

Selecting and Conducting 'Major' Risk Assessments: CFSAN's Approach

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Reasons to Use a Risk Analysis Approach for Food Safety Problems

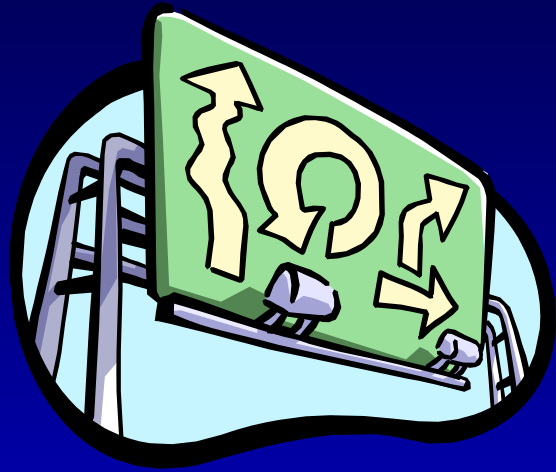
Reasons to Use a Risk Analysis Approach for Food Safety Problems

- The information you have is not the information you want
- The information you want is not the information you need
- The information you need is not the information you can obtain
- The information you can obtain costs more than you want to pay

Adapted from Bernstein, 1996

Outline of presentation

- Lessons Learned
- Steps -- Selecting risk assessments
- Steps -- Conducting risk assessments
- Organizational structure
- Recommendations



Setting the Stage

- Experience: Conducted two complex quantitative microbial risk assessments
 - *Vibrio parahaemolyticus*
 - *Listeria monocytogenes*
- Learning: While awaiting public comment, used the time to address “the bumps” and lessons learned. Led to the development of a risk analysis framework for future ‘major’ risk assessments

Risk Analysis– The Theory

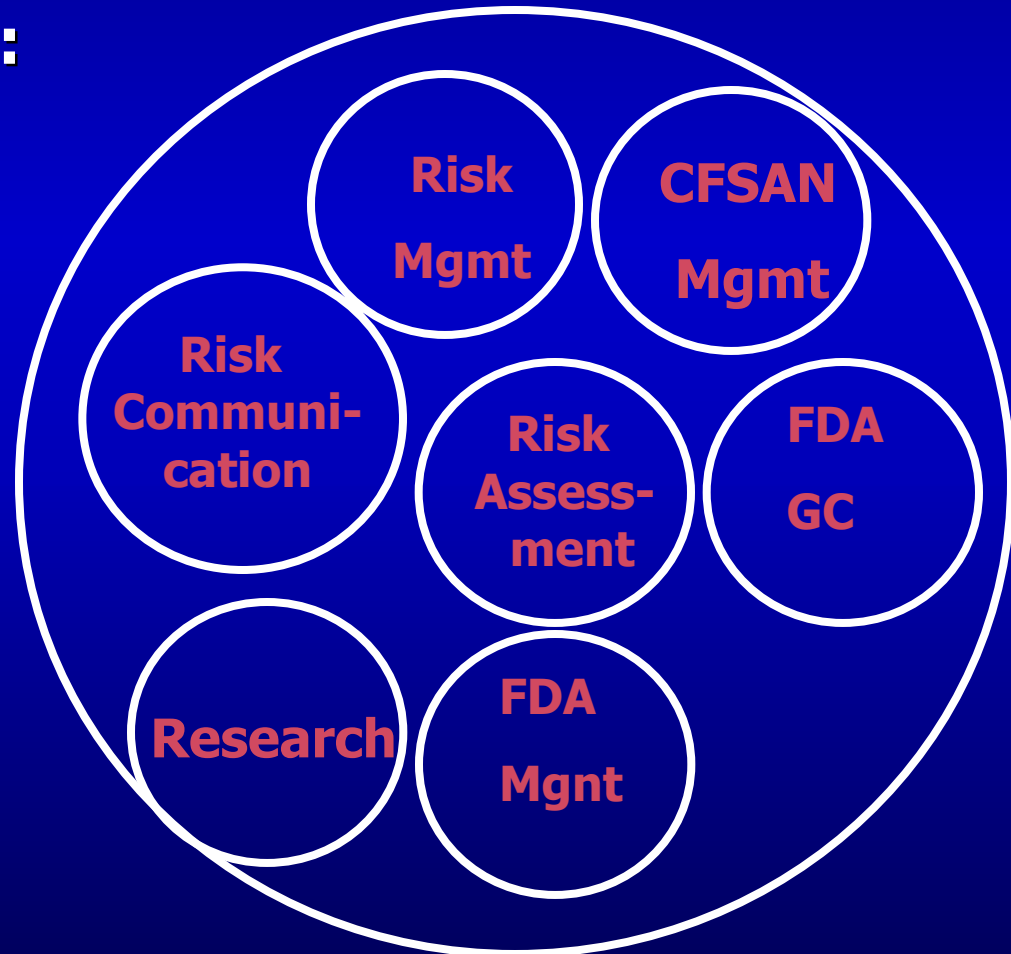
- **Traditional definition--risk analysis is composed of:**
 - Risk Management
 - Risk Assessment
 - Risk Communication

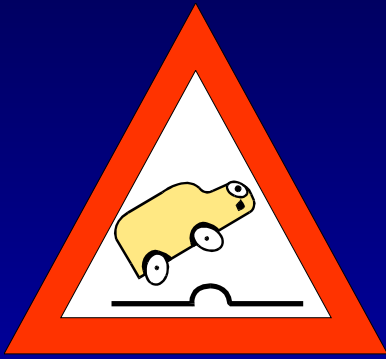


Risk Analysis- The Reality

In CFSAN risk analysis is a “stew” composed of :

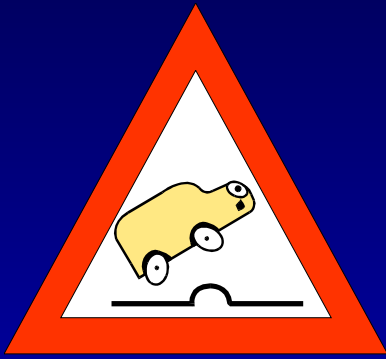
- Center Management
- Risk Managers
- Risk Assessors
- Risk Communicators
- Researchers
- Legal advisors





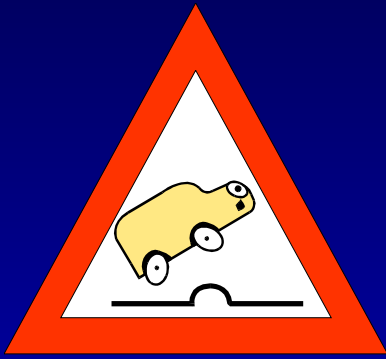
Lesson Learned (‘the bumps’)

- Resource intensive
 - >45 people worked on different phases of risk assessment and its rollout
 - Wasn’t most individual’s “day job”
- Set time frames and establish deadlines
 - Be ready to take your lumps
 - Need project manager



Lessons Learned (‘the bumps’)

- Establish why risk assessment is being done
 - Don’t assume that everyone thinks that a risk assessment is a good idea
 - What questions will the risk assessment answer?
- Establish boundaries
 - Who is in charge?
 - Who gets to decide?
 - Who settles conflicts?



Lessons Learned (‘the bumps’)

- Establish expectations
 - What can a risk assessment do?
 - Most risk managers do not understand that the more they want a risk assessment to do, the more complex and uncertain is the product





Lessons Learned (‘the bumps’)

- Communicating with risk managers
(Why can’t risk assessors speak English?)
 - Modeling
 - Explaining uncertainty vs. variability
- Communicating with risk assessors
(Why are risk managers so dense?)
- Getting risk managers to pay attention early



Lessons Learned (‘the bumps’)

- Presenting the results
 - Interpretation
 - Transparency
 - Plain language (Who writes the report?)

CFSAN's Risk Analysis Working Group

Risk Analysis Working Group

- Senior managers
- Risk managers
- Risk assessors
 - Scientists
 - “Modelers”
 - Project leaders
- Risk Communicators
- Facilitator

Risk Analysis Working Group

- Overall goal:

To improve the quality and consistency of 'major' risk assessments conducted by the Center for Food Safety and Applied Nutrition

What are 'Major' risk assessments?

- Non-routine and complex
- Quantitative or qualitative
- Involve multiple program offices and/or cross-cutting in nature
- Require a commitment of significant resources to complete

Procedures to Select and Conduct Risk Assessments

- **SELECT:** A decision-based approach to identify and select all 'major' risk assessments
 - Four phase process: concept generation, problem identification, data feasibility evaluation, disposition
- **CONDUCT:** A systematic and iterative approach to conducting risk assessments
 - Four step process: Plan, Perform, Review, Publish

The Identification and Selection Process



When SHOULD a risk assessment be conducted ?

- **Goal:**

- **Select all 'major' risk assessments on basis of**
 - **regulatory needs**
 - **available resources**
 - **feasibility**

When is a risk assessment needed?

- Risk assessment provides information for use in making regulatory decisions
- Powerful tool when:
 - When the science is complex (incomplete or conflicting data)
 - There is no consensus among stakeholders
 - There are multiple ways of managing the risk

A Four Phase Selection Process

Phase 1:
Concept Generation



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graph TD; P1[Phase 1: Concept Generation] --> P2[Phase 2: Problem Formulation]; P2 --> P3[Phase 3: Feasibility Determination]; P3 --> P4[Phase 4: Disposition];
```

The diagram illustrates a four-phase selection process. It begins with Phase 1: Concept Generation, which leads to Phase 2: Problem Formulation. This is followed by Phase 3: Feasibility Determination, and finally Phase 4: Disposition. Each phase is contained within a rectangular box with a double border, and the phases are connected by yellow arrows pointing downwards and to the right.

Phase 2:
Problem Formulation

Phase 3:
Feasibility Determination

Phase 4:
Disposition

Identification and Selection Process

Concept Generation

Problem Formulation

Feasibility Determination

Disposition (selection)

Identify and maintain list of potential RM questions for which a RA would assist with policy decisions

- Identify hazards/commodities
- State the RM question(s)
- State the RA question(s)

Where do risk assessment ideas come from?



- Stakeholders (public)
- Follow up to completed risk assessment
- Regulatory staff
- Management
- Researchers
- Other agencies

Identification and Selection Process

Concept Generation

Problem Formulation

Feasibility Determination

Disposition (selection)

Management reviews list and approves specific RAs for further evaluation (feasibility determination)

Identification and Selection Process

Concept Generation

Problem Formulation

Feasibility Determination

Disposition (selection)

Review literature to determine availability of data needed to conduct RA to answer RM questions

Recommend action:

- More research needed
- Modify RM question
- Qualitative vs. Quantitative RA

Identification and Selection Process

Concept Generation

Problem Formulation

Feasibility Determination

Disposition (selection)

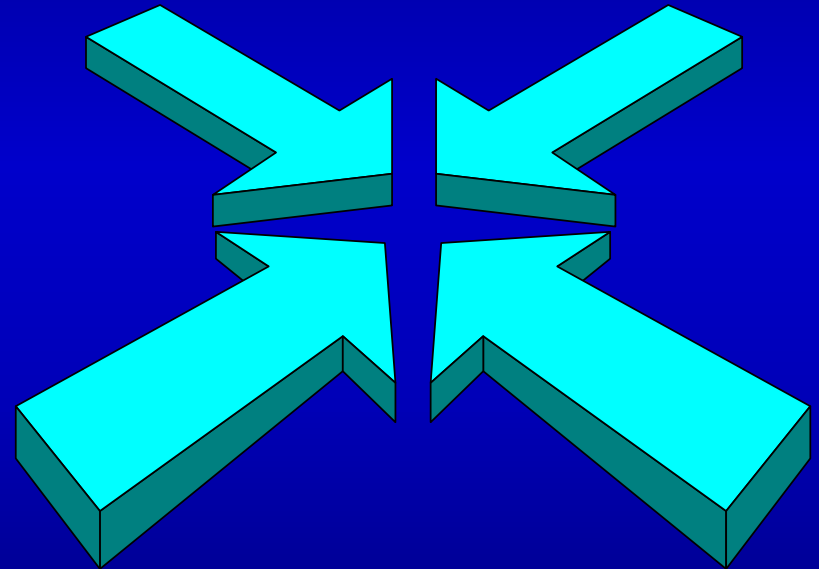
Using the results of the feasibility determination as an aid, management selects RAs to be conducted based on technical merit, resource availability, and other factors, and get commitment of resources

Conducting the Risk Assessment

Conducting the Risk Assessment

A systematic and iterative approach:

- Step 1: Plan
- Step 2: Perform
- Step 3: Review
- Step 4: Publish





Conducting the risk assessment

- **Step 1: Planning**
 - Define scope ('charge')
 - Identify resource needs
 - Assign teams
 - Develop timelines



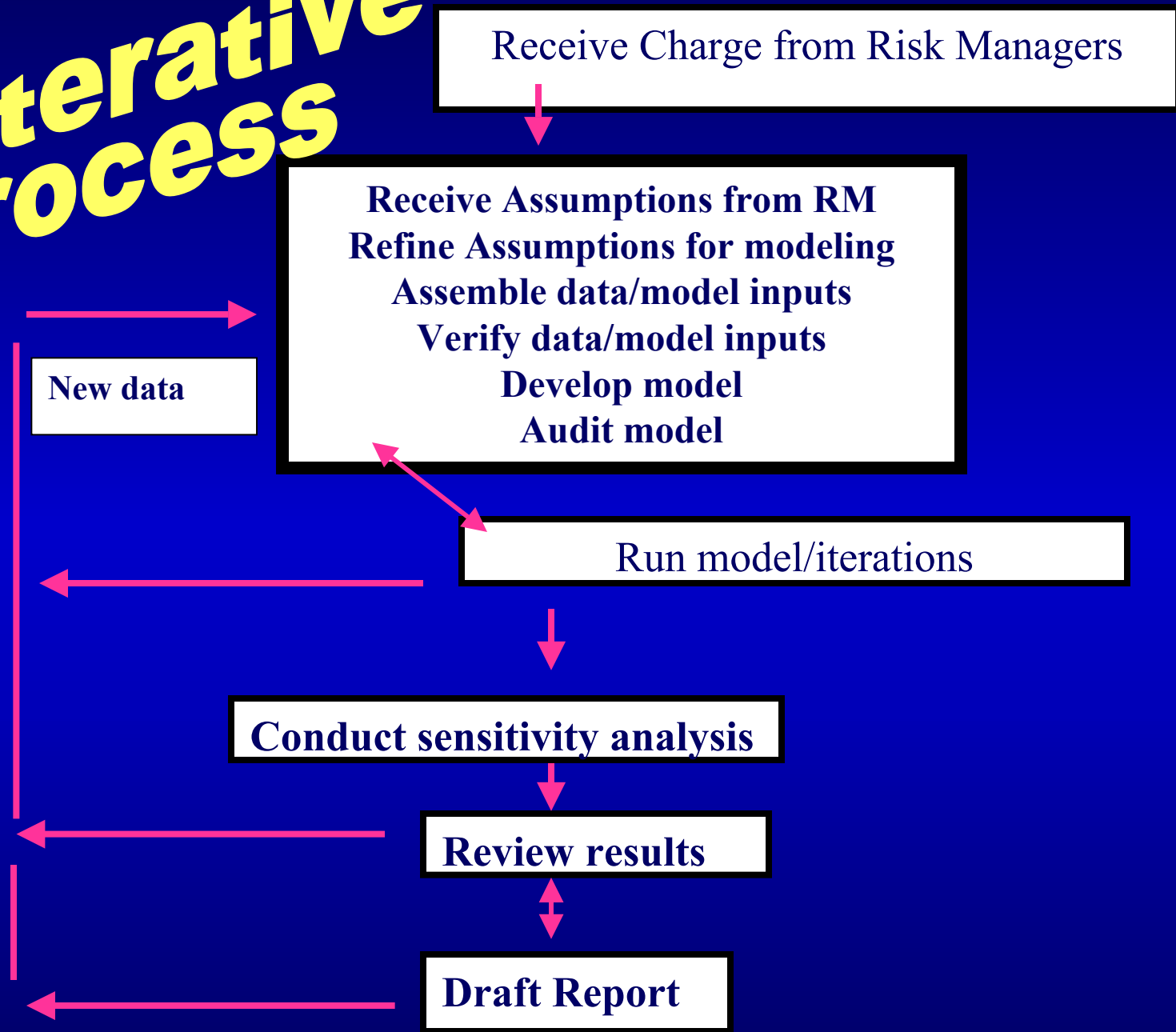
Conducting the risk assessment

■ Step 2: Perform

Answer the risk management questions!

- Collect data
- Develop model
- Review results
- Draft report

An Iterative Process



Receive Charge from Risk Managers

Receive Assumptions from RM
Refine Assumptions for modeling
Assemble data/model inputs
Verify data/model inputs
Develop model
Audit model

Run model/iterations

Conduct sensitivity analysis

Review results

Draft Report

New data

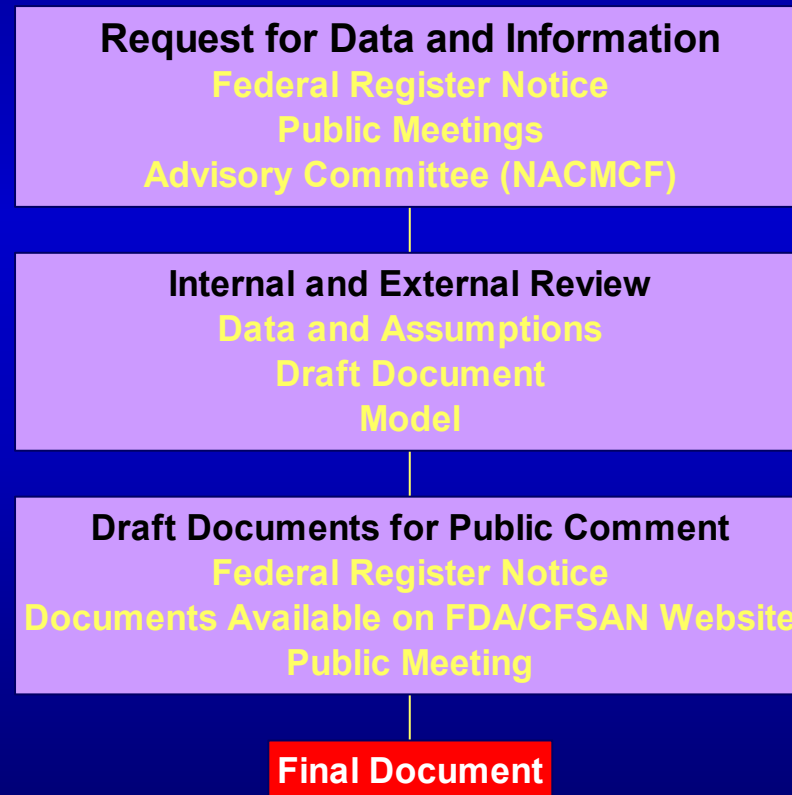


Conducting the risk assessment

■ Step 3: Review

- Review – an ongoing process
 - Advisory committees
 - Peer review
 - Scientific panels
 - Public comment
- Approve
- Clear

Technical and Scientific Reviews of the Draft Risk Assessment Documents





Conducting the risk assessment

■ Step 4: Publish

- Develop “roll out” strategy
- Public release of documents
- Make models available
- Public comment period

Organization of Risk Analysis

- Risk analysis should be conducted by teams:
 - Risk Management Team
 - Risk Assessment Team
 - Risk Communication Team
- Meet regularly to discuss process and surface issues

Organization of Risk Analysis

- Established three unique positions to help with consistency, coordination, and making decisions
 - Science Advisor for Risk Analysis
 - Risk Analysis Coordinator
 - Risk Assessment Project Manager

Selecting and Conducting a Risk Assessment Within a Risk Analysis Framework

Risk Analysis Activities	Responsible Party [*]		
	RA	RM	RC
Select the risk assessment		√	
Plan and allocate resources	√	√	√
Performance			
Conduct the risk assessment	√		
Develop management action plan		√	
Develop communication messages			√
Review			
Risk assessment documents	√	√	√
Management action plan		√	
Communication messages		√	
Issue			
Risk assessment documents	√		
Risk management action plan		√	
Risk communication messages			√

Summary of Recommendations: Implemented

- ✓ Decision-based approach to identify and select all 'major' risk assessments
- ✓ Procedure for conduct of risk assessment within risk analysis framework
- ✓ Established new organizational structure

Summary of Recommendations

- Criteria to evaluate data quality
- Procedures for the approval and release of risk assessments
- Formal peer review process
- Enhance capabilities to conduct risk assessments

New concerns—data quality and transparency

OMB's Guidelines on Data Quality

www.whitehouse.gov/omb/fedreg/reproducible.html

FDA's Guidelines on Data Quality

www.hhs.gov/infoquality/fda.html

- Data quality = objectivity, utility, integrity
- Develop information resource management procedures to review and substantiate quality of information disseminated

New concerns—data quality and transparency

OMB's Guidelines on Data Quality

- Information includes "...a risk assessment prepared by the agency to inform the agency's formulation of possible regulatory action."
- "...require sufficient transparency about data and methods that an independent reanalysis could be undertaken..."

Acknowledgement

Members of the CFSAN Risk Analysis Working Group

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Wes Long

Marianne Miliotis

Art Miller

Patricia Schwartz

Philip Spiller

Terry Troxell

Richard Whiting

Richard Williams

Susan Santos (facilitator)

Report Available

“Initiation and Conduct of All ‘Major’ Risk Assessments within a Risk Analysis Framework”

- Available on FDA website:

www.cfsan.fda.gov/~dms/rafw-toc.html