Setting Up a Risk Assessment

Risk Analysis Training

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Risk Assessment Framework

- 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

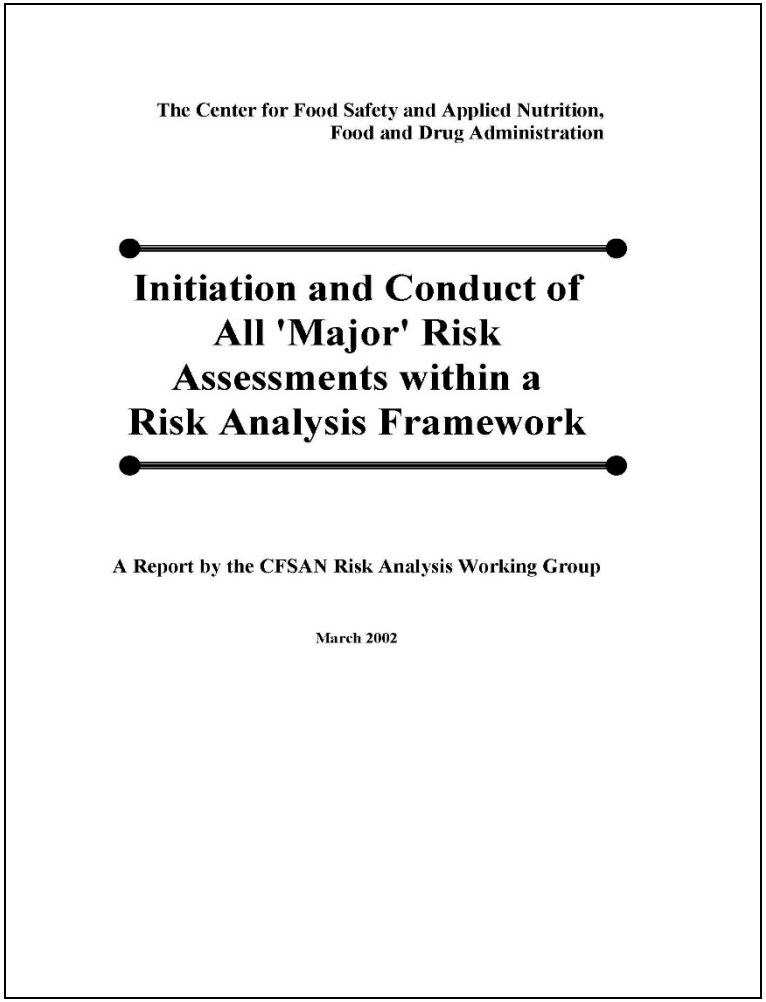
The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment (Codex).

Managing Risk Assessment Process

OMB Requirements

- Information Quality Act
- Peer Review Guidelines
- Risk Assessment Guidelines

Risk Assessment and Risk Management Framework Documents

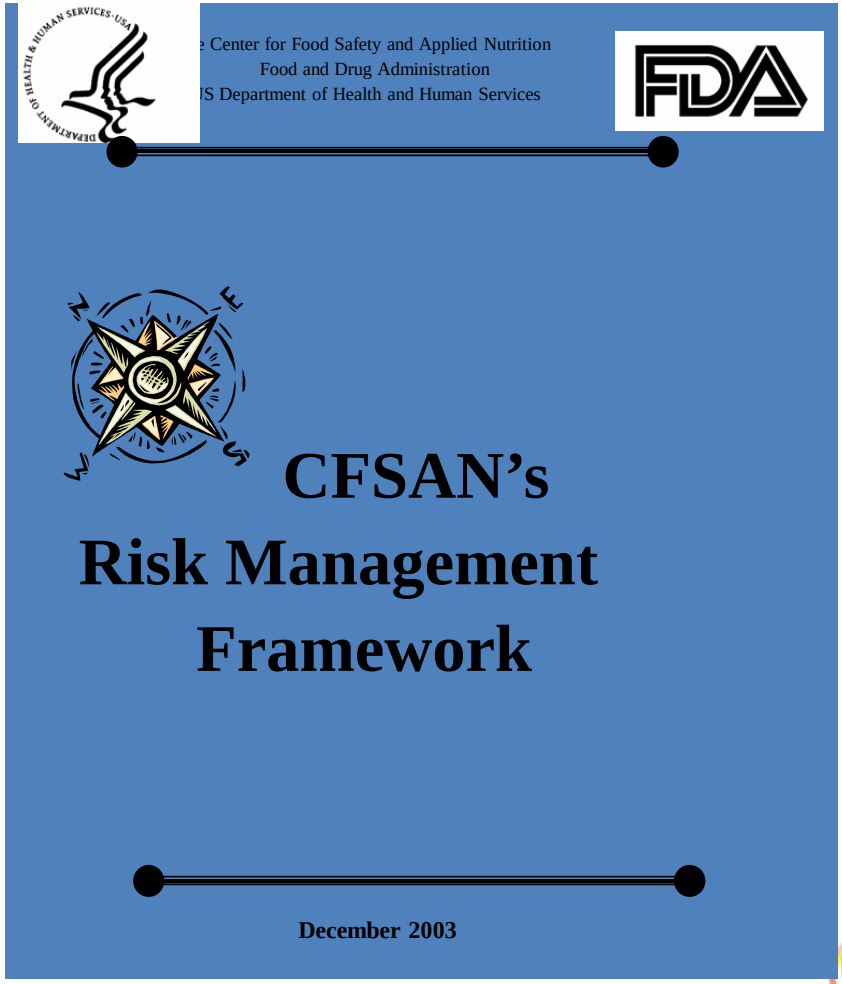


The Center for Food Safety and Applied Nutrition,
Food and Drug Administration

Initiation and Conduct of All 'Major' Risk Assessments within a Risk Analysis Framework

A Report by the CFSAN Risk Analysis Working Group

March 2002



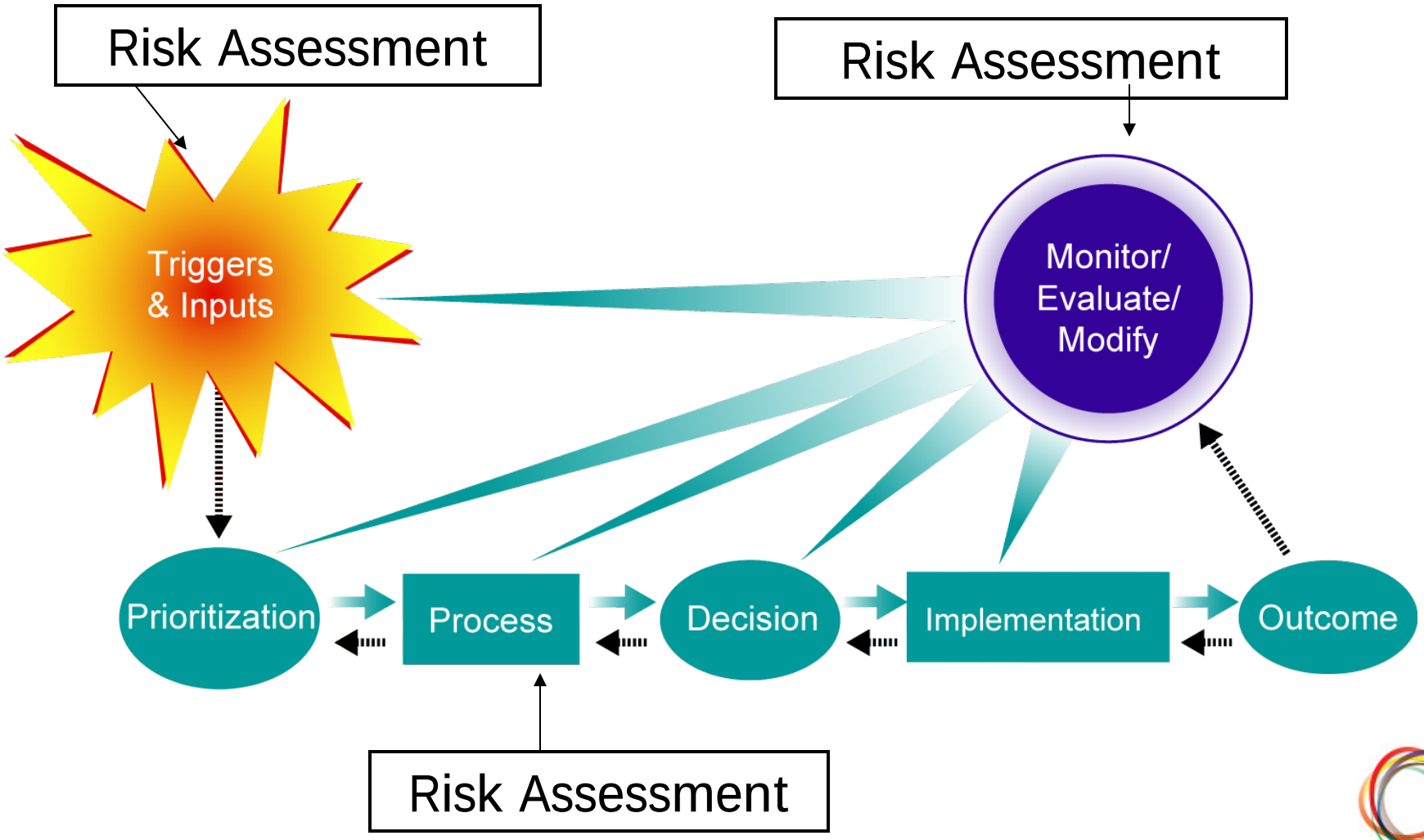
Center for Food Safety and Applied Nutrition
Food and Drug Administration
US Department of Health and Human Services

FDA

CFSAN's Risk Management Framework

December 2003

CFSAN's Risk Management Framework



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 pubic 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

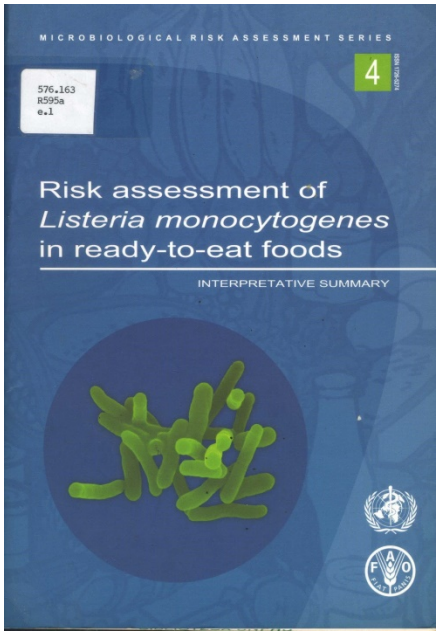
- Step 4: Publish
  - Develop “roll out” strategy
  - Public release of documents
  - Handling comments
  - Public comment period
  - Making models available

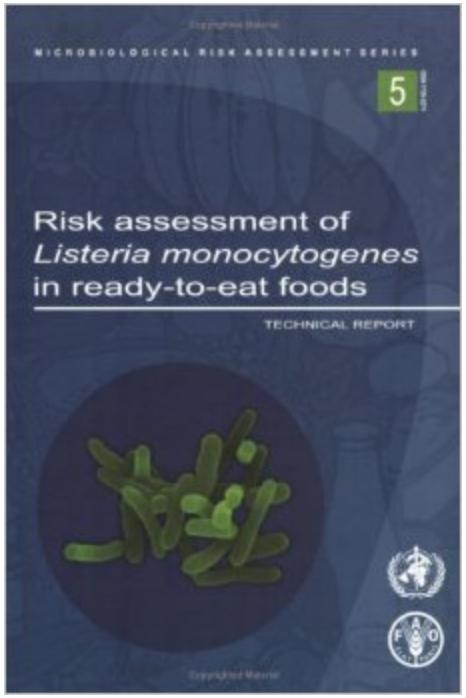
Approaches to Increase Transparency

- 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 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

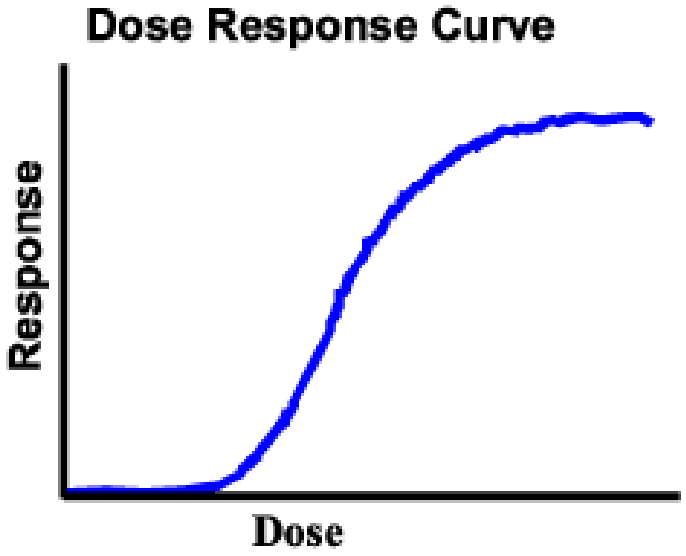
Hazard Identification

- 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

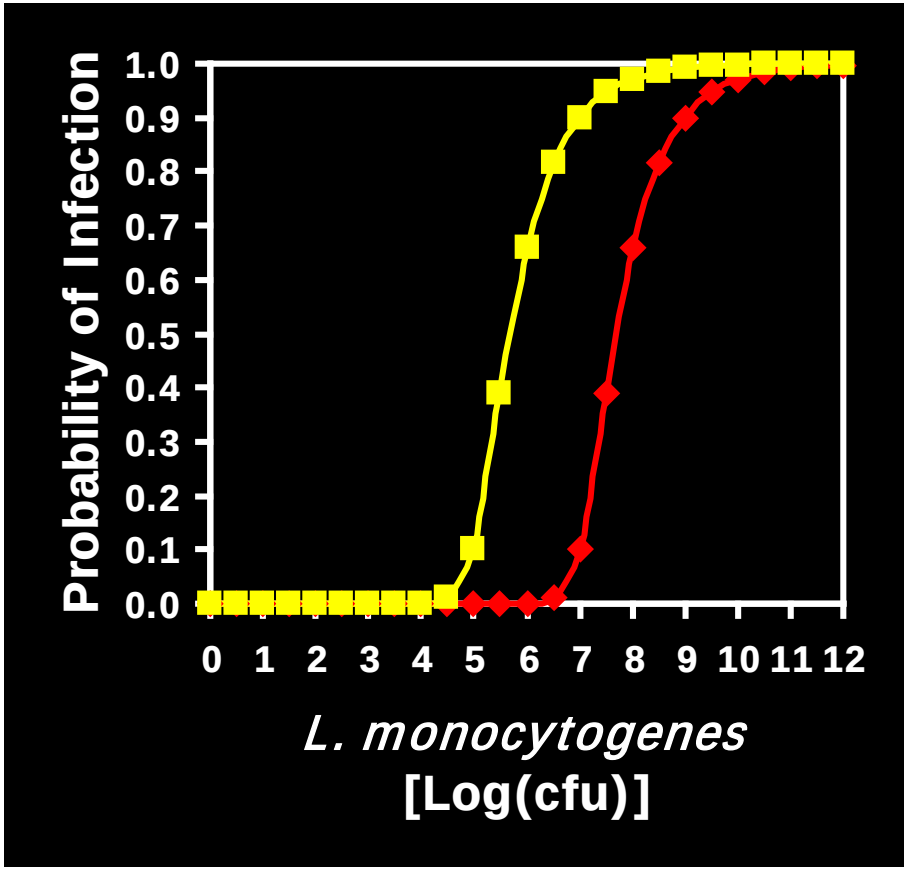
Risk Characterization

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

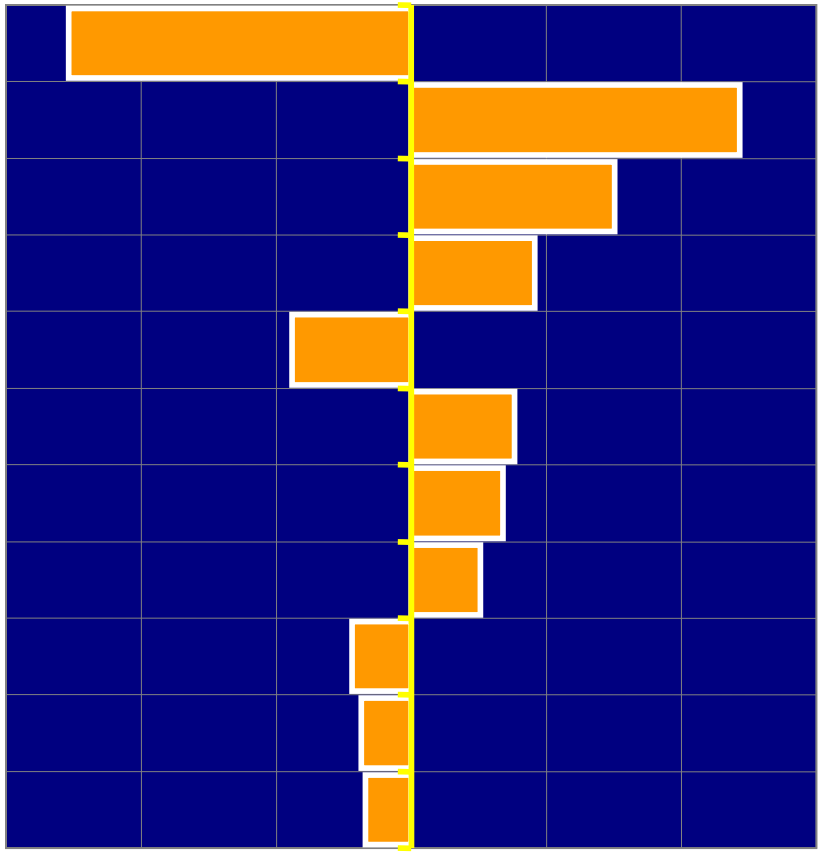
What-If Scenarios

- 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