




Asia-Pacific Economic Cooperation

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)

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Food Safety Controls

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



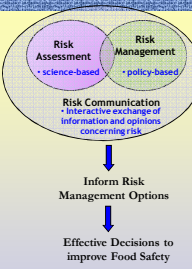
❖ **Needed a science-based approach that integrates data and information to guide food safety decisions and resources to control or prevent foodborne illness.**

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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/microbiol.htm>

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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

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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.

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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....

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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)

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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].

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Quantitative Microbial Risk Assessments (QMRAs)

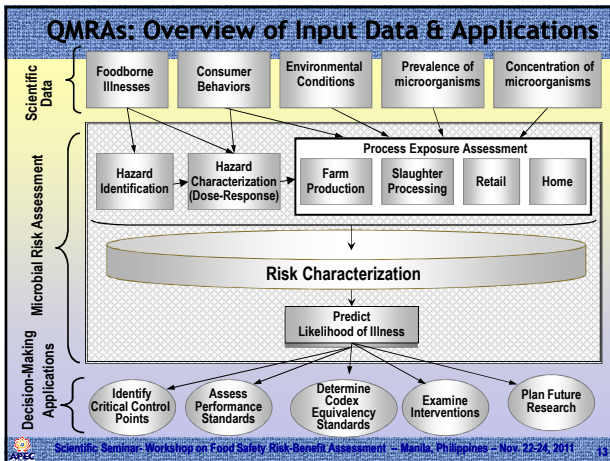
- ➔ Well known approach to food safety risk assessment for microbiological hazards
 - Comprehensive national and international microbiological risk assessments are available on various internet sites (e.g., Foodrisk.org)
- ➔ Application: understand where problem is and evaluate the public health benefits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

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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)

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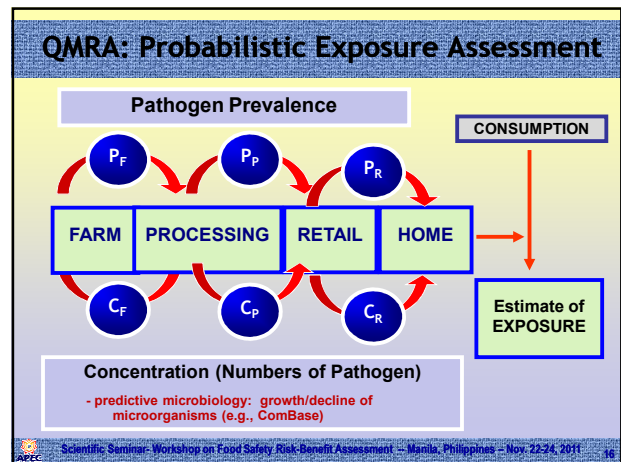
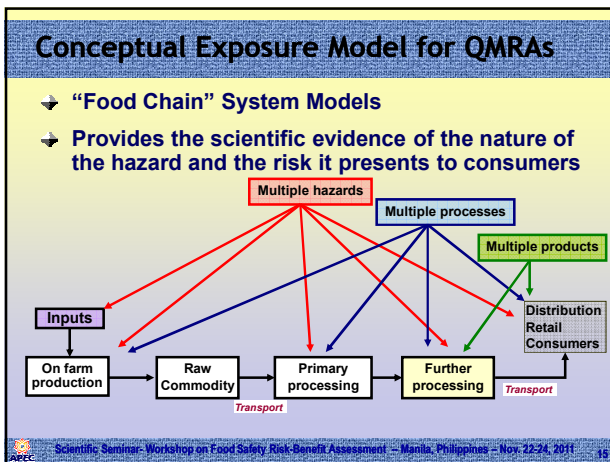


QMRA: Hazard Identification

- ➔ 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

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QMRA: Exposure Assessment

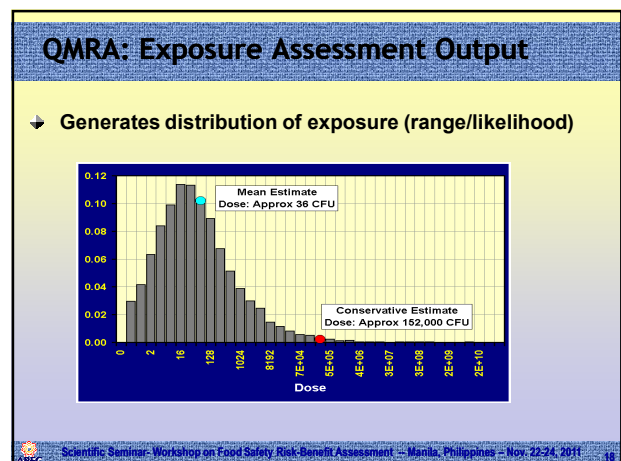
- ➔ Model parameters are characterized as distributions
- ➔ Probabilistic simulation (e.g., Monte Carlo)
 - Probabilistic modeling allows simulation of variability and uncertainty in the values; explicit procedures (FAO/WHO guidelines)

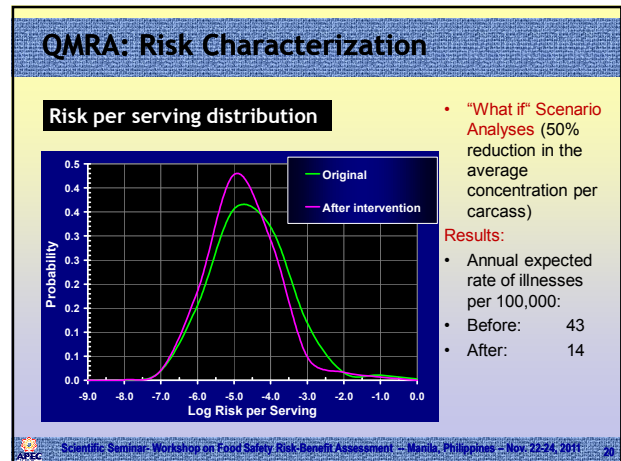
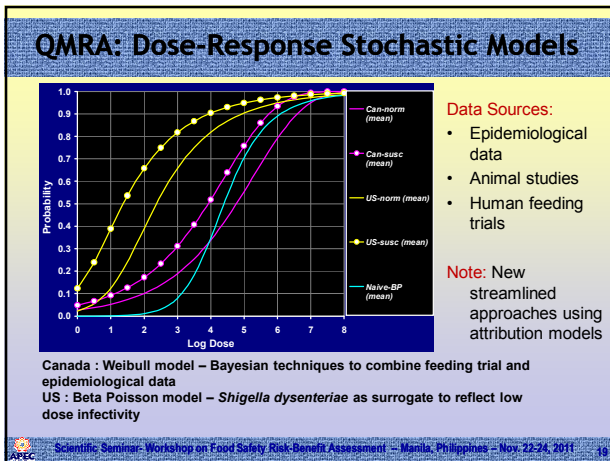
$A + B - C = D$

Normal (3, 1), Normal (6, 2), Normal (5, 1)

- ➔ Range of values for the outcome (“D”) and probability of occurring can be determined.

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- ### 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)
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- ### “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
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- ### 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)
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- ### 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
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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.



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Microbial Risk Assessment: Quality Issues

- Data Quality
- Model Validation

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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

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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

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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)

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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

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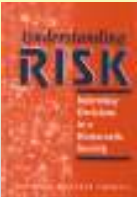
Stakeholder Input

- ➔ **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**

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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)

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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**

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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)

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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

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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**

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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

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Application of Microbial Risk Assessments

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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**)

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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)

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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)

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Application: Risk-Ranking of Foods

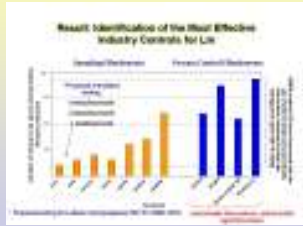
- Risk of listeriosis from ready-to-eat foods
 - FDA/USDA *Listeria* risk assessment identified deli meats as posing the greatest risk of listeriosis
 - Action: Lm Food Safety Action Plan
 - Caveat: Predicted deli meat posed greatest risk prior to foodborne outbreaks beginning in Fall 2002

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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



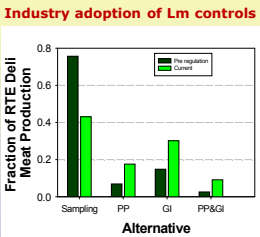
Source: http://www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf

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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



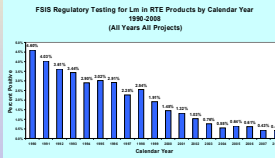
Source: http://www.fsis.usda.gov/PDF/RBV_5_Risk_Assess_Jun07.pdf

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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

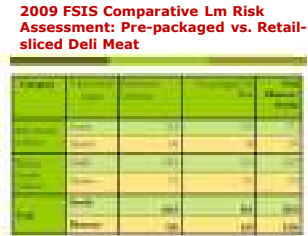


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Application: Comparing Risks in Food Chain

➔ 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 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




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

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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)



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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



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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



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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 QALY/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”

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