



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

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# JIFSAN Advisory Council 2011 Spring Symposium



## Rapid Risk Assessment

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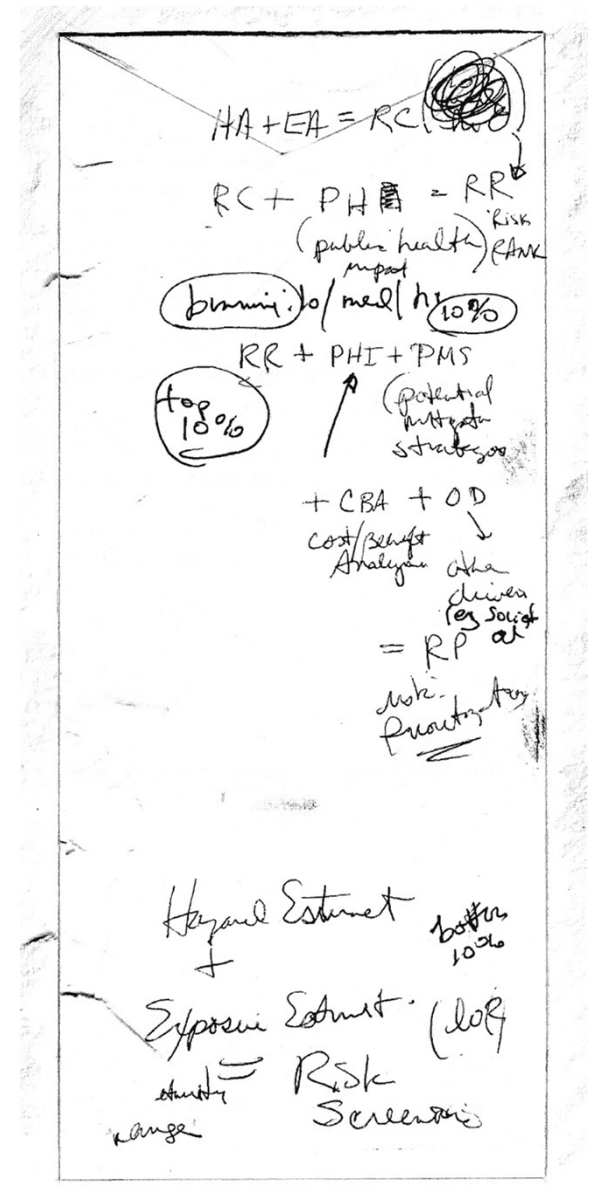
# Back-of-the-Envelope

## Back-of-the Envelope (BOTE) Calculation

- A rough calculation
- It is more than a guess, but less than an accurate calculation or mathematical proof.
- Uses simplified assumptions.
- Typically jotted down on any available scrap of paper such as the actual back of an envelope

see example →

(definition from Wikipedia)  
(BOTE by Dr. Elizabeth Calvey)





# Risk Assessment: The Basics

- A process to describe
  - what we know and
  - how certain we are of what we know
- Facilitates the application of science to policy
  - “informational bridge” between data and decisions
- Desired characteristics
  - structured, transparent, systematic, iterative



# Risk Assessment: The Process

## FDA/FSIS/CDC *Listeria* RTE Risk Assessment

- Commission project (Jan 1999)
- Public announcement and meeting (May 1999)
- Collect and analyze information & data
- Develop model
- Run model, preliminary risk estimates (Dec 1999)
- Quality control, validation (May 2000)
- Prepare report (March 2000)
- Review (Sept 2000)
- Issue draft for public comment; public meeting (Jan 2001)
- Revise & update data, model, report
- Issue revised risk assessment (Oct 2003)

**Structured, transparent, systematic, & iterative but NOT RAPID**



# Rapid RA: The Challenge

- Food safety emergencies and responses to emerging incidences call for
  - unique tools to be at the ready for assessing risk and determining the appropriate response (**often in the absence of complete information**)
- Risk assessment processes are
  - designed to encompass all available information, evaluate data, reveal data patterns, and form/test hypotheses
- Rapid risk assessments cannot
  - be as extensive as full risk assessments yet must be robust enough to stand up to scrutiny after the fact



# The Problem--Solution Approach

- A problem—solution approach
  - Ask: What is the problem? and How the problem should be defined?
- The definition of the problem will dictate the operational structure of the investigation
- The definition of the problem is flexible in time (may change direction according to evolving data & information)
- It is perhaps easier (and more common) to define problems according to existing strategies of solution



# Embrace Uncertainty

- Unknown factors
  - Scientists challenge – offer a recommendation along with explicit and transparent view of uncertainties
  - Decision-makers challenge - make decisions in the face of uncertainties
- Embrace uncertainty by:
  - recognizing it, classifying it and characterizing it



# Using Subjective Information

- When we lack explicit evidence, subjective information plays a major role in making decisions
  - How do we ensure that we obtain the most informative points of view?
  - How do we ensure that we capture experts' uncertainty?
  - How do we combine different opinions, when that is deemed necessary?



# Tools for Rapid Risk Assessment

- Risk profiles
- Decision trees
- Scenario analysis
- iRISK





# Risk Profiles

- Elements adapted from Codex method
- Review of available science and evaluation of options to control risk; identifies data gaps
- Targeted to address specific questions
- Examples
  - Norovirus/ routes of transmission
  - Hepatitis A virus/ produce
  - *Listeria monocytogenes*/ fresh-cut produce
  - Pathogens in cheese
  - Pathogens & filth in spices



# Decision Tree Approach

- An evolving tool
  - Structured; evaluates risk; unify science for guidance; qualitative but can be linked to quantitative approaches
- Factors
  - **Hazard** (e.g., pathogen characteristics, level, persistence in environment)
  - **Food** (e.g., supports pathogen growth or not, ingredient matrix effect, intended use)
  - **Firm** (e.g., validated process, credible environmental monitoring program in place or not)
- Outcomes
  - Decision tree leads to determination of high, medium or low risk depending on factors related to firm, for ingredient-hazard scenarios tested

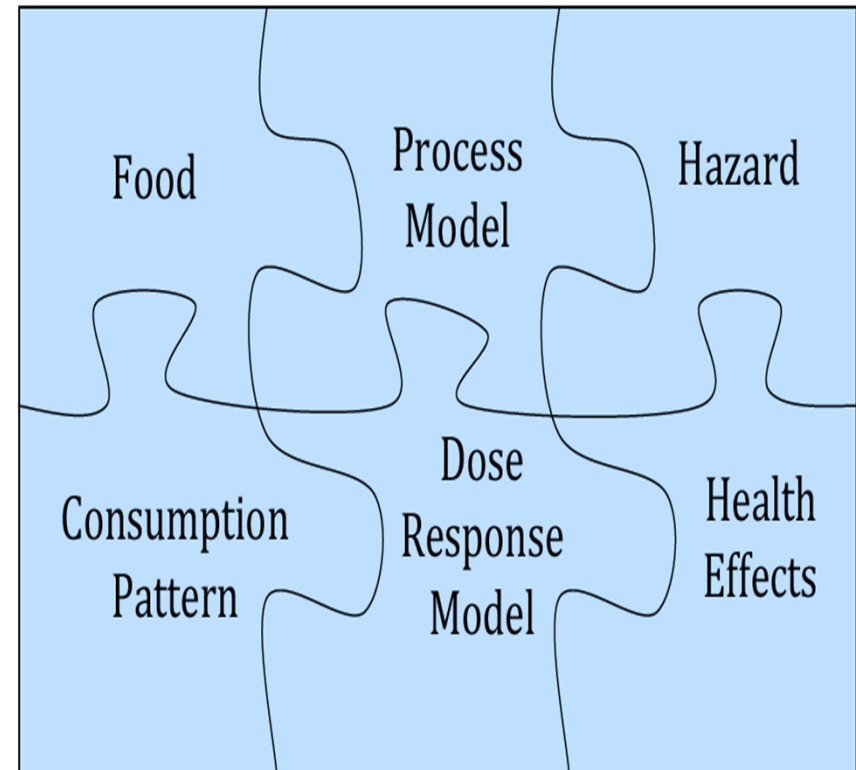


# iRISK: A Comparative Risk Assessment Tool

- Aims to enable rapid quantitative risk assessments
  - Built-in mathematical architecture for process/contamination modeling, consumption modeling, dose response modeling, and public health metric templates
  - Modular and expandable
- Serves as an intermediate between qualitative hazard analysis/risk evaluation and resource-intensive comprehensive risk assessments

# iRISK: Features (1)

- Comparison across many dimensions
  - Hazards (chemical & pathogens)
  - Foods/Commodities
  - Processing/handling scenarios
  - Populations
- Compare food risks at any stage, throughout the food supply system
- A straightforward user interface
- On-line access; broad accessibility; sharing of data and models
- Available at [www.foodrisk.org](http://www.foodrisk.org) (anticipate in early 2012)





# iRISK: Features (2)

- iRISK process involves construction of scenarios
- Scenarios built through user interface
- Calculations carried out using Analytica Decision Engine
- Results presented in a PDF file; full documentation

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**Repository: FDA**

**Risk Scenario: EHEC in Fresh-Cut Spinach, Total Population**

**Information**

**Name:** EHEC in Fresh-Cut Spinach, Total Population

**Hazard:** Enterohemorrhagic Escherichia coli (EHEC) ▼

**Food:** Spinach-Fresh-Cut ▼

**Process Model:** Enterohemorrhagic Escherichia coli in Spinach-Fresh-Cut ▼

**Consumption Model:** Spinach-Fresh Cut in Total Population ▼

**Dose Response Model:** Beta-Poisson for EHEC--Heterogeneous ▼

**DALY Template:** EHEC in the Total Population

\* indicates the item is incomplete

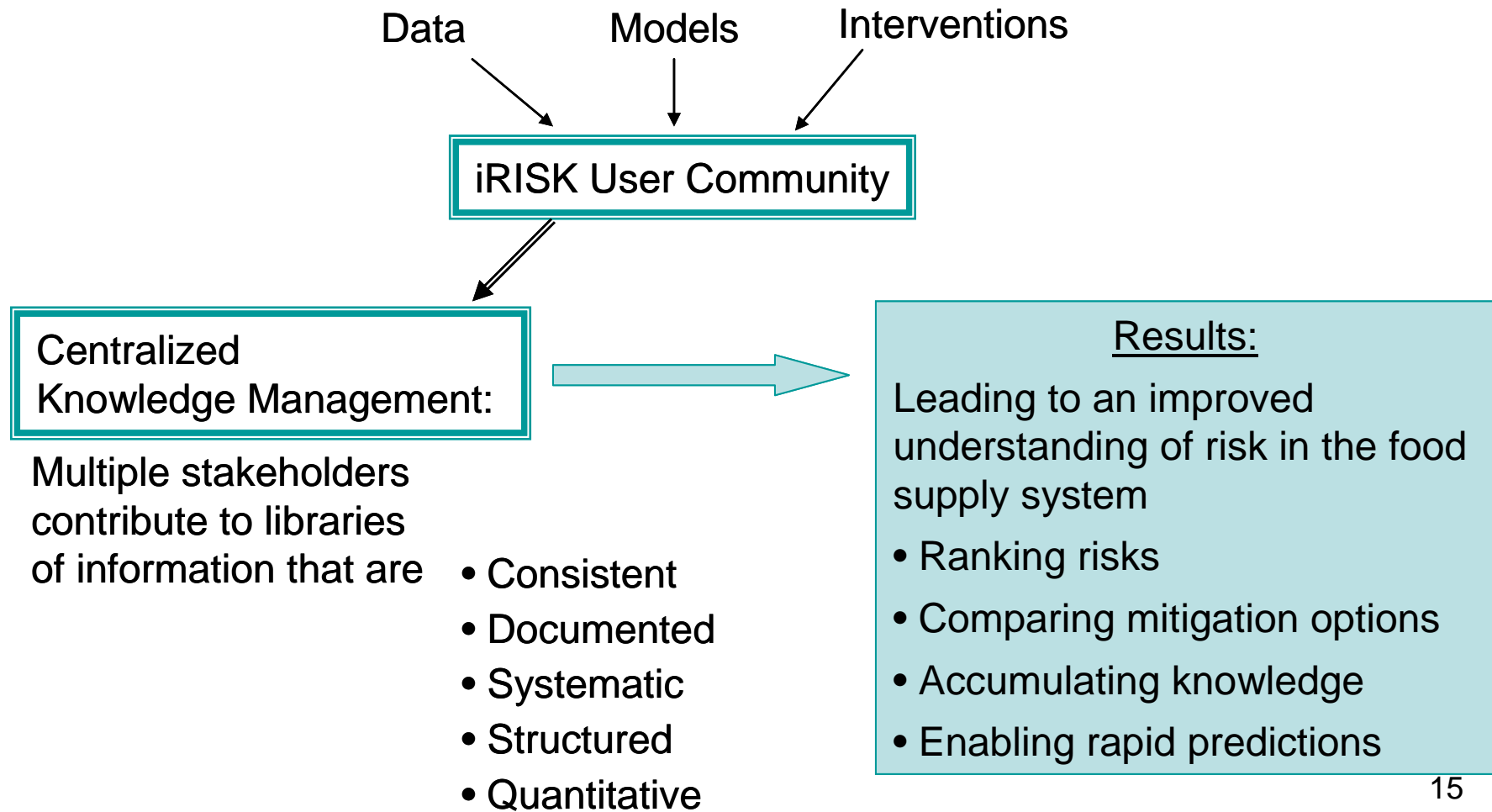
**Description:**

**Modified By:** **Created By:**

**Modified On:** 20-Jan-2011 **Created On:** 08-Apr-2010

Create Report

# iRISK: Vision for the future





# Progress Addressing Rapid RA

- Knowledge gained and expertise developed from in-depth quantitative risk assessments enables rapid risk assessments
  - Dose-response models
  - Mathematical equations and algorithm to describe exposure pathways
  - Scenario analysis using existing models as new risk management questions arise





# What is needed to advance the tools?

- Collaboration and leveraging of resources
  - Government, industry and academic
  - Encourage data sharing through iRISK web-portal
- Articulation of key risk management questions to answer
  - So the “right” scenarios are developed, validated and deployed
- Targeted collection of data
  - Better understanding of the food supply system
  - Baseline prevalence and enumeration data for specific hazards in specific commodities at specific points in the food supply chain (farm, processor, transportation, retail)



## FAO/WHO Workshop on Guidance for Application of Risk Analysis During Food Safety Emergencies

- March 21-25, 2011, Rome
- **Participants:** U.S., Canada, Australia, Belize, Indonesia, Malaysia and Ireland, along with FAO, WHO, EFSA and OIE
- **Workshop goal:** To draft a guide for authorities to use in constructing plans for the use of rapid risk assessment during emergencies. The guide may be useful to prepare for, or use during, a food safety emergency.
- The guide will serve as a companion piece to the recently published *FAO/WHO Framework for Developing National Food Safety Emergency Response Plans*
- Includes information on risk assessment, risk management and risk communication.
- Guide will be published in December 2011 in English, Spanish and French.



# For More Information:

## FDA's Risk Assessment Program

<http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm>

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