Setting Up a Risk Assessment

Risk Analysis Training
The Codex framework divides risk assessment into a four step process:

- Risk identification
- Hazard characterization
- Exposure assessment
- Risk characterization

Process is typically done in an iterative manner.
Risk Assessment Steps

**Hazard Identification**
The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods (Codex).

**Hazard Characterization**
The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable (Codex).

**Exposure Assessment**
The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures to other sources if relevant (Codex).

**Risk Characterization**
The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment (Codex).
Managing Risk Assessment Process
OMB Requirements

• Information Quality Act
• Peer Review Guidelines
• Risk Assessment Guidelines
Initiation and Conduct of All 'Major' Risk Assessments within a Risk Analysis Framework

A Report by the CFSAN Risk Analysis Working Group

March 2002

CFSAN’s Risk Management Framework

December 2003
CFSAN’s Risk Management Framework

- Risk Assessment
- Prioritization
- Process
- Decision
- Implementation
- Outcome
- Monitor/Evaluate/Modify
- Risk Assessment
- Triggers & Inputs
IQA Requirements

• To meet these requirements, a framework for major FDA/CFSAN major risk assessments:
  – Are announced to the public
  – Announce a data call
  – Have draft assessment peer reviewed
  – Have draft review by Interagency Risk Assessment Consortium
  – Publish draft and ask for public comment
  – Are modified as appropriate
  – Make models available to stakeholders
Procedures to Initiate and Manage Risk Assessments: Two-Phases

1. INITIATE: A decision-based approach to identify and select the risk assessment
   - Four components: Concept generation, Problem identification, Data feasibility, Disposition

2. MANAGE: A systematic and iterative approach to the conduct of risk assessments
   - Four components: Plan, Perform, Review, Publish
Conducting the Risk Assessment

• **Step 1: Planning**
  – Define scope
  – Refine questions
  – Identify resource needs
  – Assign teams
  – Develop timelines
Site Visits

• **Why go on a site visit:**
  – Better understand the food industry and see first-hand industry control measures; differences between practices at different facilities
  – Establish a relationship with industry stakeholders (they are a source of data and information)

• **Where we went...**
  – Smoked seafood manufacturing plant
  – Cheese manufacturing plant
  – Fresh-cut/ fresh processing facilities Ships (commercial cruise and Naval vessel)
Conducting the Risk Assessment

• Step 2: Perform
  – Answer risk management questions
  – Routine meetings with risk management and risk communication advisors
  – Development of “what-if” scenarios
Conducting the Risk Assessment

• Step 3:
  – Review – ongoing process
    • Advisory Committees
    • Peer Review
    • SGE Panels
    • Public Comment
  – Approve
  – Clear
Conducting the Risk Assessment

• Step 4: Publish
  – Develop “roll out” strategy
  – Public release of documents
  – Handling comments
  – Public comment period
  – Making models available
Approaches to Increase Transparency

• As a means of facilitating communication and enhancing transparency, risk assessment are commonly published in four formats
  – Technical Report
    • Full details and appendices (can be several hundred pages)
  – Interpretive Summary
    • Summary of approach and key findings (plain language, 20 – 30 pages)
  – Executive Summary
    • Abstract format with focus on key findings and risk management implication
  – Mathematical Models
    • Available upon request; may require training
Interpretive Summary

- Introduced by FDA, it is a “plain language” summary of a risk assessment that is designed to provide stakeholders with a basic understanding of the risk assessment approach and findings.

- Typically under 25 pages
Preliminary Activities
Preliminary Activities

• Before starting a risk assessment, there needs to be a clear articulation of the risk management questions that are to be addressed
  – This may require the development of a “risk profile”
  – Often requires series of communications between the risk managers and risk assessors to convert risk managers’ questions into “risk questions” that can be addressed by a risk assessment

• Once a risk assessment is commissioned there should be a functional separation between the risk assessors and risk managers
Preliminary Activities

• During this phase, a substantial amount of effort is related to data acquisition and understanding factors that will impact risk
  – In depth literature review
  – Review of past outbreaks and epidemiology
  – Identification of subject matter experts
  – Visit to food production/manufacturing facilities
  – Review past risk assessments
  – Identification of current mitigation programs including assessments of their effectiveness
• May benefit from a Meta-analysis
Preliminary Activities

• Followed by decisions on what data can/should be used
  – Inclusion/exclusion rules
  – Determination of “data weighting” rules
  – Determination of what factors will be evaluated including eliminating minor risk factors (keep it simple)

• Finalize general risk assessment approach, outputs, and post-assessment evaluation (e.g. sensitivity analyses, scenario development)
  – This is typically a time to discuss with risk managers
Hazard Identification
Hazard Identification

The primary purpose of this phase is to establish the adverse effects that are associated with a hazard

- What are the medical syndromes associated with the hazard?
- Who are the subpopulations affected by the hazards and what are factors that contribute to their susceptibility?
- What are the sequellae associated with the hazard?
Hazard Identification

- The magnitude of activities associated can vary to a substantial degree depending on the extent of studies and reported cases
  - New chemical compound (e.g., new food additive, new pesticide) – Little toxicological data and much of it may not be pertinent to humans
  - Pathogenic foodborne bacteria – A substantial body of case/outbreak/medical data including data on highly susceptible populations
- Effects of hazard well established
Hazard Identification

• The output of the hazard identification phase is decisions about what aspects of a hazard will be considered in the risk assessment and the rationale behind those decisions

• Risk assessment team would typically meet with risk managers to get concurrence
Hazard Identification

• Important to “Keep It Simple”
  – Risk assessment should be complex enough to be fit for purpose
  – Should avoid adding complexity not needed to address risk management questions
  – Avoid “Christmas Tree” effect
Hazard Characterization
Hazard Characterization

• The primary purpose of this phase is to establish the relationship between consumed dose and the frequency and severity of adverse responses

• In quantitative risk assessments involves the generation of one or more dose response curves
Dose-Response Relations

- Dependent on the "balance" between the hazard, the consuming population, and the food
Exposure Assessment
Exposure Assessment

• The purpose of this phase is to determine what went in the consumer’s mouth in order to determine dose consumed
  – Frequency of contamination
  – Level of contamination
  – Serving sizes
  – Frequency of consumption
  – Storage conditions and duration
  – Cooking/pasteurization
  – Effect of processing
Exposure Assessment

• The specific data needed will be dependent on type of risk assessment needed
  – Hazard Pathway Analysis: Will likely need in-process data to examine potential interventions
  – Risk Ranking: May only need retail data if not concerned about different manufacturing, distribution, and marketing practices
Exposure Assessment

- Will typically need to make predictions about the levels in the food purchased and that actually prepared and eaten by the consumer
  - For chemical hazards often assume that levels remain constant
  - For microbiological hazards generally use predictive microbiology models to estimate growth and/or inactivation of the microorganism
Exposure Assessment

- The ultimate output of this phase is ranges doses consumed based on:
  - Levels of hazard in the food at consumption
  - Size of the serving consumed
  - Frequency of eating occasions
  - What percentage of the servings are consumed by “high susceptibility” individuals
Risk Characterization
Risk Characterization

• Combine exposure assessment and hazard characterization to produce risk characterization

• Usually expressed in terms of frequency of adverse effect
  – Frequency per serving (e.g., number of cases per million servings)
  – Frequency per annum (e.g., number of cases per year)

  • Frequency per serving X Number of servings consumed
Risk Characterization

• Can perform severity analyses quantitatively by developing multiple endpoint dose-response models
  – Infection
  – Morbidity
  – Mortality
  – Sequela
• Convert to DALY’s to get common metric
Post-Assessment Analyses
What-If Scenarios

• One of the key advantages of performing a quantitative, probabilistic risk assessment is the ability to do “what-if” scenarios

• Provides a means to estimate the likely impact of different mitigation strategies
Risk Characterization

• **Sensitivity Analyses:**
  – Vary the parameter values and see which variables have the most effect
  – Depicted using tornado graph
Cost-Benefit Analyses

- Combined the results of risk assessment with economic analyses to evaluate the relative cost of different risk management/mitigation options.
Shelf Life of Risk Assessment

- Risk assessments have a finite life spans
- Doing a risk assessment changes the risk