Risk Ranking and Risk Prioritization Tools

Workshop on Produce Safety in Schools
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Managing Food Safety Risk

- We have a full table
- Trying to do everything means that nothing gets done well
- Have to make decisions on where we will focus our efforts
Risk Ranking: Terminology

- Also referred to as:
  - Hazard ranking
  - Risk attribution
  - Comparative risk assessment

- Applied to identify the most significant public health risks for a given situation

- Used in other fields – engineering, insurance, transportation and environmental sciences
Risk Prioritization

Risk prioritization goes beyond risk ranking in that it compares scenarios (combinations of specific commodities, hazards, and control measures) using multiple criteria, and not just the public health risk.

Some of these additional criteria may include:

- cost of interventions or control measures
- feasibility of implementing control measures
- practicality of control measures
- effectiveness of control measures
- level of public concern
- level of certainty in the estimates
- political will
Risk Analysis

Comprised of three components:
- Risk management
- Risk assessment
- Risk communication
What Triggers Risk Management?

- Four broad types
  - **Crisis**: real or perceived public outcry; media coverage; outbreak
  - **Science/technology**: new knowledge uncovers a public health hazard of previously unknown risk
  - **Emerging or “on the horizon”**: environmental events affecting products
  - **Strategic**: needs identified through systematic planning
Examples of Risk Management Decisions

- Conduct additional research
- Detention of imported product
- Develop action plan
- Do nothing (it’s a decision!)
- Education and outreach
- Enforcement action, industry recall
- Guidance
- Preventative control program e.g. HACCP
- If safe—approve; if not safe—disapprove
- Encourage industry innovation
- New legal theory
- New policy
- New technologies
- Performance standard
- Policy or regulation
- Remove from the market
- Seizure
- Set and enforce tolerance levels
- Untitled and Warning letter
Risk Assessment: The Basics

Risk assessment is...
- a systematic tool to better understand the complex interaction of hazards, food and human hosts
- one of the most objective and scientific ways to
  - analyze the complexities of our food supply system
  - focus our food safety efforts
  - determine the relative effectiveness of prevention and control practices
- an approach to integrate science with state-of-the-art information technology to help manage food safety risks
Risk Assessment: The Basics

A process to describe what we know and how certain we are of what we know

Answers 4 key questions:

- What can go wrong?
- How likely is it to occur?
- What are the consequences?
- What factors can influence it?
Four Examples…

Qualitative
Semi-quantitative (2)
Quantitative
Example: Qualitative

2007 CFSAN Domestic Priorities List
The purpose of the 2007 ‘priority’ list is to target field resources toward higher public health risk problems.
Ranked food/hazard pairs into 3 qualitative bins
   • higher, moderate, lower risk

Based on 2 criteria:
   • Likelihood of an adverse event from consumption
   • Severity of hazard
The worksheet was designed to:

- Be flexible and easy to use
- Provide a transparent decision-making process
- Consider both data and expert opinion
Likelihood
(How many people get ill)

Factors considered:

- The epidemiological link between the hazard and health effect due to consumption/use of the product (i.e., outbreaks)
- Frequency and level of the hazard associated with specific product (i.e., surveys, recalls)
- Frequency of consumption or use of product and amount
- Effect of production, processing, handling in terms of how they influence the hazard in the product at the point of consumption/use (i.e., lethality step in processing)
Severity
(How ill do people get?)

Factors considered:
- Typical outcome (e.g., diarrhea; death)
- Duration of illness
- Long-term problems after initial illness (e.g., chronic sequelae)?
- Is the entire population susceptible or a specific at-risk subpopulation (e.g., infants, elderly)?
<table>
<thead>
<tr>
<th>Severity</th>
<th>Unlikely (no illnesses)</th>
<th>Likely (some illnesses)</th>
<th>Very likely (many illnesses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate (mild)</td>
<td>lower</td>
<td>lower</td>
<td>medium</td>
</tr>
<tr>
<td>Serious (incapacitating)</td>
<td>lower</td>
<td>medium</td>
<td>higher</td>
</tr>
<tr>
<td>Severe (life-threatening)</td>
<td>medium</td>
<td>higher</td>
<td>higher</td>
</tr>
</tbody>
</table>
Example: Semi-quantitative

Produce Risk Ranking Tool
Produce RR Tool: Purpose

- Transparent and systematic method
- Compare different commodity/pathogen combinations to determine which present the most significant risks and prioritize them as candidates for interventions
- Identify higher-risk combinations for subsequent quantitative microbial risk assessment efforts
Produce RR Tool: Features

- Characterize risk by:
  - 9 criteria (grouped into 4 dimensions)
  - 4 bins (scores)
  - 5 weights

- Identify commodity/hazard combinations based on outbreak data
  - 11 commodity categories
  - 3 hazard categories
  - Total 51 commodity/hazard pairs evaluated
Dimensions & Criteria

- **Strength of Epidemiological Association**
  - Epidemiological link
  - Disease multiplier

- **Severity of Disease**
  - Hospitalization rate
  - Death Rate

- **Pathogen Characteristics that Affect Disease**
  - Population susceptibility
  - Infectious dose

- **Commodity Characteristics**
  - Prevalence of contamination
  - Consumption
  - Growth potential/ shelf life
## Example Scoring: Epi Link

<table>
<thead>
<tr>
<th>Score</th>
<th>Category</th>
<th>No. of Outbreaks</th>
<th>Total Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Weak</td>
<td>any</td>
<td>≤ 100</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>1 - 2</td>
<td>&gt; 100</td>
</tr>
<tr>
<td>3</td>
<td>Strong</td>
<td>3 - 5</td>
<td>&gt; 100</td>
</tr>
<tr>
<td>4</td>
<td>Very strong</td>
<td>&gt; 5</td>
<td>&gt; 100</td>
</tr>
</tbody>
</table>
Produce RR Tool: Results

- Top 14 Commodities & Pathogen (Score)
  - Leafy greens & *E.coli* 0157:H7 (70)
  - Tomatoes & *Salmonella enterica* (61)
  - Leafy greens & *Salmonella enterica* (59)
  - Melons & *Salmonella enterica* (59)
  - Mixed produce & *E.coli* 0157:H7 (59)
  - Crucifers & *E.coli* 0157:H7 (56)
  - Melons & *E.coli* 0157:H7 (56)
  - Mixed produce & *Salmonella enterica* (52)
  - Herbs & *E.coli* 0157:H7 (50)
  - Green onions & *Cryptosporidium parvum* (50)
  - Carrots & *Salmonella enterica* (50)
  - Non-citrus fruit & *Salmonella enterica* (50)
  - Leafy greens & Norovirus (50)
  - Tomatoes & Norovirus (50)
Example: Semi-quantitative

iRISK: A web-based comparative risk assessment tool
iRisk – An On-Line Tool for Comparing Food Safety Risks

- Assess public health impacts for chemicals and pathogens
- Compare food risks at any stage, throughout the food supply system
- Allows the sharing of data and models
- Current version in beta testing – public availability planned
iRisk: Output

An example of the first part of the output for a single simple scenario

### FDA Risk Scenario Summary Report

**Report Time:** 2008-Oct-23 20:40:16 PM

Disclaimer and introduction will go here.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Final Concentration (log cfu/g microbial, g/g chemical)</th>
<th>Final Prevalence</th>
<th>Mean Risk of Illness</th>
<th>Total EO or Consumers</th>
<th>Total DALYs</th>
<th>Annual DALYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathogenic E. Coli in Lettuce: Exponential</td>
<td>-8.97E-1</td>
<td>1.00E-2</td>
<td>0.59</td>
<td>3.66E+10</td>
<td>2.40E+8</td>
<td>2.40E+8</td>
</tr>
</tbody>
</table>

Scenario details are included on following pages.
Example: Quantitative

2003 FDA/FSIS *Listeria monocytogenes* in Ready-to-Eat Foods
The problem:
Which foods should receive the most regulatory attention in order to improve public health?
2003 LM RTE RA: Features

- Compares risk of listeriosis from 23 categories of ready-to-eat foods
  - E.g., seafood, cheese, produce, meat, salads
- Compares risk for 2 matrices
  - Risk per serving (individual risk)
  - Risk per annum (population risk)
- Compares risk for different populations
  - Three at-risk subpopulations
  - The total population
Components of Risk Assessment

Hazard Identification
Describes bacteria/ host /food characteristics that impact the risk

Exposure Assessment
How often is the bacteria ingested?
How many bacteria are then ingested?

Hazard Characterization
For a given ingested dose, how likely is the adverse effect?

Risk Characterization
What is the probability of occurrence of the adverse effect?
2003 Listeria RTE Foods Risk Assessment: Results

Deli meat

Risk per Annum

Pasteurized Milk

Risk per Serving
## Results: Risk Categories

<table>
<thead>
<tr>
<th>Decreased Risk Per Annum</th>
<th>A and B</th>
<th>C and D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very High Risk</strong></td>
<td>Deli Meats</td>
<td>High Risk</td>
<td>Moderate Risk</td>
</tr>
<tr>
<td></td>
<td>Frankfurters (not reheated)</td>
<td>Pâté and Meat Spreads</td>
<td>No food categories</td>
</tr>
<tr>
<td><strong>High Risk</strong></td>
<td>High Fat and Other Dairy Products</td>
<td>Moderate Risk</td>
<td>No food categories</td>
</tr>
<tr>
<td></td>
<td>Pasteurized Fluid Milk</td>
<td>Cooked RTE Crustaceans</td>
<td>Moderate Risk</td>
</tr>
<tr>
<td></td>
<td>Soft Unripened Cheese</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moderate Risk</strong></td>
<td>No food categories</td>
<td>Moderate Risk</td>
<td>Low Risk</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cooked RTE Crustaceans</td>
<td>Preserved Fish</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Raw Seafood</td>
</tr>
<tr>
<td><strong>Low Risk</strong></td>
<td>Deli Salads</td>
<td>Low Risk</td>
<td>Very Low Risk</td>
</tr>
<tr>
<td></td>
<td>Dry/Semi-dry Fermented Sausages</td>
<td>No food categories</td>
<td>Cultured Milk Products</td>
</tr>
<tr>
<td></td>
<td>Frankfurters (reheated)</td>
<td></td>
<td>Hard Cheese</td>
</tr>
<tr>
<td></td>
<td>Fresh Soft Cheese</td>
<td></td>
<td>Ice Cream and Frozen Dairy Products</td>
</tr>
<tr>
<td></td>
<td>Fruits</td>
<td></td>
<td>Processed Cheese</td>
</tr>
<tr>
<td></td>
<td>Semi-soft Cheese</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Soft Ripened Cheese</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vegetables</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Decreased Risk Per Serving

- A and B
- C and D
- E

### Risk Levels

- Very High Risk
- High Risk
- Moderate Risk
- Low Risk
- Very Low Risk

- Deli Meats
- Frankfurters (not reheated)
- Pâté and Meat Spreads
- Unpasteurized Fluid Milk
- Smoked Seafood
- High Fat and Other Dairy Products
- Pasteurized Fluid Milk
- Soft Unripened Cheese
- Cooked RTE Crustaceans
- No food categories
- Deli Salads
- Dry/Semi-dry Fermented Sausages
- Fresh Soft Cheese
- Fruits
- Semi-soft Cheese
- Soft Ripened Cheese
- Vegetables
- Preserved Fish
- Raw Seafood
- Cultured Milk Products
- Hard Cheese
- Ice Cream and Frozen Dairy Products
- Processed Cheese
Conclusion

Steps in risk assessment/ risk management:
- Clearly define the food safety problem to be addressed
- Decide approach and key assumptions
- Develop criteria (for risk ranking)
- Conduct assessment; validate and verify results
- Provide assessment results to decision-makers
- Decision-makers consider options; make decisions and implement
- Important: periodically review, evaluate & modify decisions, if needed
Man's mind, once stretched by a new idea, never regains its original dimensions.

~Oliver Wendell Holmes