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

Goal..

- The purpose of the 2007 'priority' list is
  - to target field resources toward higher public health risk problems

2007 CFSAN Domestic Priorities List: Features

- 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

Data and Information Collection

The worksheet was designed to:

- Be flexible and easy to use
- Provide a transparent decision-making process
- Consider both data and expert opinion

Domestic Product/Hazard Prioritization Worksheet

Name:_____ Office:_____ Date:_____

Product Category	Identify Specific Product	Hazard Category	Identify Specific Hazard
Additives		Bacterial	
Cosmetics		Viral	
Dairy/Egg		Parasitic	
Dietary Supplements		Chemical	
Infant Formula/Med. Food		Natural toxin	
Plant Products		Allergen	
Seafood		Serious Labeling Deficiency	
Other		Other (e.g. BT)	

Characteristics	Check All That Apply	Other Pertinent Information
Evidence of Hazard Identified with Product (give no. & timeframe)		
• Recalls [ex., Class I, Class II, or Class III]		
• Adverse Event Reports		
• Outbreaks associated w/product		
• Over/Under-fortification (circle one)		
• Sample data		
• Toxicology data		
• Other (Identify & explain) _____		
Exposure		
Is the product reasonably likely to be consumed by a population that is vulnerable/susceptible to this hazard?		
How frequently is this product consumed? Daily/Weekly/Less Frequent (circle one)		
Would you expect to find contamination of this product once per year? More?/Less?		
Severity of Effect: (circle one below or identify on attached cost per hazard list)		
• Very High (life threatening, death or permanent disability reasonably likely to occur)		
• High (serious illness, permanent or temporary disability may occur)		
• Medium (Minor or moderate illness which is unlikely to result in disability)		
• Low (No disability or physical complaints)		
• Other (identify & explain) _____		
Sources of Hazard in the Farm-to-Table Continuum		
Where does contamination typically occur? How? (Identify typical violations to practices that could result in contamination- ex.GAP's, GMP's)		
• Farm/Sea _____ (ex., GAP's)		
• Processing facility _____ (ex., GMP's, HACCP)		
• Warehouse/Transport _____ (ex. GMP's)		
• Retail _____ (ex., temp. abuse)		
• Consumer _____ (ex., cross contamination)		
• Other _____ (identify & explain)		
Is product typically processed or treated after the point of contamination? Yes____ No____		
If yes, will the processing/treatment eliminate the hazard?		
Evidence of Problems Identified with Facilities (give no. & timeframe)		
Inspection Results:		
• Official Action Indicated ____		
• Voluntary Action Indicated ____		
• No Action Indicated ____		
Inspectional Findings:		
• Significant hazard identified? (describe in remarks)		
• Other hazard (Identify: ex., filth, uncertified color additives)		
Adverse Event Reports		
Outbreaks traced back to facility		
Industry-wide problem?		
Other (Identify & explain) _____		
Miscellaneous Information (ie, Federal/State MOU's, 3rd Party inspections)		
1.		

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)?

Relative Risk Ranking

		Likelihood		
		Unlikely (no illnesses)	Likely (some illnesses)	Very likely (many illnesses)
Severity	Moderate (mild)	lower	lower	medium
	Serious (incapacitating)	lower	medium	higher
	Severe (life-threatening)	medium	higher	higher

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

Score	Category	No. of Outbreaks	Total Cases
1	Weak	any	≤ 100
2	Moderate	1 - 2	> 100
3	Strong	3 - 5	> 100
4	Very strong	> 5	> 100

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.

Scenario	Final Concentration (log cfu/g microbial, g/g chemical)	Final Prevalence	Mean Risk of Illness	Total EO or Consumers	Total DALYs	Annual DALYs
Pathogenic E. Coli in Lettuce: Exponential	-8.97E-1	1.00E-2	0.59	3.65E+10	2.40E+6	2.40E+6

Scenario details are included on following pages.

Example: Quantitative

2003 FDA/FSIS *Listeria monocytogenes* in Ready-to-Eat Foods

2003 FDA/FSIS *Listeria monocytogenes* in Ready-to-Eat Foods Risk Assessment

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

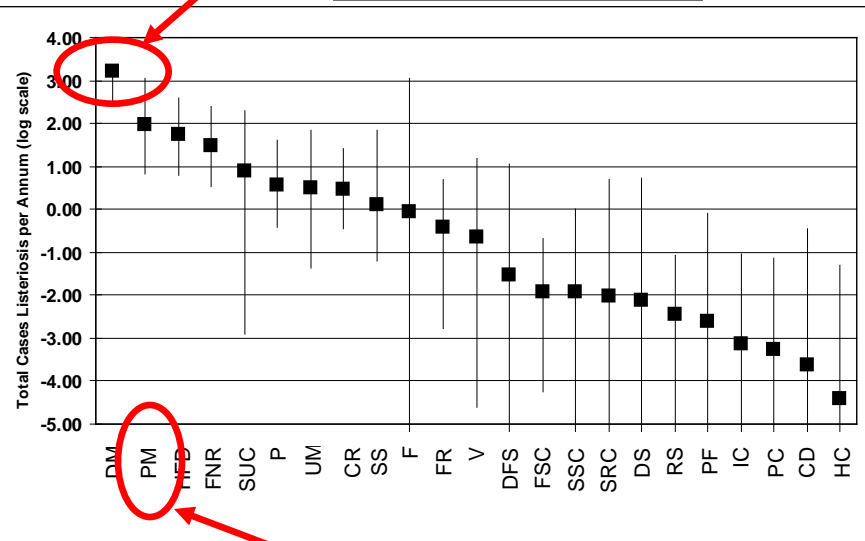For a given ingested dose,
how likely is the adverse effect?

Risk Characterization

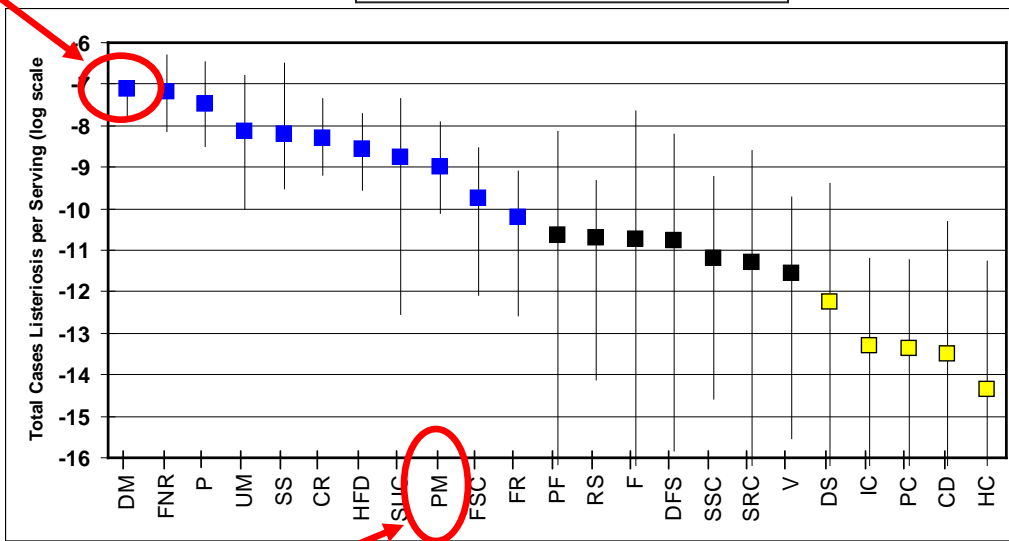What is the probability of occurrence of the adverse effect?

2003 Listeria RTE Foods Risk Assessment: Results

Deli meat

Risk per Annum

Risk per Serving

Pasteurized Milk

Results: Risk Categories

Decreased Risk Per Annum →

Decreased Risk Per Serving ↓

	A and B	C and D	E	
	Very High Risk Deli Meats Frankfurters (not reheated)	**High Risk** Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**Moderate Risk** No food categories	**1**
	High Risk High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese	**Moderate Risk** Cooked RTE Crustaceans	**Moderate Risk** No food categories	**2**
	Moderate Risk No food categories	**Moderate Risk** Deli Salads Dry/Semi-dry Fermented Sausages Frankfurters (reheated) Fresh Soft Cheese Fruits Semi-soft Cheese Soft Ripened Cheese Vegetables	**Low Risk** Preserved Fish Raw Seafood	**3**
	Moderate Risk No food categories	**Low Risk** No food categories	**Very Low Risk** Cultured Milk Products Hard Cheese Ice Cream and Frozen Dairy Products Processed Cheese	**4**

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

Questions or Comments?
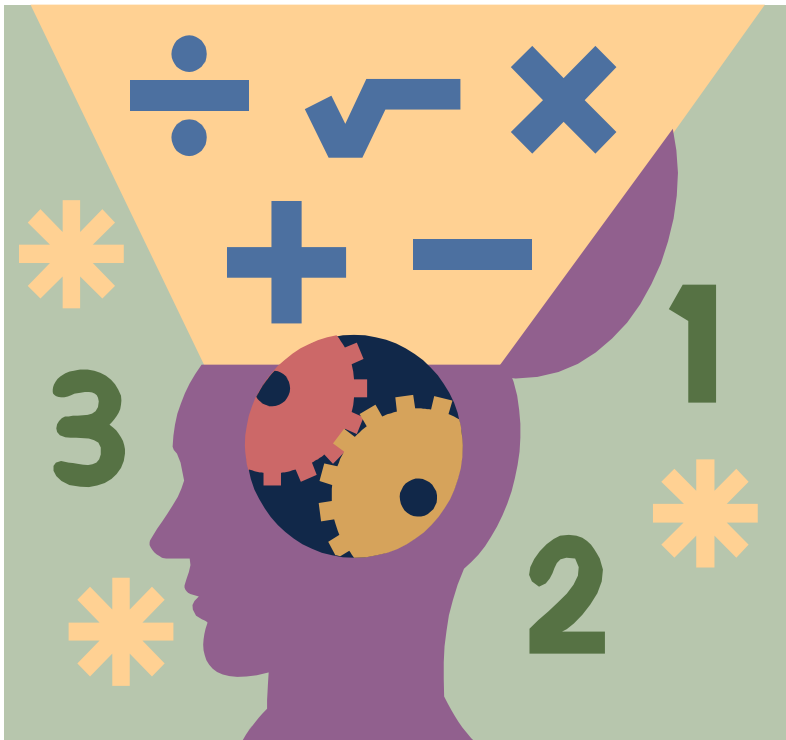
Man's mind, once stretched by a new idea, never regains its original dimensions.

~Oliver Wendell Holmes