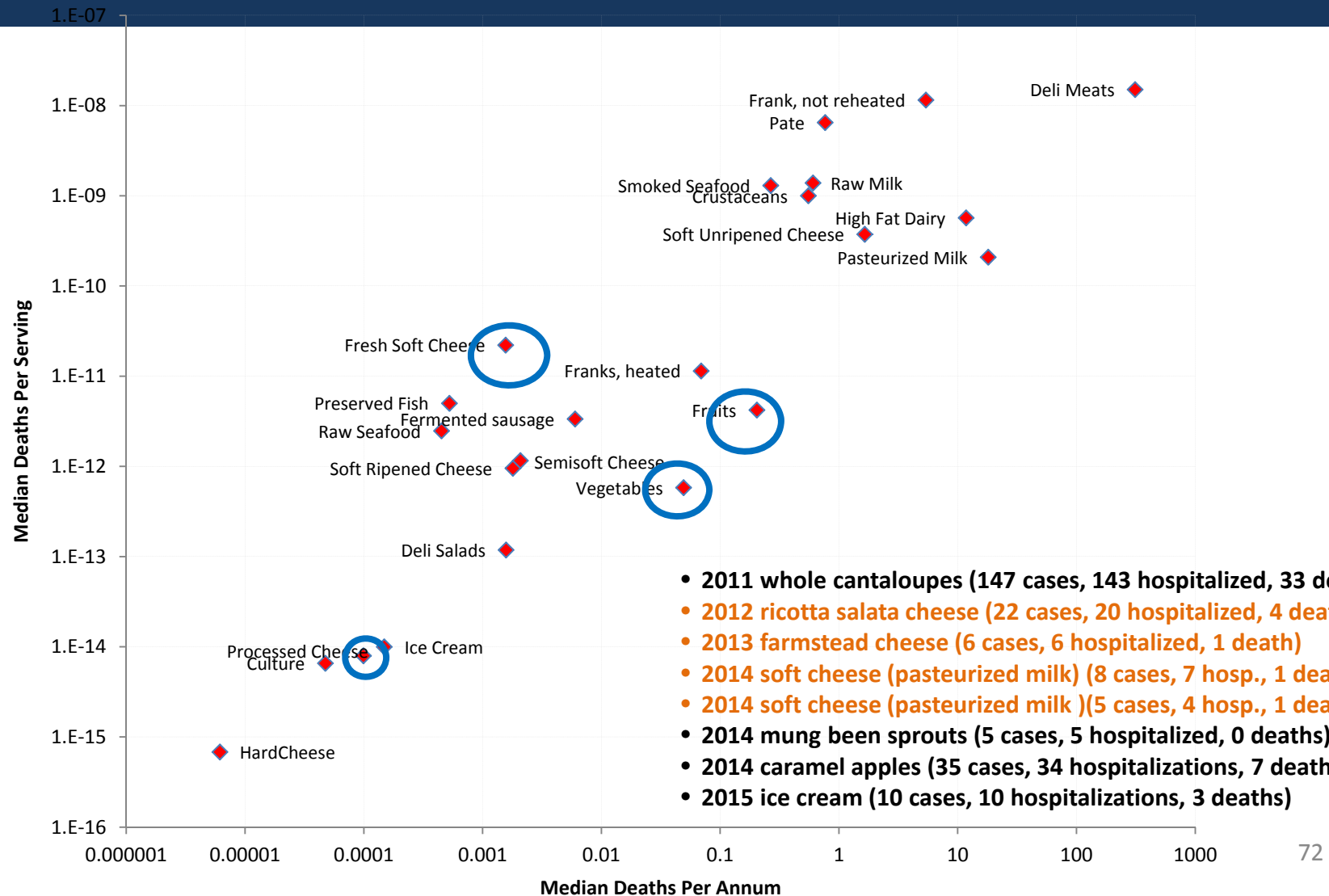| Year	Hot Dogs		Deli Meats	
	Cases	Deaths	Cases	Deaths
1998	112	14	0	0
1999	4	0	7	2
2000	0	0	30	4
2001	0	0	28	0
2002	0	0	54	8
2003	0	0	0	0
2004	0	0	0	0
2005	0	0	13	1
2006	0	0	0	0
2007	0	0	0	0
2008	0	0	0	0
2009	0	0	0	0
2010	0	0	8	2
2011	0	0	0	0

42% decline in the incidence of listeriosis since 1998

The U.S. Centers for Disease Control and Prevention attributes much of this success to effective risk-based USDA-FSIS policies and program focused on preventing *Lm* in RTE meat and poultry products.

*Adapted from Cartwright *et al.* 2013

* Adoption of effective *Lm* controls to mitigate risk from "high risk" foods such as deli meats.

Food Safety and Inspection Service:
Recent Listeriosis Outbreaks Among Previously Identified "Low Risk" Foods (2003 FDA-FSIS Risk Ranking)

- **2011 whole cantaloupes (147 cases, 143 hospitalized, 33 deaths)**
- **2012 ricotta salata cheese (22 cases, 20 hospitalized, 4 deaths)**
- **2013 farmstead cheese (6 cases, 6 hospitalized, 1 death)**
- **2014 soft cheese (pasteurized milk) (8 cases, 7 hosp., 1 death)**
- **2014 soft cheese (pasteurized milk)(5 cases, 4 hosp., 1 death)**
- **2014 mung been sprouts (5 cases, 5 hospitalized, 0 deaths)**
- **2014 caramel apples (35 cases, 34 hospitalizations, 7 deaths)**
- **2015 ice cream (10 cases, 10 hospitalizations, 3 deaths)**

Food Safety and Inspection Service
Recent Listeriosis Outbreaks & Continued Focus on Prevention

2011 Cantaloupe Outbreak

- 147 cases, 33 deaths (28 states)
- Previously "**low**" to "**moderate**" **risk** RTE food (2003 FDA-FSIS risk ranking)
- Growth **now** suspected
- Ages <1 to 96 years (median: 78 years)
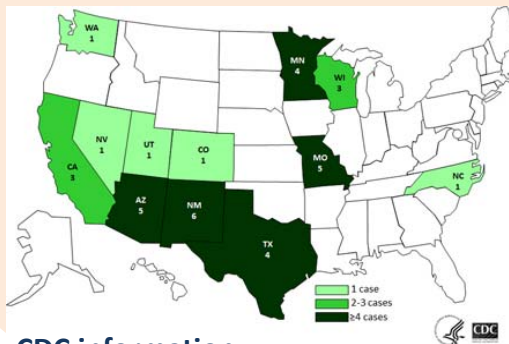- Outbreak PFGE subtyping & traceback (Listeria Initiative)

2014 Caramel Apple Outbreak

- 35 cases, 7 deaths (12 states)
- Unique food vehicle; previously "low risk"
- Growth **now** suspected
- 3 **healthy children** develop meningitis (5-15 years old)
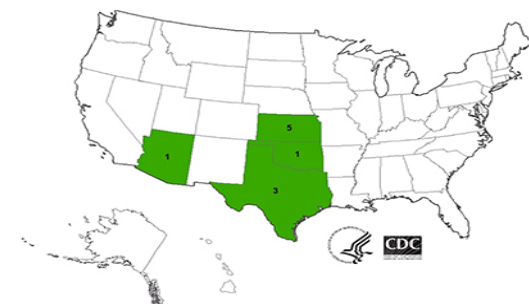- Outbreak identified with modernized surveillance (WGS/Listeria Initiative)

2015 Ice Cream Outbreak

- 10 cases, 4 deaths (4 states)
- Unique food vehicle; previously "very low risk"
- **Low levels** of *Lm*
- All were hospitalized who were exposed (susceptible)
- Outbreak identified with modernized surveillance (WGS/Listeria Initiative)

- *Lm* remains a food safety concern for industry and public health partners

- Conducted and applied risk assessments to guide national food safety policies and inspection programs

  - Risk assessments provide a systematic, objective, and transparent approach and improve stakeholder engagement

- Demonstrated success in mitigating the risk of listeriosis associated with "high risk" foods (e.g., deli meats)

  - >75% reduction of Lm in tested meat & poultry products

  - No outbreaks associated with federally inspected deli meats in a decade

- Recent outbreaks highlight continued gaps in knowledge regarding dose-response (*Lm* growth, strain virulence, host susceptibility)

  - Healthy children, low doses, and growth in new food vehicles previously thought to be "low risk" (i.e., not to support *Lm* growth)

- Remain committed to risk-based policies focused on prevention

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Questions?

Food Safety and Inspection Service

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