Microbial Risk Assessment: Activities and Applications Within the Food Safety and Inspection Service

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Bethesda, MD

United States Department of Agriculture
Food Safety and Inspection Service

• Public health regulatory agency
  - Farm-to-table food safety system
• Ensure the safety of meat, poultry and processed egg products
  - ~ 7,600 full-time inspectors
  - ~ 5,921 processing establishments inspected daily
  - ~ 1,100 slaughter establishments in which every animal inspected
• Statutory requirements
  - FMIA, PPIA, EPIA

Foodborne Disease

• Latest CDC estimates indicate the following annual burdens due to foodborne diseases in the U.S. per year:
  - 325,000 serious illnesses resulting in hospitalizations
  - 76 million cases of gastrointestinal illnesses
  - 5,000 deaths

Risk Analysis at USDA/FSIS

• Cornerstone of USDA/FSIS food safety program
  - Scientific basis for food safety policies and allocation of inspection resources
  - FSIS corporate strategic plan/SOPs
• Powerful public health tool
  - Allows for transparency and stakeholder involvement to ensure credibility and scientific accountability

Overview of QMRA Applications

• Inform various agency decisions
  - Industry regulations (standards)
  - Allocation of agency inspection resources
  - Food safety research priorities
  - Equivalence criteria (trade)
  - Recalls
• Scientific basis for food safety decisions
  - Explicitly link policies to public health outcomes

Microbial Risk Assessment Activities: 1998-2003

• USDA/FDA risk assessment for Salmonella Enteritidis in eggs and egg products (1998)
• E. coli O157:H7 in ground beef (2001)
• E. coli O157:H7 in non-intact beef (2002)
• USDA/FSIS risk assessment for Listeria in deli meats (May 2003)
• FDA/FSIS risk ranking of ready-to-eat foods for Lm (2001/updated September 2003)
**Microbial Risk Assessment Activities: 2004-2006**

- Risk-based *Listeria monocytogenes* verification sampling algorithm (2005)
- *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in egg products (2005)
- *Salmonella* spp. in ready-to-eat meat and poultry products (2005)
- Poultry Slaughter Risk Assessment (draft 2006, updated 2008)

**Microbial Risk Assessment Activities: 2007-2008**

- Risk-based *E. coli* O157:H7 verification sampling algorithm (2007)
- Comparative risk assessment for *L. monocytogenes* in ready-to-eat meat and poultry products (draft 2004/updated 2008)
- FoodNet Interagency Salmonella Attribution Model (2008)
- Pre-harvest Intervention *E. coli* risk assessment (draft 2008)
- Interagency Highly Pathogenic Avian Influenza (2008)

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**Microbial Risk Assessment Process**

1. Identify Food Safety Problem
2. Formulate Risk Management Questions/Options
3. Risk Assessment Proposal
4. Conduct a Risk Assessment
5. Choose another option
6. Revise RA Model, Report, and Response to Comments
7. Present RA to Public for Comment
8. Integrate RA into decision process (regulation, directives, notices) & disseminate (e.g., web posting)

**Application: Listeria Risk Assessments**

- FDA-FSIS Quantitative Risk Assessment for *Listeria monocytogenes* in Ready-to-Eat Foods
- FSIS *Listeria* Risk Assessment
- Risk-based *Listeria monocytogenes* Verification

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**Public Health Context: *Listeria monocytogenes* (Lm)**

- Causes sepsis, abortion and encephalitis in humans and in animals
- Incubation period 7 - 60 days
- Human listeriosis occurs in both epidemic and sporadic cases
- Affects predominantly elderly and immuno-compromised people, pregnant women and newborns
- Approx. 2,500 human cases/year in the U.S., resulting in 350 - 450 deaths/year
- Responsible for majority of microbial food recalls
- National health objective is to decrease incidence of listeriosis by 50% to 0.25 per 100,000 persons

**General Risk Management Questions**

- Which ready-to-eat foods pose the greatest risk of listeriosis?
  - 2003 FDA-FSIS Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat (RTE) Foods
- Which interventions effectively control Lm?
  - 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat
- How can FSIS target its inspection resources to effectively address Lm?
  - 2005 FSIS Risk-based Verification Sampling for Lm in ready-to-eat meat and poultry products
**Which Ready-to-Eat Foods Pose the Greatest Risk of Listeriosis?**

- Risk Assessment: 2003 FDA/FSIS Listeria Risk Assessment
- 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

**Relative Risk Ranking and Predicted Median Cases of Listeriosis for U.S. Population on per Serving and per Annum Basis**

<table>
<thead>
<tr>
<th>Relative Risk Ranking</th>
<th>Predicted Median Cases of Listeriosis for 25 Food Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Per Serving Basis</td>
</tr>
<tr>
<td>1. Deli Meats</td>
<td>7.55x10^5</td>
</tr>
<tr>
<td>2. Frankfurters, not reheated</td>
<td>4.09x10^4</td>
</tr>
<tr>
<td>3. Pâté and Meat Spreads</td>
<td>3.22x10^4</td>
</tr>
<tr>
<td>4. Unpasteurized Fluid Milk</td>
<td>2.53x10^4</td>
</tr>
<tr>
<td>5. Smoked Seafood</td>
<td>3.06x10^4</td>
</tr>
<tr>
<td>6. Cooked Ready-to-Eat Crustaceans</td>
<td>2.74x10^4</td>
</tr>
</tbody>
</table>

* Only the top 9 riskiest food categories are shown

**Which Interventions Effectively Control Lm?**

- 2003 FSIS Listeria Risk Assessment
- Evaluated the effectiveness of industry controls in mitigating the risk of Listeriosis associated with deli meats
- Industry regulations (standards)
- Post-lethality intervention
- Growth inhibitors
- Sanitation
- Built from FDA/FSIS Listeria risk assessment
- Processor-to-table risk assessment

**Specific Risk Management Questions**

- 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?
USDA/FSIS Risk Management Strategy

Interim Final Rule (issued June 2003, effective October 6, 2003; 9 CFR 430 RTE)
- Based on the 2003 FSIS Listeria risk assessment and the 2003 FDA-FSIS Risk-Ranking for Lm in ready-to-eat foods
- Established three alternative control measures
  - Post-lethality treatment and antimicrobial agent/process with sanitation (Alt. 1)
  - Post-lethality treatment (Alternative 2a) or antimicrobial agent/process with sanitation (Alt. 2b)
  - Sanitation alone (Alt. 3)

FSIS Directive 10,240.4 (10/2/03)
- Established a risk-based sampling program to verify compliance with Lm Rule

How Can FSIS Allocate Its Sampling Resources According to Risk?

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

Purpose of the FSIS Risk-Based Listeria Verification Program

- To prevent adulteration of product by Lm.
- To focus USDA/FSIS verification sampling efforts on establishments producing product predicted to pose the greatest risk of listeriosis based on two previously developed Listeria risk assessments and real time laboratory data.
- To evaluate an establishment's food safety system so that FSIS can focus on establishments with less effective Lm control measures.
- To provide an appropriate incentive for establishments to adopt more effective Lm control measures.
- To protect public health.
Data Sources: FSIS Listeria Risk-Ranking Algorithm

Risk Factors
- Product Type
- Plant Antimicrobial
- Production Volume
- Testing History

Calculations
- Raw Plant Score
- Final Plant Score

Lessons Learned
- Must have well defined risk management questions
- QMRAs are not a “one size fits all”
- Complexity of the MRA depends on the purpose for developing the risk assessment
- Risk assessors and risk managers are independent, but interdependent
- Iterative interaction between risk assessors and risk managers is needed to develop QMRAs useful to informing policies

Future Directions
- USDA/FSIS is committed to developing MRAs
- High level of transparency in the decision-making process
- Readily share information to facilitate more expedient development and application of MRA (post models on the web)
- Web accessible and downloadable models
- Develop and publish standard modeling methods
- Integration into agency IT infrastructure and data integration to support quantitative MRAs
- Integrate MRA process models into IT systems and update on an annual basis
- FSIS will continue to expand the integration and application of QMRA to inform food safety decisions designed to improve public health through safer food

Thank You

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