Traditional Food Safety Risk Assessment Procedures: Microbiological

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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

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:
  - hazard identification
  - hazard characterization
  - exposure assessment
  - risk characterization

- Provide public health information for guiding food safety decisions.

**Primary Components of Risk Assessments**

- **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)**


**Various Types of Microbial Risk Assessments**

- **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)
Scientific Seminar: Workshop on Food Safety Risk Assessment

**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

**QMRA: Probabilistic Exposure Assessment**

- **Pathogen Prevalence**
- **Concentration (Numbers of Pathogen)**
  - predictive microbiology: growth, decline of microorganisms (e.g., *Campylobacter*)

**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.
Uncertainty analysis is an important part of scenario analysis. "What if" scenarios can help identify key opportunities for risk mitigation and evaluate policy options. Sensitivity analysis can help identify "drivers" of risk and evaluate preventive measures. Uncertainty analysis is crucial for conducting risk assessments and prioritizing food safety research.
## 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 QMRAs
  - 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

## Economic Analysis

- Conduct an economic analysis of the costs to monetize the outputs of a risk assessment

## 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
  - 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-going 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

**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 QMARAs: “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 QMARAs)
- Risk-based inspection allocation algorithms (based on QMARAs)
- 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 QMARAs

**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
   - Description of the public health problem
2. Description of the pathogen
   - Susceptible populations; annual incidence; outcome of exposure; severity of clinical manifestations; long-term complications; treatment available; % food borne
3. Characteristics of food borne transmission
   - Epidemiology; etiology; food chain, use, and handling; other foods; frequency and chain of food borne outbreaks; sporadic cases; epidemiological data from outbreaks; regional, seasonal, ethnic differences in incidence; economic impact or burden
4. 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
5. Other elements
   - Economic consequences; public perception of problem and risk
6. Available information and gaps
   - Existing risk assessments; scientific information; source; expertise; guidance
7. Risk assessment need and questions

### 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?
- Which industry practices effectively control Lm?
- How can we more effectively use inspection resources to ensure industry controls Lm?

### 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-harvest interventions and use of antimicrobials were substantially more effective than sanitation measures
  - Caveat: Changed risk management strategy to focus beyond testing/sanitizing


Application: Allocation of Inspection Resources

- How can we effectively allocate our inspection resources to ensure industry practices effectively control Lm?
  - FSIS’ risk-based sampling efforts 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


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 (academic/industry)


Application: Comparing Risks in Food Chain

- Where should we focus efforts to further reduce listeriosis?
  - USDA comparative Lm risk assessment evaluated the risk of listeriosis from prepackaged vs. retail-sliced deli meat
  - Finding: Approximately 83% of Listeria 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


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 for 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”