USDA Perspective:
Need for Prioritizing Potential Risks from Contaminants in Food

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Presented to
Workshop: Tools for Prioritizing Food Safety Concerns
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Overview

• Background need for a science-based process/framework for prioritizing risks from chemical and microbial contaminants in food

• USDA’s Food Safety and Inspection Service (FSIS) approach for:
  • Microbiological contaminants
  • Chemical/residue contaminants
The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.
Listeria monocytogenes (Lm) as an example
• Identify Food Safety Problem
• Prioritization based on factors such as:
  • Foodborne outbreaks
  • Epidemiological and clinical findings
  • Public health concern
  • New scientific findings
  • Surveillance and monitoring information
  • Changes in industry practices
• Public input important; mechanism for public access regarding status of agenda
• Prioritization can change
## Food Categories

### SEAFOOD
- Smoked Seafood (finfish and mollusks)
- Raw Seafood (finfish, mollusks, and crustaceans)
- Preserved Fish (dried, pickled, and marinated finfish)
- Cooked Ready-to-Eat Crustaceans (shrimp and crab)

### PRODUCE
- Vegetables (raw)
- Fruits (raw, dried)

### DAIRY
- Fresh Soft Cheese (queso fresco, queso de Crema, Queso de Puna)
- Soft Unripened Cheese, >50% moisture (cottage cheese, cream cheese, ricotta)
- Soft Ripened Cheese, >50% moisture (brie, camembert, feta, mozzarella)
- Semi-soft Cheese, 39-50% moisture (blue, brick, Monterey, muenster)
- Hard Cheese, <39% moisture (cheddar, Colby, parmesan)
- Processed Cheese (cheese foods, spreads, slices)
- Pasteurized Fluid Milk
- Unpasteurized Fluid Milk
- Ice Cream and Other Frozen Dairy Products
- Cultured Milk Products (yogurt, sour cream, buttermilk)
- High Fat and Other Dairy Products (butter, cream, other miscellaneous milk products)

### MEAT
- Frankfurters (reheated)
- Frankfurters (not reheated)
- Dry/Semi-Dry Fermented Sausages
- Deli Meats (cooked, ready-to-eat)
- Pâté and Meat Spreads

### COMBINATION FOODS
- Deli-type Salads (fruit, vegetable, meat, pasta, egg, or seafood salads)
### Risk Ranking: Predicted Median Cases of Listeriosis for US Population

#### Background
- Need for a science-based process/framework for prioritizing risks from chemical and microbial contaminants in food.
- USDA's Food Safety and Inspection Service (FSIS) approach for:
  - Microbiological contaminants
  - Chemical/residue contaminants

#### Predicted Median Cases of Listeriosis for 23 Food Categories

<table>
<thead>
<tr>
<th>Relative Risk Ranking</th>
<th>Predicted Median Cases of Listeriosis for 23 Food Categories</th>
<th>Per Annunum Basis</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Per Serving Basis(^a)</td>
<td>Food</td>
</tr>
<tr>
<td>1</td>
<td>Deli Meats</td>
<td>7.7x10(^{-8})</td>
</tr>
<tr>
<td>2</td>
<td>Frankfurters, not reheated</td>
<td>6.5x10(^{-8})</td>
</tr>
<tr>
<td>3</td>
<td>Pâté and Meat Spreads</td>
<td>3.2x10(^{-8})</td>
</tr>
<tr>
<td>4</td>
<td>Unpasteurized Fluid Milk</td>
<td>7.1x10(^{-9})</td>
</tr>
<tr>
<td>5</td>
<td>Smoked Seafood</td>
<td>6.2x10(^{-9})</td>
</tr>
<tr>
<td>6</td>
<td>Cooked Ready-to-Eat Crustaceans</td>
<td>5.1x10(^{-9})</td>
</tr>
<tr>
<td>7</td>
<td>High Fat and Other Dairy Products</td>
<td>2.7x10(^{-9})</td>
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<tr>
<td>8</td>
<td>Soft Unripened Cheese</td>
<td>1.8x10(^{-9})</td>
</tr>
<tr>
<td>9</td>
<td>Pasteurized Fluid Milk</td>
<td>1.0x10(^{-9})</td>
</tr>
</tbody>
</table>
Interventions to Reduce Risk

• Combinations of interventions appear to be much more effective than any single intervention in mitigating the potential contamination of RTE product with L. monocytogenes and reducing the subsequent risk of illness or death
  • Testing and sanitation of food contact surfaces
  • Pre-and post-packaging interventions
  • Use of growth inhibitors/product reformulation
Lm Control Measures

- Established three alternative control measures:
  - Post-lethality treatment and antimicrobial agent/process with sanitation (Alternative 1)
  - Post-lethality treatment (Alternative 2a) or antimicrobial agent/process with sanitation (Alternative 2b); and
  - Sanitation alone (Alternative 3)
Risk Based Verification Sampling

- Generate a ‘risk ranking’ for all RTE establishments making post-lethality exposed product:
  - Alternative they opt to use to control Lm
    - 2003 FSIS Lm Risk Assessment
  - Product type: potential for Lm to grow
    - 2003 FDA FSIS Risk Ranking
  - Compliance history of the establishment
  - Volume of production
  - Voluntary measures chosen by the establishment
Risk-Based Inspection

- Risk varies across products produced at various establishments
- Exposure: Characteristics that contribute to presence and amount of hazard in a serving of food
  - Product supports the survival and growth of a pathogen
  - Process specifics (time and temperature conditions; line speed)
  - Interventions in place
  - Test and hold programs and testing
  - Disposition of the product
  - Empirical indicators include microbial test results
- Exposure: Number of servings that contain a likely amount of hazard
  - Production volume
Risk-Based Resource Allocation

- Definitive drivers of risk must be identified and, ultimately, understood quantitatively.
- Valid descriptions of establishments according to those risk factors are needed.
- Eventually, a global model, one tracking all pathogens and processes will allow FSIS to allocate resources of all types (sampling and inspection) according to the risk to human health. In the mean time, we build mechanistic models for each pathogen and process pair (Lm in RTE).
National Residue Program (NRP) as an example
The foundation of the NRP was a government action to control the occurrence of toxic chemicals in the food supply that resulted from the agricultural and industrial use of new chemicals.

Purpose of the NRP is twofold:

• First is to determine what toxic chemicals are present in meat, poultry, and egg products (exposure assessments).

• Second is to keep the meat, poultry, and egg products free from toxic chemicals before reaching consumers.
Once these compounds have been identified, FSIS will:

- Prioritize what chemicals to monitor in the NRP based on risk
- Determine if risk management actions need to be taken
Considerations for Ranking of Compounds for NRP

• Public Health
  • Acute or chronic toxicity concern
  • Impact on new and existing human diseases
  • Development of resistance & impact on human health

• Duration and usage

• FSIS historical testing information
  • Number of animals treated
  • No. of violations reported

• Availability of laboratory resources

• Withdrawal time
Tool for Ranking Criteria

- Score for Acute or Chronic Toxicity Concerns (“T”) (FDA)
- Predicted or actual score for “FSIS Historical Testing Information on Violations” (“V”) (FSIS)
- Score for “Impact on new and existing human disease” (“D”) (CDC)
- Relative Public Health Concern Score (R)
  \[ R = V \times \left[ \frac{(D + 3 \times T)}{4} \right] \]
- Professional judgment is always an important consideration in ranking the compounds
Considering Toxicity for Ranking

- **Acute effects:**
  - Anaphylactic reactions e.g., Penicillins
  - Neuromuscular effects e.g., Organophosphates
  - Potentially life threatening e.g., Clenbuterol
- **Subchronic toxicity:**
  - Adrenal damage e.g., Carbadox and olquindox
- **Chronic toxicity:**
  - Carcinogenicity e.g., Nitroimidazoles and Nitrofurans
Clenbuterol

- In one 6 month period in 1993 more than 1,200 hospitalizations and 3 deaths in France and Spain were reported to have resulted from eating beef livers contaminated with the illegal growth promotant clenbuterol.
- These patients were reported to complain of tremor, headaches, tachycardia, atrial fibrillation and dizziness 1-3 h after eating veal liver.
The End

Thank you very much