Asia-Pacific Economic Cooperation

USDA

Traditional Food Safety Risk Assessment Procedures: Microbiological

Janell R. Kause
Director, Risk Assessment Division
Food Safety and Inspection Service, USDA

1

Asia Pacific Economic Cooperation

World Health Organization: Foodborne Pathogens

- **Foodborne illness is a preventable disease affecting all people**
  - Significant impact on public health
  - Significant trade implications for APEC Economies
- **250+ types of foodborne illness identified**
  - Existing and emerging pathogens
- **Foodborne illness underreported**
  - WHO Consultation to Develop a Strategy to Estimate Global Burden of Foodborne Diseases (2006)

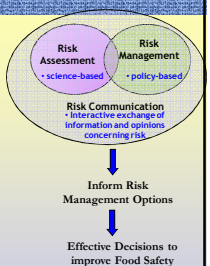
Food Safety Controls

- **Hygiene**
- **Inspection**
- **End product control**
- **Food laws and regulations**
- **Food control management, inspection and laboratory services**
- **Consumer education and industry outreach**

❖ **Needed a science-based approach that integrates data and information to guide food safety decisions and resources to control or prevent foodborne illness.**

Microbial Food Safety Risk Analysis

- **Cornerstone of international* and national** food safety programs**
  - Science-based food safety decisions
  - Increased transparency/ stakeholder involvement
- **Risk assessments integrate a wide variety of scientific data**
  - Epidemiological data (outbreak, case-control studies)
  - Testing data (national studies/monitoring)
  - Predictive microbiological models
  - Industry practices/, retail sanitation, consumer behavior
- **WTO/SPS Agreement, Article 5.1**
  - Measures based on an assessment of the risk to human health



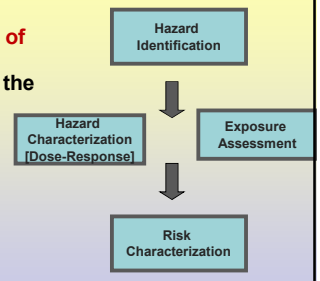
** Codex Procedural Manual, 2004*
*** U.S. Draft Microbial Risk Assessment Guidelines: http://www.epa.gov/raf/microbial.htm*

Microbial Risk Assessment: Guide Food Safety Decisions

- **Systematically address food safety issues**
- **Integrate data and information through a formal and transparent conceptual framework to guide regulatory decisions**
  - Logical
  - Science based
  - Transparent
  - Holistic
- **Evaluate public health benefits associated with policy options ("what if" scenarios)**
- **Focus finite resources on hazards that pose the greatest risk to public health**
- **Several applications in a public health policy**

What is a Microbial Risk Assessment?

- Scientific process for estimating the **probability of an adverse public health effect** *and* **the severity** of the effect; consists of the following components:
  1. hazard identification
  2. hazard characterization
  3. exposure assessment
  4. risk characterization



- Provide public health information for guiding food safety decisions.

Primary Components of Risk Assessments* [Codex]

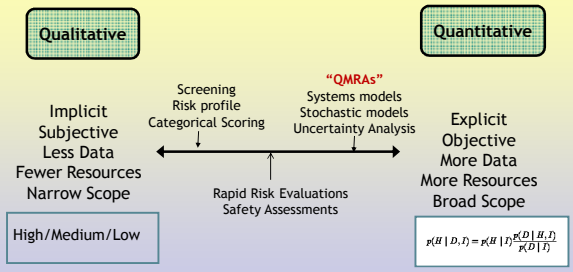
- **Hazard Identification**
  the identification of….*agents capable of causing adverse health effects…*
- **Hazard Characterization**
  the *qualitative and/or quantitative* evaluation of the *nature of the adverse health effects* …Includes *dose-response* assessment
- **Exposure Assessment**
  the *qualitative and/or quantitative* evaluation of the *likely intake …*
- **Risk Characterization**
  the *qualitative and/or quantitative* estimation, including attendant uncertainties, of the *probability of occurrence* and severity of…adverse health effects….

Codex Risk Assessment Principles*

- **Health and safety decisions based on risk assessment**
- **Risk assessments**
  - Based on science
  - Incorporate four steps of the risk assessment process
  - Document in a transparent manner
  - Used available quantitative information to the extent possible
  - Risk characterization presented in readily understandable/useful form
- **Functional separation: risk assessors and risk managers (interdependent relationship)**

** "Statement of Principle" in Codex Procedural Manual (2004)*

Various Types of Microbial Risk Assessments



The "best" risk assessment is the one that "is fit for purpose" and most directly informs the risk management issue [WTO/SPS, Article 5.1].

Quantitative Microbial Risk Assessments (QMRAs)

- **Well known approach to food safety risk assessment for microbiological hazards**
  - Comprehensive national and international microbiological risk assessments are available on various internet sites (e.g., Foodrisk.org)
- **Application: understand where problem is and evaluate the public health benefits of risk management options.**
- **Expertise and resources required**

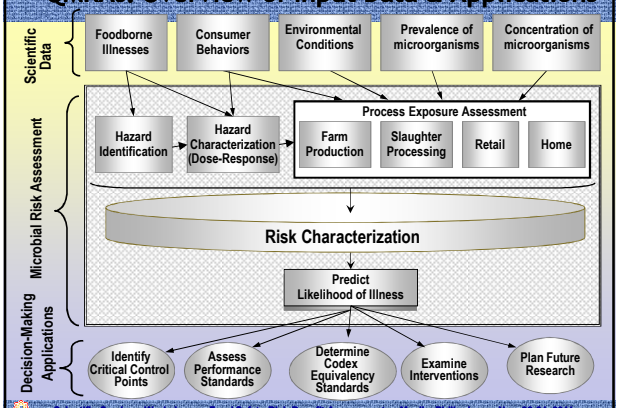
Overview of Traditional QMRAs

- **"Food chain" System Model : Farm-to-consumption approach**
- **Product-Pathogen Pair (focus)**
- **Include 4 Codex Components :**

- *Hazard identification* (Hazard association with illness – Public health outcomes)
- *Exposure assessment* (Production to consumption pathways : review of literature and data)
- *Hazard characterization* (Organism, host and matrix characteristics – Disease characteristics - Dose/response data - epidemiological and outbreak information)
- *Risk characterization* (Risk estimation – risk management options assessment/scenario analysis; characterization of uncertainty)

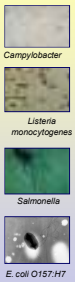
- **Probabilistic modeling (EA and DR)**
- **Resource intensive (time/budget/expertise)**

QMRAs: Overview of Input Data & Applications



QMRA: Hazard Identification

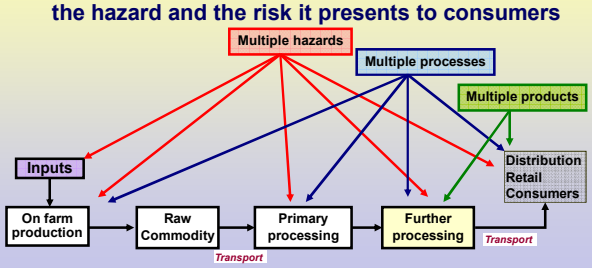
- **Traditionally*: Product-Pathogen Pairs**
  - *Salmonella* Enteritidis in eggs and egg products
  - *Listeria monocytogenes* in ready-to-eat foods (cheese, deli meats)
  - *Campylobacter* or *Salmonella* in poultry
  - Vibrio in seafood
  - *E. coli* O157:H7 in beef
- **Likelihood of presence, survival, growth in food(s)**
  - food matrix (pH, aw, salinity, etc.), competitive exclusion
- **Qualitative portion of risk assessment**
  - systematic review of the literature
  - microbiological data (contamination)



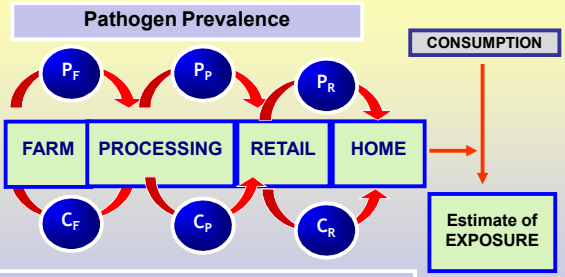
* More QMRAs considering multiple pathogens, foods, and processes

Conceptual Exposure Model for QMRAs

- **"Food Chain" System Models**
- **Provides the scientific evidence of the nature of the hazard and the risk it presents to consumers**

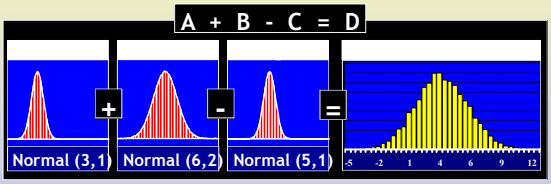


QMRA: Probabilistic Exposure Assessment



QMRA: Exposure Assessment

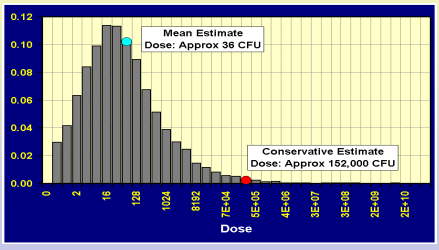
- **Model parameters are characterized as distributions**
- **Probabilistic simulation (e.g., Monte Carlo)**
  - Probabilistic modeling allows simulation of variability and uncertainty in the values; explicit procedures (FAO/WHO guidelines)



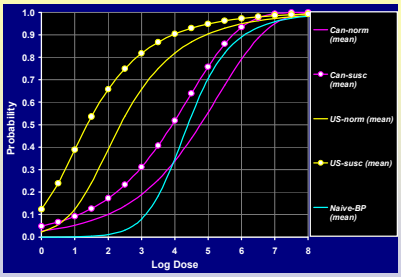
- **Range of values for the outcome ("D") and probability of occurring can be determined.**

QMRA: Exposure Assessment Output

- **Generates distribution of exposure (range/likelihood)**



QMRA: Dose-Response Stochastic Models



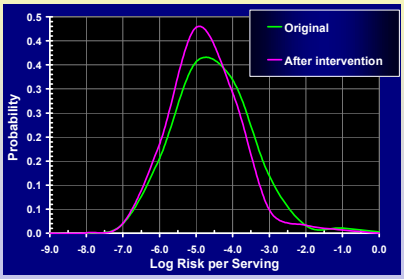
Data Sources:
- Epidemiological data
- Animal studies
- Human feeding trials

Note: New streamlined approaches using attribution models

Canada : Weibull model – Bayesian techniques to combine feeding trial and epidemiological data
US : Beta Poisson model – *Shigella dysenteriae* as surrogate to reflect low dose infectivity

QMRA: Risk Characterization

Risk per serving distribution



- "What if" Scenario Analyses (50% reduction in the average concentration per carcass)

Results:
- Annual expected rate of illnesses per 100,000:
- Before: 43
- After: 14

Risk Characterization

- **Important components of risk characterization:**
  - Baseline Risk ("Current Status")
  - Scenario Analysis ("What if" Predictions"
  - Sensitivity Analysis ("Drivers"/Influence)
  - Uncertainty Analysis (Certainty of predictions)

"What if" Scenario Analysis

- Identify key opportunities for risk mitigation
- Evaluate policy options
  - various types of performance standards
- Evaluate changes in behaviors
  - slaughter, processing, retail, or consumer
- Evaluate adoption of interventions
  - consider compliance, effectiveness, frequency
- Evaluate introduction of a hazard
- Evaluate preventive measures

Sensitivity Analysis

- Systematic investigation of
  - Model parameters
  - Model inputs
  - Assumptions (risk assessors, expert committees, risk managers)
  - Model functional form
- Parametric variation of input variable values to examine effects of output
- Evaluate "drivers" of risk (influential variables)

Uncertainty Analysis

- Variety of methods to characterize
  - quantitative: sensitivity analysis, 2nd order modeling
- Can be reduced with additional data/information
- Differs from "variability"
  - Variability is part of nature
- Uncertainty can be difficult to separate from variability
  - Along with the sensitivity analysis, provides information to prioritize food safety research
- Uncertainty analysis is an important part of conducting risk assessments
  - Provides estimates of certainty of risk predictions

Utility of Traditional QMRAs: "Benefits" in Economic Analysis

- Integrate outputs of QMRA into cost-benefit analysis
- Moving towards models that have the economic analysis as an extension of the QMRA
  - Conduct a risk assessment to evaluate the public health benefits of various policy options
  - monetize the outputs of a risk assessment for the "benefits" portion of a cost-benefit analysis
  - conduct an economic analysis of the costs to industry as a result of various policy options
  - Weigh both the public health benefits (reduction in food safety risks) and societal costs.

Microbial Risk Assessment: Quality Issues

- Data Quality
- Model Validation

Data Considerations

- Transparent and reproducible data/data analysis
- Data Quality
  - integrity, representative, reproducible
  - information associated with study design, test sensitivity, etc.
  - Identification, collection, categorization of data /verification of compliance with established criteria
  - best available science to inform Agency decisions
- Data Priorities
  - based on a sensitivity analysis and an uncertainty analysis
  - data gaps that "drive the public health risk" are a focus

Model Calibration/Validation

- Model inputs
  - Availability of information – data
  - Quality/transparency of evidence
- Model Assumptions
  - Quality/transparency of analysis
- Interpretation
  - Quality/transparency of inference
  - Basis (vs. rules) for inference of probabilities
- Validation/Calibration
  - Calibration to epi. data/micro. testing data

Model Quality Assurance

- Presentation of calculations (transparency)
- Explanation of assumptions (choice of data)
- Expression of uncertainties (in scenarios, models, and parameters)
- Challenge: validation of models
  - Calibration of model to epidemiological data and/or microbiological data
- Make model and/or software model code publicly available (internet)

Peer Review Process

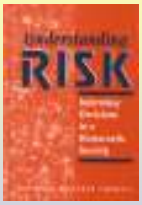
- Iterative peer review processes (internal/external)
- Broad range of scientific expertise (modelers, subject area experts)
- Reviewers are given a focused charge.
  - Overall approach given "risk management questions" to be informed
  - Logical structure of model; model mathematics/equations
  - Appropriateness of data
  - Reasonableness of model assumption
  - Risks appropriately characterized
  - Key sources of variability and uncertainty identified
  - Audit model

Stakeholder Input

- **Potential Food Safety Issues**
  - Involvement to make government officials aware of concerns
- **Risk Assessment**
  - Prior to initiation of RA
    - "call for data" and public meeting(s)
  - Engage stakeholders at partners
    - regular meeting throughout the development of the risk assessment
    - provide data and information
    - garner input on risk management options/scenarios to be explored
    - on-gong updates for stakeholders
  - Ensure equal access to information

Stakeholder Involvement Is Important Because . . .

- It's central to risk analysis process
- Supports democratic decision making ("Orange Book")
- Focus on social dimensions of interacting with decision makers and other users of the risk assessment in an iterative, analytic-deliberative process.
- Ensures public values are considered
- Develops understanding needed to make better decisions
  - Social values are important in decision-making



National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*, 1996; (available at www.nas.edu)

Revisiting: Various Types of Microbial Risk Assessments

- **The type of risk management concern determines the type of microbial risk assessment to be developed**
  - Not a "one size fits all"
  - Fit for purpose

Beyond Traditional QMRAs: "Assessments of Risk"

- Systems modeling (e.g., farm or plant-to-table quantitative microbial risk assessments (QMRA))
- Attribution modeling (e.g., Danish model)
- Risk Profile (e.g., USDA non-O157 risk profile)
- Rapid risk evaluations
- Risk-benefit analyses
- Decision analyses (integrating risk assessment and economic analyses)
- Risk-based sampling algorithms (based on QMRAs)
- Risk-based inspection allocation algorithms (based on QMRAs)
- Risk-ranking models (e.g., FDA/USDA Lm/RTE risk assessment)
- Data mining & regression analyses combined with attribution to illness (e.g., USDA Poultry Slaughter Risk Assessment)

Planning and Scoping: Type of Microbial Risk Assessment

- **Planning and Scoping (Problem Formulation)**
  - Clearly defined risk management objectives
    - Determines the "type of microbial risk assessment" to be conducted
  - Well specified scenarios
  - Evaluation of the availability and quality of the data (sufficiency of information)
  - Tiered approach prior to initiation of "full" quantitative microbial risk assessment
    - determine the depth of analyses needed to inform the risk management decision
    - use of "effectiveness ratio" for QMRAs

Emerging Microbial Hazards: Risk Profile

- Often an early step in Microbial Risk Analysis
  - Prior to conducting a microbial risk assessment
- Outlines the major aspects of risk management concern
- Initial collection and evaluation of data (epidemiology, microbiology, etc.) to evaluate a microbiological hazard of concern
  - systematic review of the literature/weight of evidence
- Often used to assess emerging hazards (e.g., non-O157 STECs) of concern
- Used to identify/assess potential control options
- Can be used to:
  - guide food safety risk management decision
  - food safety research
  - commission a risk assessment

Microbial Risk Profile (Codex)

1-Pathogen-commodity of concern

2-Description of the public health problem

- description of the pathogen
- description of the disease

(susceptible populations; annual incidence; outcome of exposure; severity of clinical manifestations, long term complications; treatment available; % food borne)

- characteristics of food borne transmission

(epidemiology; etiology; food char., use and handling; other foods; frequency and char. of food borne outbreaks, of sporadic cases; epidemiological data from outbreaks; regional, seasonal, ethnic differences in incidence; economic impact or burden)

3-Food production, processing, distribution and consumption

(char. of commodity; description of farm to table continuum, incl. impacting factors; what is known about the risk, how it arises and who is affected; summary, extent, effectiveness of current RM practices; additional RM strategies)

4-Other elements

(economic consequences; public perception of problem and risk)

5-Available information and gaps

(existing risk assessments; scientific information: source; expertise; guidance)

6- Risk assessment need and questions

Application of Microbial Risk Assessments

Microbial Risk Assessment Applications

- Establish food safety policies based on predicted public health benefits (policy development)
  - Ex: Salmonella and Campylobacter performance standards for industry
- Allocate inspection resources among establishments based on the relative public health risk (assurance)
- Measure federal performance in achieving public health goals (evaluation)
- Evaluate the effectiveness of past public health policies (effectiveness)
- Respond to emergencies (response)

Managing the Risk of Listeriosis: Various QMRAs

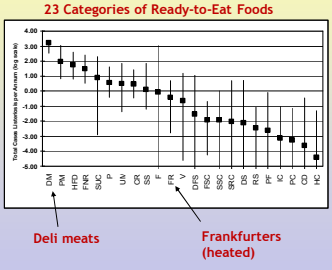
- Which ready-to-eat foods pose the greatest risk of listeriosis?
  - FDA-USDA Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (2001, updated 2003)
- Which industry practices effectively control Lm?
  - USDA/FSIS *Listeria* Risk Assessment (2003)
- How can we more effectively use inspection resources to ensure industry controls Lm?
  - FSIS Risk Based Verification Sampling for *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products (2005)

Managing the Risk of Listeriosis: Various QMRAs (continued)

- Where [along the food chain] should we focus our efforts to further reduce listeriosis?
  - Comparative Lm Risk Assessment: Pre-packaged vs. Retail-sliced Deli Meat (2010)
- What retail behavior contribute (or prevent) to cross-contamination of ready-to-eat foods?
  - Interagency Retail Lm Risk Assessment (2011)

Application: Risk-Ranking of Foods

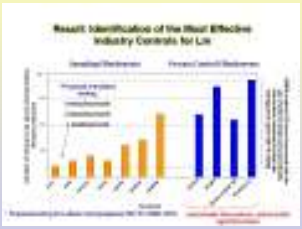
- Risk of listeriosis from ready-to-eat foods
  - FDA/USDA *Listeria* risk assessment identified deli meats as posing the greatest risk of listeriosis
  - Action: Lm Food Safety Action Plan
  - Caveat: Predicted deli meat posed greatest risk prior to foodborne outbreaks beginning in Fall 2002



Application: Evaluating Process Controls

Which industry practices effectively control Lm?

- *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 risk management strategy to focus beyond testing/sanitizing



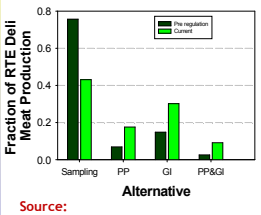
Source: http://www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf

Application: Allocation of Inspection Resources

How can we effectively allocate our inspection resources to ensure industry practices effectively control Lm?

- 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



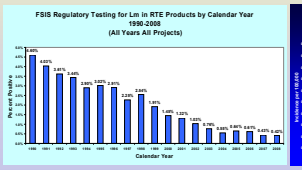
Source: http://www.fsis.usda.gov/PDF/RBVS_Risk_Assess_Jun07.pdf

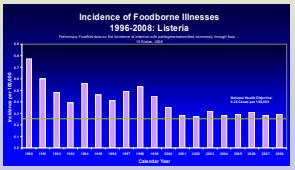
Reduction of Listeriosis in the U.S.

Why a plateau in listeriosis?

Percent Positive Listeria in Product 1990-2008

Incidence of Foodborne Listeriosis 1996-2008



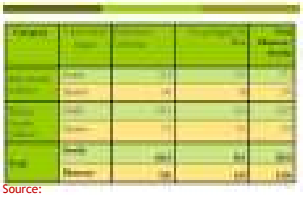


Application: Comparing Risks in Food Chain

Where should we focus efforts to further reduce listeriosis?

- UDSA 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 reduce risk overall)
- **Action:** 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



Source: http://www.fsis.usda.gov/PDF/Comparative_RA_Lm_Report.pdf

Application: Evaluating Factors that Prevent/Contribute to Cross-Contamination

What retail factors contribute (or prevent) to cross-contamination of ready-to-eat foods with Lm?

- **Interagency risk assessment model** tracks *Lm* cross contamination across different sites and foods in the deli area. By changing the input parameters, different worker behaviors or food characteristics were evaluated.
- **Preliminary findings:** Cross-contamination of Lm between scale, slicer, prep table, sink and food products was significant. Frequent contact was between gloves and other sites. Slicers contributed most to Lm transfer.
- **Caveat:** complex model runs on a supercomputer; targeted data collection efforts (academia/industry)

2011 Interagency Retail Lm Risk Assessment

Lessons Learned: Microbial Risk Assessment

- Must have well defined risk management questions/policy options (practical application of risk assessment)
- Microbial risk assessments are not a "one size fits all"
- Complexity of the risk assessment depends on the purpose for developing the risk assessment (need: tiered approach)
- 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

Lessons Learned: Microbial Risk Assessment

- Risk assessment 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
- * Move towards funding targeted data collection efforts/research for risk assessments to improve quality/availability of data for risk assessments
- Characterization of certainty of risk estimates is important for decision makers
- Rigorous peer review is essential
- Stakeholder involvement from the beginning and throughout the process ensures utility

Summary

- The "lessons learned" from traditional microbial risk assessments can be readily applied to "risk-benefit" analysis
- Food safety risk assessment is an evolving field – one that will look at various "hazards" in a food (and normalizes based on QUALY/DALY/WTP/COI) – to provide a more holistic look at the "risk" from a food
  - Food safety "risk-benefit analysis" and "QMRA" continues to evolve, inform each discipline, and moves towards "decision support modeling"