Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
Opportunities to Collect Data and Improve Lm Risk Assessments

Janell R. Kause
Scientific Advisor for Risk Assessment
Food Safety and Inspection Service, USDA
Past Risk Estimates vs. Current Outbreaks

Data/Data Gaps

What next?
In 2003, which RTE foods were predicted to pose the greatest risk of listeriosis per serving?

Predicted Cases of Listeriosis per Serving—Total Population

[Graph showing predicted cases of listeriosis per serving for various food categories.]
<table>
<thead>
<tr>
<th>Relative Risk Ranking</th>
<th>Food</th>
<th>Predicted Median Cases of Listeriosis for 23 Food Categories</th>
<th>Per Serving Basis</th>
<th>Per Annum Basis</th>
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</thead>
<tbody>
<tr>
<td>High Risk</td>
<td>Deli Meats</td>
<td></td>
<td>7.7x10^-8</td>
<td>1598.7</td>
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<tr>
<td></td>
<td>Frankfurters, not reheated</td>
<td></td>
<td>6.5x10^-8</td>
<td>90.8</td>
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<tr>
<td></td>
<td>Pâté and Meat Spreads</td>
<td></td>
<td>3.2x10^-8</td>
<td>56.4</td>
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<tr>
<td></td>
<td>Unpasteurized Fluid Milk</td>
<td></td>
<td>7.1x10^-9</td>
<td>30.5</td>
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<tr>
<td></td>
<td>Smoked Seafood</td>
<td></td>
<td>6.2x10^-9</td>
<td>7.7</td>
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<tr>
<td></td>
<td>Cooked Ready-to-Eat Crustaceans</td>
<td></td>
<td>5.1x10^-9</td>
<td>3.8</td>
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<tr>
<td></td>
<td>High Fat and Other Dairy Products</td>
<td></td>
<td>2.7x10^-9</td>
<td>3.1</td>
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<tr>
<td></td>
<td>Soft Unripened Cheese</td>
<td></td>
<td>1.8x10^-9</td>
<td>2.8</td>
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<tr>
<td></td>
<td>Pasteurized Fluid Milk</td>
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<td>1.0x10^-9</td>
<td>1.3</td>
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<td>Moderate Risk</td>
<td>Fresh Soft Cheese</td>
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<td>Frankfurters, reheated</td>
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<td>0.4</td>
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<td>Preserved Fish</td>
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<td>2.3x10^-11</td>
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<td></td>
<td>Raw Seafood</td>
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<td>2.0x10^-11</td>
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<tr>
<td>Low Risk</td>
<td>Fruits</td>
<td></td>
<td>1.9x10^-11</td>
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<td>Dry/Semi-dry Fermented Sausages</td>
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<td>Semi-soft Cheese</td>
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<td>Vegetables</td>
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<td>Deli-type Salads</td>
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<td>Ice Cream and Other Frozen Dairy Prod.</td>
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<td>4.9x10^-14</td>
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<td>Processed Cheese</td>
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<td>4.2x10^-14</td>
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<td>Cultured Milk Products</td>
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<td>Ripe Soft Cheese</td>
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<tr>
<td></td>
<td>Fruits</td>
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<td></td>
<td>Vegetables</td>
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<td>&lt;0.1</td>
<td></td>
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<td></td>
<td>Ice Cream and Other Frozen Dairy Products</td>
<td></td>
<td>&lt;0.1</td>
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</tbody>
</table>
Deli Meats and Frankfurters-Not Reheated

- High predicted relative risk per serving and per annum
- High rates of contamination, support rapid growth of LM, stored for extended periods
- Consumed extensively
- Need for immediate attention—develop new control strategies and/or consumer education programs
Diverse group

- Fruit, Vegetables, Dry/Fermented Sausages

- Many include bactericidal step or inhibitors
- Presence of *L. monocytogenes* primarily associated with recontamination or poor initial sanitation
- Safety is *primarily associated with continued vigilance of proven control measures*
2003 Risk Designation – Very Low

Cultured Milk Products, Hard Cheese, Ice Cream and Frozen Dairy Products, Processed Cheese

- Low per serving and per annum risk
- Bactericidal treatment plus condition that prevents growth or inactivates
- *Not likely to be a significant source of foodborne listeriosis*
Recent Outbreaks….

- 2011 whole cantaloupes (Jensen farms)
- 2012 ricotta salata cheese (imported)
- 2013 farmstead cheese (Crave Brothers)
- 2014 Hispanic soft cheese from pasteurized milk (Roos Foods)
- 2014 Hispanic soft cheese from pasteurized milk (Oasis Brands)
- 2014 mung been sprouts (Wholesome Soy Products)
- 2014 caramel apples 2015 ice cream (Blue Bell)

Shifting food vehicles (from RTE meats to produce) (CDC: Cartwright, 2013)
Questions Based on Current Outbreaks

✓ Host?
  ➢ CDC MMWR June 2013 – 7% seemingly healthy
  ➢ Illnesses in children with no underlying conditions?

✓ Hazard?
  ➢ More virulent strains of Lm associated with outbreaks? Lower dose?

✓ Exposure?
  ➢ Deaths from foods identified as “low risk” (no/low growth) – low dose?
  ➢ Variability in typical consumer handling and storage; change practices when products are purchased because they last longer?
  ➢ Cross contamination? Ingredients? Environment (processing/retail)?
Reconsider….

• Wrong paradigm or overly confident in a single paradigm (e.g., high levels + susceptible consumer = adverse outcome?
  • Does not fit with recent outbreak evidence/WGS likely to provide even better linkage and more to come….

• Black Swan – maybe? Too many outbreak occurrences to be a “rare” event that “low risk” foods associated with severe listeriosis/deaths
Some data being collected….

- Hazard ID – WGS/strain var. and virulence
- Exposure:
  - Newer growth curves (predictive micro.; in Combase?)
  - Newer consumer behavior data
  - Contamination at retail?
  - Ecology
  - Transmission/Transfer Coefficients (studies)
Collect Additional Data

- Outbreak Data
- Behavior Data
- Product Formulation/Predictive Micro. Data
Collect More Detailed Data During Outbreak Investigation

✓ Levels of Lm in foods
✓ Who is getting sick? Why?
  ➢ Host factors (intrinsic: immunity; extrinsic: behavior (consumption, food storage/handling))
✓ Foodborne disease outbreak questionnaire (JIFSAN exclusive)
  ➢ Routine vs. Dose-Response (symptoms/severity, host factors, consumption quantified); Use?

➤ Behavior along supply chain: processing, retail, etc.
➤ Cross contamination?
➤ GMPs followed?

➤ CDC’s Listeria Initiative & Council to Improve Foodborne Outbreak Response (CIFOR)
Collect Behavior Data Along Supply Chain

- How much growth?
  - In part dependent on time-temperature of storage/handling
- Ecosure Data (quantifiable time-temperature information)
  - 2007 Cold Temperature Database/Cooking Temperature Database
- Age of Information – representative?
Utilize Product Formulation Data: Branded Food Products Database

✓ Growth & detailed product formulation info. (pH, aw, etc.)

Work Statement: The Partnership will ensure that comprehensive, food composition, food industry data will be made available to those who utilize such data including the government, the scientific community, proprietary end users, and the food industry in the enhanced USDA National Nutrient Database.

Goal: The Partnership’s goal is to enhance the public’s health, which is significantly dependent on diet, through increased nutrient knowledge of the nation’s food supply.
Opportunity to Strengthen Risk Assessments

- Modernize Technologies/Processes
- Data Integration/Evaluation
- Expanded Collaboration
Newer scientific tools...

- Whole genome sequencing to identify cases as part of outbreak sooner and get better and more information
- Better consumer recall of foods consumed (ID food)
- Gather data on consumer food handling practices
- Test the product
Data Integration/Evaluation

- On-going data collection (sampling hazards, time/temp. via sensors, etc.)
- Integrated information – IT: FSIS’s Public Health Information System
- Utilize predictive analytics – powerful with “Big Data” to identify risk factors & prevent problems before they happen
- “Metrics that matter” – evaluate the performance of food control systems (validation of controls)
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 authorities, stakeholders, and the public to ensure the safety of meat, poultry, and processed egg products.
Public-Private Data Collection: Retail Food Safety

USDA Collaboration Goals:
- Acquire *Listeria monocytogenes* sampling data in retail delis in three states
- Use the data to parameterize, validate, and calibrate innovative interagency retail risk assessment model.

**Critical:** Collaboration established through regular and on-going engagement (2009-2013); partnered with Cornell University and Purdue University.

Outputs:
- Improved ability to **predict the impact** of a wide variety of retail practices, conditions, and product supply on the safety of deli-prepared foods.
- Used to **enhance retail food safety** practices.

FDA Collaboration Goals:
- Acquire *Salmonella*, *E. coli*, *Listeria monocytogenes*, and norovirus sampling data from industry collaborators
- Use the data to parameterize, validate, and calibrate FDA’s predictive geospatial risk assessment model
- Test the model’s ability to predict enteric pathogen contamination of produce

**Novel:** Innovative public-private collaboration (using historical industry data in QRAs; research cooperative agreements)

**Outputs:**
- Improved ability to **forecast/predict produce contamination**.
- Use forecasts to **target sampling and other interventions** to enhance food safety.
Models for Collaboration

Public-Private Collaboration Intermediaries

- Shared understanding of risks
- Understand interdependencies in complex food supply chain
- Predict and prevent problems

Risk Assessors/Scientists

Specific Data Shared

Stakeholder Engagement

Leverage public and private resources to improve insights and drive innovation and strategic management of food safety risks.
Past risk assessments guided policies/programs - Success

Which Food?

- Quantitative Assessment of the Relative risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (Sept. 2003; “FDA/FSIS Listeria Risk Assessment” [risk-ranking of RTE foods; deli meat highest risk])

Which process control?

- Risk Assessment for *Listeria monocytogenes* in Deli Meat (May 2003) [evaluated predicted effectiveness of Lm controls during processing]

Where is the problem now?

- *Comparative Risk Assessment for Listeria monocytogenes in Ready-to-eat Meat and Poultry Deli Meats* (May 2010) [83% of deli meat-associated listeriosis cases attributed to retail preparation]

What is happening downstream?

- *Interagency Risk Assessment: Listeria monocytogenes in Retail Delicatessens* (September 2013) [retail practices]
Successful Risk-Based Lm Control

Significant Reduction of Lm in RTE Meat and Poultry Products

- FSIS results of routine regulatory testing of finished RTE meat and poultry products analyzed for Lm (1990-2011). Approximately 4,000-10,000 samples taken annually.
Now….risk assessment to focus on where the problems currently are…..

➢ Invest in updating the 2003 FDA/FSIS Listeria risk assessment to get new attribution estimates (which product poses greatest risk)?

➢ Commit to getting better contamination data (levels) on produce and across industry (lower prevalence today/more samples) [Risk-ranking of RTE foods needed?]

➢ Still need to subsequently develop process models for highest risk foods to evaluate effectiveness of Lm controls for produce and develop risk-based inspection or other mechanism to “incentivize” behaviors (adoption of Lm controls; investment in equipment; etc.)
Science-based, Data-driven, Risk-Informed Protection of Public Health
Questions?

Thank you.