Food Safety Risk Assessments

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Technical Developments: The New Economic Reality
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• Public health agency in USDA
  - considers entire food safety system (from production to table)
  - collaborates with FDA, APHIS, and other food safety agencies

• Ensure meat, poultry and processed egg products are safe, wholesome, and correctly labeled and packaged

• Statutory requirements
  - Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act

• Scientific tools to guide food safety decisions
  - data & understanding: epidemiology (risk factors/attribution), food testing (identification of hazards – chemical, microbial, etc.)
  - prediction & prevention: risk assessment
Public Health Context

Annual estimates of foodborne disease*

- 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths

Emerging concerns

- STECs (non-O157), *Clostridium difficile*, norovirus, specific sub-types of known pathogens
- nanotechnology, GMOs, allergens, antimicrobial resistance
- dioxin, melamine, other chemical contaminants

Cross-cutting issues

- safety & freshness associated with locally grown; direct farm-to-market
- globalization: equivalence (WTO/SPS Agreement)
- effectiveness/consistency in labeling: nutrition/food safety
- food safety interventions: nutrition, quality, acceptance; risk trade offs

* Centers for Disease Control and Prevention (Mead et al., 1999); updated estimates expected CY 2010
• Cornerstone of our food safety program
  – safety of meat, poultry, and egg products
  – entire food safety system
  – partnership with other agencies (FDA, APHIS, EPA, CDC), states, and academia

• Powerful tool to guide the development of food safety policy
  – current and emerging food safety issues
  – transparency and stakeholder involvement to ensure credibility and scientific accountability

What is Risk Assessment?

Office of Public Health Science, FSIS

- Scientific process for estimating the probability of exposure to a hazard and the resulting public health impact (risk); consists of the following components:
  1. hazard identification
  2. hazard characterization
  3. exposure assessment
  4. risk characterization

- Predicts public health benefits of changes in policies, practices, and operations (and includes the certainty of these predictions).

- It is used to facilitate the application of science to policy (the “bridge between data and decisions”).
Regulatory Requirements for Risk Assessment

- Regulatory Requirements (Public Law 103-354)
  - The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 requires that any regulation published by USDA concerning human health, human safety or the environment and having an annual economic impact of at least $100 million in 1994 dollars contain a risk assessment and cost-benefit analysis.

- World Trade/SPS Agreements (equivalency)

- Presidential Executive Order 12866, significant regulatory actions
The “best” risk assessment is the one that most directly informs the risk management issue.
Risk Assessment Process

Codex process for microbial risk assessment (RA)
- Hazard Identification
  - In-depth literature review
- Hazard Characterization
  - Dose-response
- Exposure Assessment
  - Likely intake of pathogen
- Risk Characterization
  - Consequences, given the above

National Resource Council process for chemical RA
- Hazard Identification
- Dose-Response
- Exposure Assessment
- Risk Characterization
Overview: Risk Assessment Applications

Quantitative risk assessment integrates a wide variety of science and data to provide a comprehensive understanding of the food safety system.
Risk Assessment
Applications at USDA/FSIS

Current

• Establish food safety policies (policy development)
• Allocate inspection resources to verify industry controls (assurance)
• Measure federal performance in achieving public health goals (evaluation)

Future

• Standardize and harmonize risk assessment methodology
• Establish measurable performance objectives for industry based on national public health goals (risk management metrics)
• Address both chemical and microbial hazards simultaneously in assessing risk from foods
• Apply probabilistic approach to address chemical food safety risks
• Integrate multiple environmental exposure routes of a hazard into food safety system in determining food safety risk
Why is risk assessment used to guide decisions?

- Systematically address food safety issues
- Formal and transparent conceptual framework that integrates data and information to guide decisions
  - logical
  - science based
  - transparent
  - holistic
- Evaluate public health benefits associated with policy options ("what if" scenarios)
- Focus finite resources on the greatest risk (foods, hazards, process, and/or practices)
- Several applications for public health professionals, food safety managers, and other stakeholders
Questions Involving the Use of Risk Assessment

How do you determine if there is an emerging food safety issue?

How are risk assessments developed to guide food safety policies?
Evaluating Emerging Food Safety Issues & Developing Risk Management Strategies

1. Evaluate Food Safety Problem
   - Identify emerging issues/improve understanding of existing issues
   - Develop Risk Profile

2. Public Health Goals
   - Healthy People 2020
   - Risk management objectives

3. Formulate Various Policy Options
   - Agency-wide input
   - External (Stakeholder) Input

4. Identify Viable Policy Options
   - cost-effectiveness
   - legal constraints
   - technically feasible

5. Regulatory Impact Analysis
   - Conduct a risk assessment
   - Conduct a cost-benefit analysis

6. Select Food Safety Policy
   - Balance public health benefits (risk reduction) with societal costs

7. Implement Food Safety Policy
   - regulation - guidance
   - training - outreach
   - allocate resources

8. Evaluate Effectiveness of Food Safety Policy
   - inspection - FSAs
   - verification sampling
   - attribution data (trend analysis)
Managing the Risk of Listeriosis: Use of Various Types of QMRAs

Which ready-to-eat foods pose the greatest risk of listeriosis?


Which industry practices effectively control Lm?


How can FSIS target its inspection resources to ensure industry controls Lm?

• FSIS Risk Based Verification Sampling for *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products (2005)

Where should FSIS focus its efforts to further to reduce listeriosis?

• FSIS Comparative Lm Risk Assessment: Pre-packaged vs. Retail-sliced Deli Meat (2009)
Which foods pose the greatest risk of listeriosis?

- FDA/FSIS *Listeria* risk assessment identified deli meats as posing the greatest risk of listeriosis.
- **Action:** Lm Food Safety Action Plan.
- **Caveat:** Predicted deli meat posed greatest risk prior to foodborne outbreaks beginning in Fall 2002.

### Diagram:

**23 Categories of Ready-to-Eat Foods**

- **Deli meats**
- **Frankfurters (heated)**
Which industry practices effectively control Lm?

- FSIS *Listeria* risk assessment identified post-lethality interventions and use of antimicrobials were substantially more effective than sanitation measures.
  - **Action**: Interim Final Rule for Lm (2003)
  - **Caveat**: Changed FSIS risk management strategy to focus beyond testing/sanitizing.

**Source:**
How can FSIS effectively allocate its inspection resources to ensure Lm controls?

- FSIS’ risk-based Lm sampling allocated FSIS verification sampling resources among establishments predicted to pose the greatest risk each month (10,000 samples/year)

- **Result:** industry adopted more effective Lm control measures

- **Caveat:** first risk-based food safety inspection program in U.S. using QMRAs

![Industry adoption of Lm controls](http://www.fsis.usda.gov/PDF/RBVS_Risk_Assess_Jun07.pdf)
Why a plateau in listeriosis?
Office of Public Health Science, FSIS

• FSIS comparative Lm risk assessment evaluated the risk of listeriosis from prepackaged vs. retail-sliced deli meat

• **Finding**: approximately 83% of listeriosis cases attributed to deli meat were associated with those sliced at retail (growth inhibitors significantly reduce risk overall)

• **Action**: FSIS and FDA focus on retail Lm contamination -- developing a new risk assessment to evaluate retail cross-contamination and Lm controls

2009 FSIS Comparative Lm Risk Assessment: Pre-packaged vs. Retail-sliced Deli Meat

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<th>Category</th>
<th>Public Health Impact</th>
<th>Retail-sliced Deli Meat</th>
<th>Pre-packaged Deli Meat</th>
<th>Total Illnesses/Deaths</th>
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<tr>
<td>With Growth Inhibitor</td>
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<tr>
<td>Deaths</td>
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<td>Illnesses</td>
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</table>

Source:
• Tiered approach to understanding and controlling Lm
  – Identify which food vehicle posed the greatest risk (Lm Action Plan)
  – Identify which processing intervention would best control Lm (FSIS Listeria Rule)
  – Identify where to focus inspection efforts among processors (FSIS risk-based sampling)
  – Identify where further reductions in listeriosis can be realized (e.g., retail/sanitation)
  – Understand how cross-contamination occurs to effectively control Lm at retail

• Risk assessment findings guided Agency and industry efforts to successfully reduce Lm contamination in meat and poultry products

• RA: identified and provided basis for implementing better Lm controls
Lessons Learned

- Must have well defined risk management questions
- RAs are not a “one size fits all”
- Complexity of the RA depends on the purpose for developing the risk assessment
- Risk assessors and risk managers are independent, but interdependent
- Risk profiles are essential for characterizing the current public health risk for emerging hazards (tiered approach to risk assessment)
Lessons Learned

- Involve stakeholders early in the process
- RA models can be modular and built more quickly using prior risk assessment models
- Integrating economics and risk assessment into a single model saves time in decision-making
- Use risk assessments as a predictive tools - conduct scenario analyses
- Characterization of certainty of risk estimates is important for decision makers
- Rigorous peer review is essential
Future Direction

- Broader food safety perspective and use of risk assessments
- Food safety risks will be “food-based” (multiple hazards) rather than traditional product-hazard based
- Risk management metrics: predict which performance objectives will meet established public health goal
- Increasing interagency collaboration & consideration of cross-cutting issues
- Evaluation of risk-risk trade-offs
- Greater focus on emerging issues and prevention
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FSIS Risk Assessment Website: