iRISK
A Comparative Risk Assessment Tool

October 4, 2012

Welcome to the Webinar

Today's Speakers

Sherri Dennis, FDA

Yuhuan Chen, FDA

Todd Ruthman, RSI

_____

Acknowledgements:

- Susan Mary Cahill, FDA (Q&A moderator)
- JIFSAN and FDA staff (webinar logistics and support)

Purpose of Webinar

To introduce iRISK, FDA's new publicly available food safety risk assessment tool. Available at https://irisk.foodrisk.org

Today's Presentation

- Overview – the purpose of iRISK

- What is iRISK and who will use it?

- How iRISK works

- Demonstration, examples

- Summary and questions & answers

Overview – the Purpose of iRISK

NAS Recommendation

…to develop tools for risk ranking in a risk-based system for enhancing food safety decision-making.

"A good risk-ranking model should be fit for purpose and be scientifically credible, balanced, easy to use, and flexible."

ENHANCING FOOD SAFETY
THE ROLE OF THE FOOD AND DRUG ADMINISTRATION
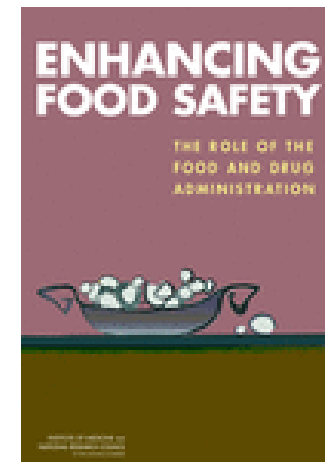
(National Academy of Sciences, 2010)

iRISK is:

an interactive, web-based system that enables users to conduct fully quantitative, fully probabilistic risk assessments of food safety hazards relatively rapidly and efficiently.

iRISK – Novel Capacities

- Allows risk comparisons across many dimensions

  - Hazards (microbial and chemical)
  - Foods/Commodities
  - Production/processing/handling scenarios
  - Populations

- Enables relatively rapid risk assessments and evaluation of intervention effectiveness

- Provides a straightforward user interface

- Allows online access to ensure broad accessibility, saving and sharing data

iRISK Development: A Collaboration of Experts

2006 Prototype framework developed

- *FDA/IFT Cooperative Agreement; Newsome et al. 2009 JFS 74(2):R39-R45*

2007 Operationalized prototype in web-based format

- *Risk Sciences International (RSI) Contract*

2008 RTI Inventory & Evaluation

- *Recommends iRISK as tool for further development*

2009 Develop library to populate iRISK

- *RTI Contract; 50 commodities & 20 hazards*

2010 External Peer Review

- *Versar Contract; 5 expert reviewers*
- *FDA responses to peer review comments*

  (http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm)

2011 Develop iRISK public version

- *RSI Contract; Beta testing*

Any questions about the overview?

Send us a note on the chat line

What is iRISK and who will use it?

What is iRISK?

A risk ranking tool to compare public-health impact of microbial and chemical hazards (and more...)

One Hazard in Different Foods

Salmonella

Fresh Produce

Shell Eggs

Nuts

Multiple Hazards in a Single Food

Leafy Greens

Norovirus

Cyclospora

Enterohemorrhagic *E. coli*
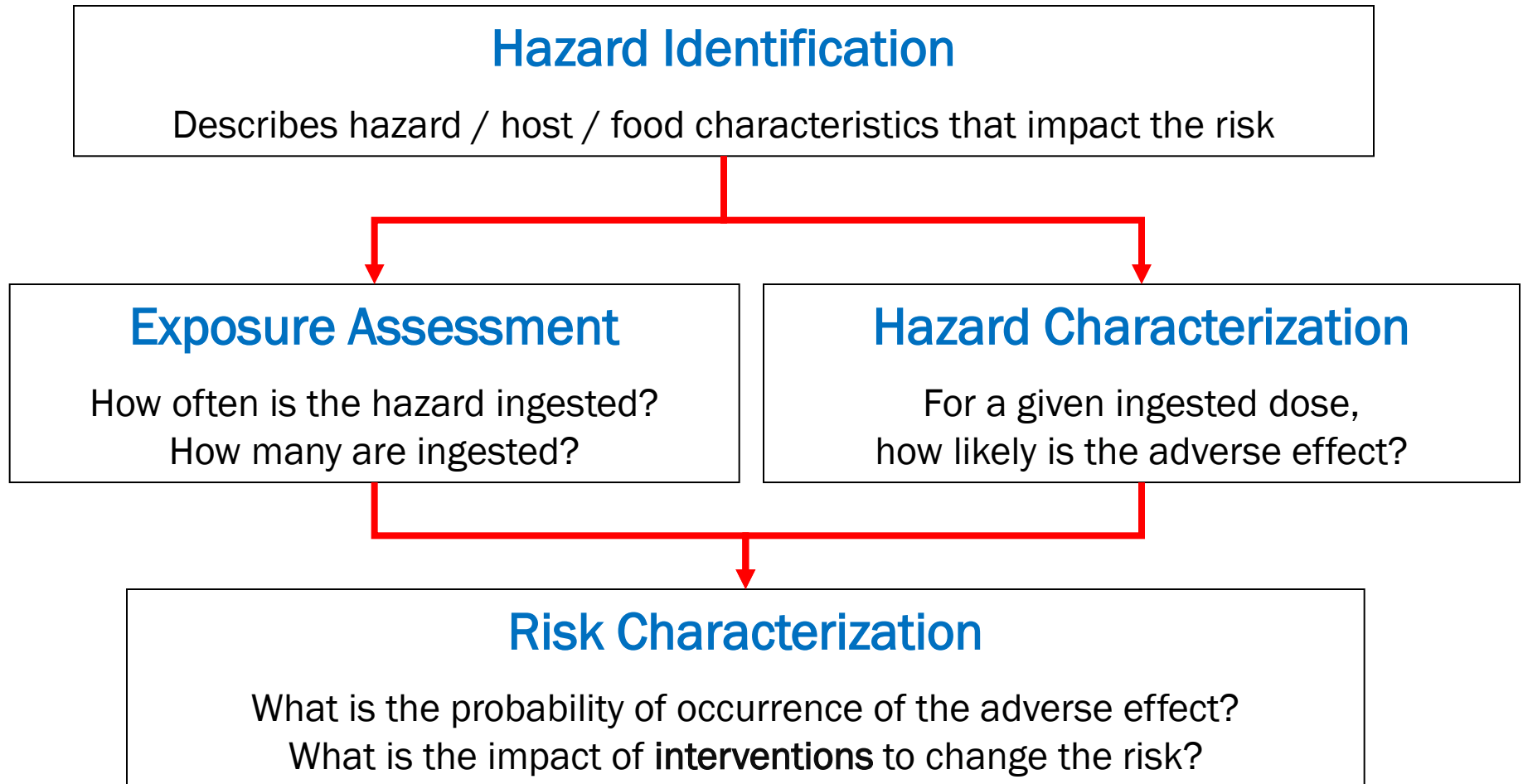
Multiple Hazards in Multiple Foods

L. monocytogenes in Soft Cheese

Scombrotoxin in Raw Tuna

Salmonella in Peanut Butter

iRISK Model Uses Established Components of Risk Assessment

Hazard Identification

Describes hazard / host / food characteristics that impact the risk

Exposure Assessment

How often is the hazard ingested?
How many are ingested?

Hazard Characterization

For a given ingested dose,
how likely is the adverse effect?

Risk Characterization

What is the probability of occurrence of the adverse effect?
What is the impact of **interventions** to change the risk?

13

(Codex Working Principles)

What iRISK can do – a snapshot

- **Enables users to construct risk scenarios more easily** (user inputs data via online interface)

- **Carries out calculations** via Monte Carlo simulation

- **Saves data and presents results** in two forms:

  - brief, convenient table

  - accompanying full-documentation report, for reference

iRISK: Some Features

- Built-in math / probabilistic calculation functions

- Built-in standard data entry templates

  Users input data reflecting their real-world situations

- Built-in quick tutorial with examples

- Enables assessment/comparison of risks at all stages in food supply system

- Enables intervention comparisons

- Results presented as public-health metrics

Externally Peer Reviewed

- **underlying structure, mathematical equations, usability of interactive web interface reviewed**

- **Examples of FDA response:**
  - enhanced user interface navigation
  - more distribution templates
  - model convergence and stability analysis
  - enhanced risk scenario reporting

What iRISK can produce: a preview

- **Risk estimates (public health metrics)**
  - Total illnesses per year
  - Mean risk of illness; avg. probability of illness from an eating occasion
  - Health impact metric, expressed as Disability Adjusted Life Years (DALY)

- **Ranking of risk**
  - Among food-hazard combinations, multiple hazards in single food, single hazard in multiple food commodities

- **Impact of interventions** applied at various points in food chain

Target Users and Audiences

Risk managers and decision makers

- need risk assessments to inform their decisions

Risk assessors and food safety professionals

- need to quantitatively assess risk, determine public-health impact of preventive controls & interventions

Academia

- Students, professors, researchers

...and others who need a platform on which to collaborate and share risk scenarios

Any questions about what iRISK is and who will use it?

Send us a note on the chat line

How does iRISK Work?

In iRISK, "risk" is defined as:

Probability x Consequence

Production, Processing, Transportation, Storage, Retail, Cooking, Consumption

Dose-response, Probability of illness, Population Health Burden

Probability and Extent of Exposure   x   Probability and Severity of Consequences
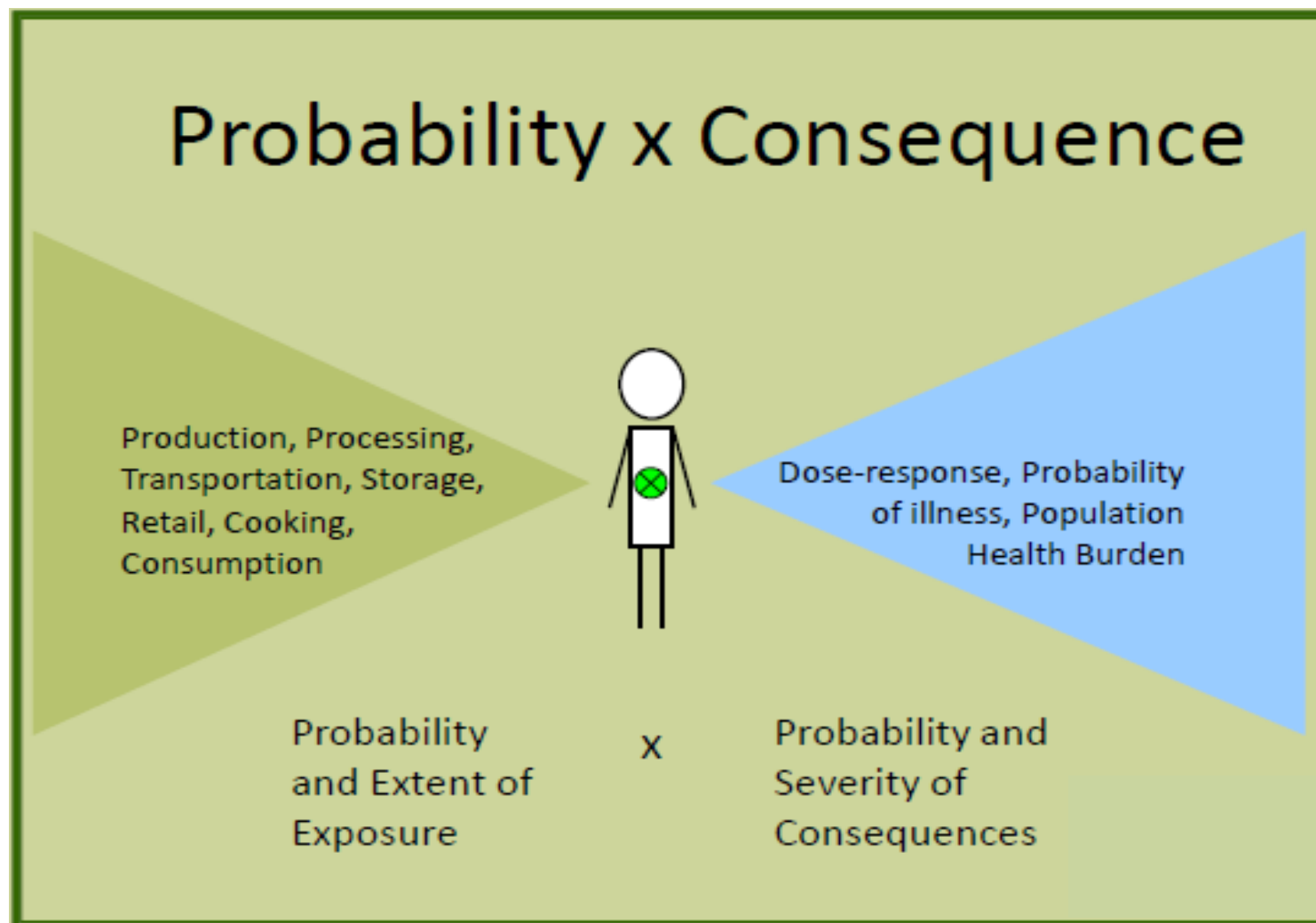
How iRISK Works

- **Integrates data & information on seven elements…**
  - food
  - hazard
  - population
  - process model (food production/ processing/ handling)
  - consumption patterns
  - dose-response
  - health effects

…using the built-in templates & generates risk estimates through Monte Carlo simulations

Relationship of the Seven Elements of a Risk Scenario (Risk Model)
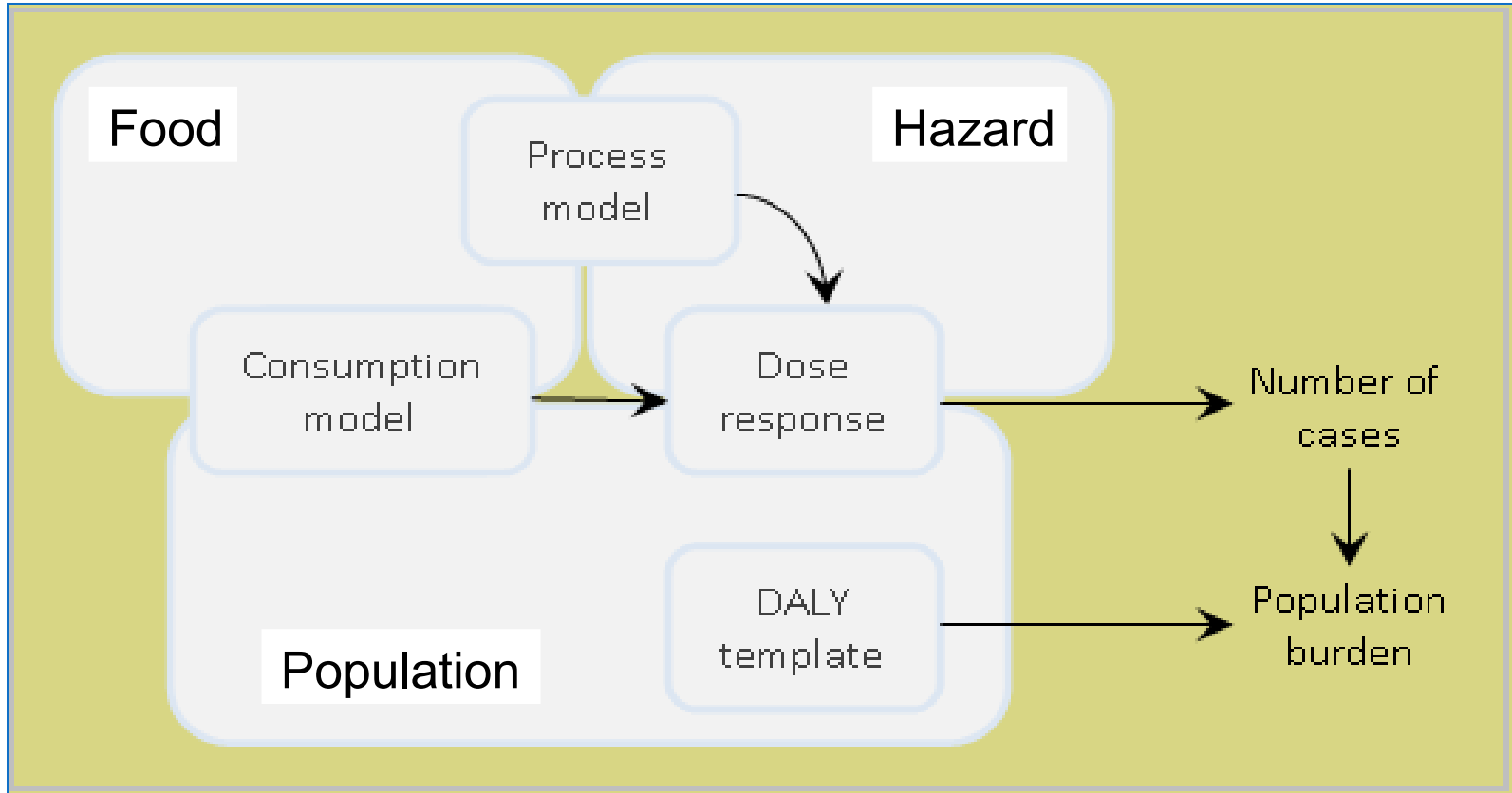
Address the question: What *risk* does a food-hazard pair pose to a population?

Users Develop and View Risk Models via Online Interface

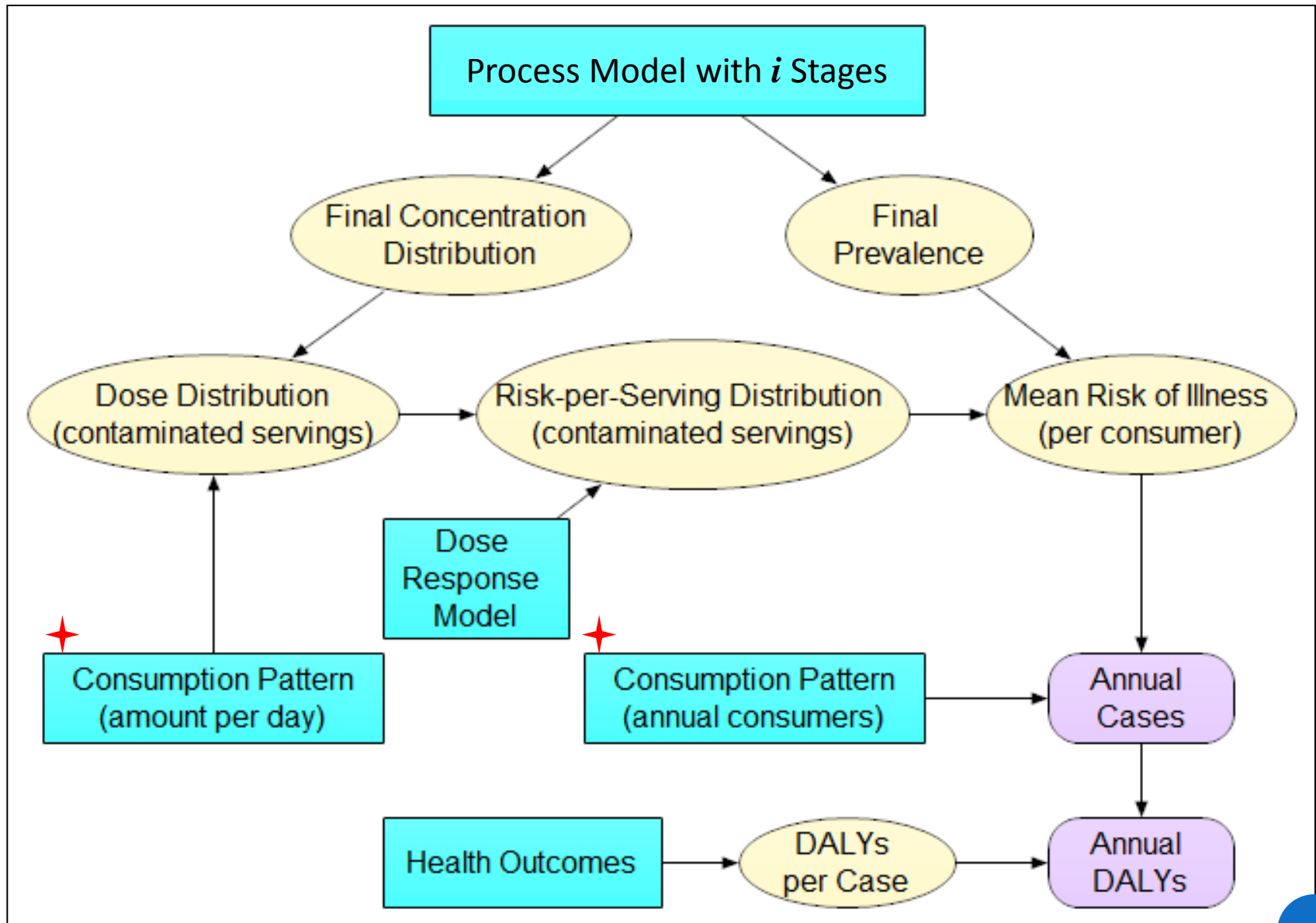# iRISK Model Structure (Microbial Hazards*)
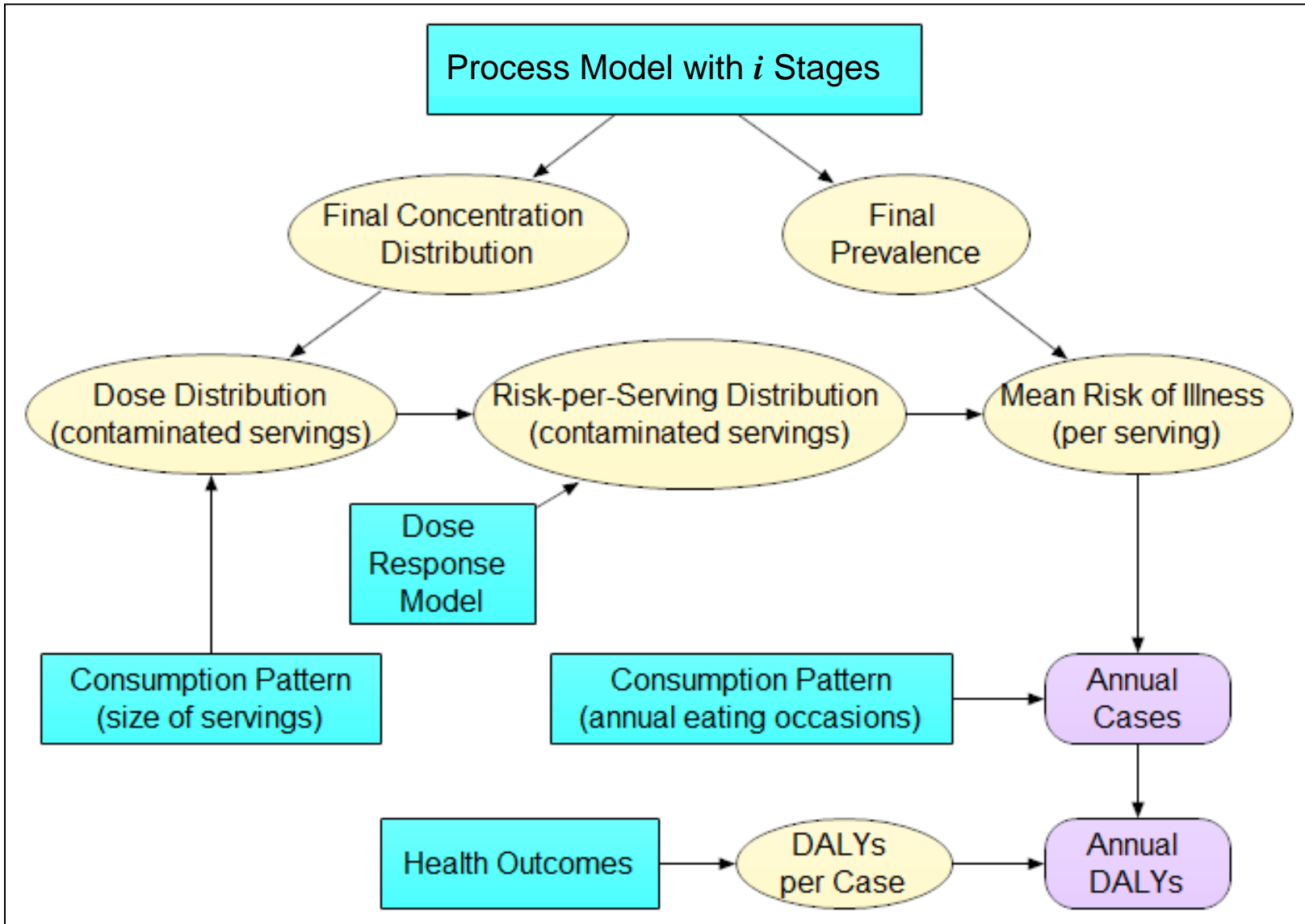
Key: [User input] (iRISK output) * Also applicable to chemical hazards that cause acute effects.

25

iRISK Model Structure (Chronic Chemical Hazards)

Examples of User Input (Data)

- Process model

  ▪ Initial prevalence and levels

  ▪ production/processing/handling steps

- Consumption patterns

- Dose-response relationship

- Health outcomes

...all represented by quantitative data

Example – Process Model

Name and Initial Conditions | Process Stages (1) | Scenarios (5) | Notes (2)

Name: L. monocytogenes in soft ripened cheese

Hazard: Listeria monocytogenes

Food: Soft ripened cheese

Initial Unit Mass: 227 g

Initial Units are Contaminated: ☑

Initial Prevalence: 0.0104

Initial Concentration:

Units: $\log_{10}$ cfu / g

Distribution: Triangular

Minimum: -1.39

Mode: -1.15

Maximum: 0.699

Save   Save and Close   Close

Last Modified: 06-Aug-2012 09:57:10

Quick Links: Soft ripened cheese (F) | Listeria monocytogenes (H)

28

Example – Process Model

- iRISK provides a template for users to develop a process model with multiple steps, chooses a process type, and populates the model with data.

- iRISK lists process types through which the hazard concentration and/or prevalence can change at various steps in food chain, such as:

  growth, inactivation, environmental contamination.

Process Model: "Process Type"

- **Describes a typical process step where contamination occurs, increases, or decreases**

  (built-in choices for users to select, as part of process model)

1. Increase by growth	4. Pooling	7. Redistribution (partial)
2. Increase by addition	5. Partitioning	8. Redistribution (total)
3. Decrease	6. Evaporation or Dilution	9. No change

Example – Process Model

- **Allows evaluation of specific interventions**
  - interventions applied at any step(s) of food production /manufacturing / handling, from farm to table

- **Ask iRISK** – "what if?"

Example – Process Model

- iRISK produces results for contamination in food at the point of consumption (probability of finding contaminated units, concentration of hazard); for example:

Process Model Details for: L. monocytogenes in soft ripened cheese			
Initial Prevalence:	0.0104	Final Mean Prevalence:	0.0104
Initial Concentration:	Triangular (Minimum: -1.39, Mode: -1.15, Maximum: 0.699) log10 cfu/g		
Initial Mean Concentration:	-0.338 log10 cfu/g	Final Mean Concentration:	3.56 log10 cfu/g
Initial Unit Size:	227 g	Final Unit Size:	227 g

Example – Consumption Patterns

iRISK 1.0   Home   Models   Reports   Sharing   Help

Home -> irisk@foodrisk.org's Models -> Foods -> Soft Ripened Cheese -> Total Consumption

Consumption Model

Name and Parameters	Population Groups (3)	Scenarios (1)	Notes (0)

Population Group	eo/yr	Body Weight	Consumption	
Adults 60+	1.8E+08	Fixed Value (Value: 0) Kg	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo	View
Intermediate Aged (5-59)	1.7E+09	Fixed Value (Value: 0) Kg	Triangular (Minimum: 10, Mode: 28, Maximum: 168) g/eo	View
Perinatal	1.2E+07	Fixed Value (Value: 0) Kg	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo	View

Quick Links: Soft Ripened Cheese (F)

- iRISK provides templates for users to enter data; e.g., the number of servings and serving size in the population group of interest.

Example – Dose-Response Model

- iRISK offers choices of pre-structured dose-response models.
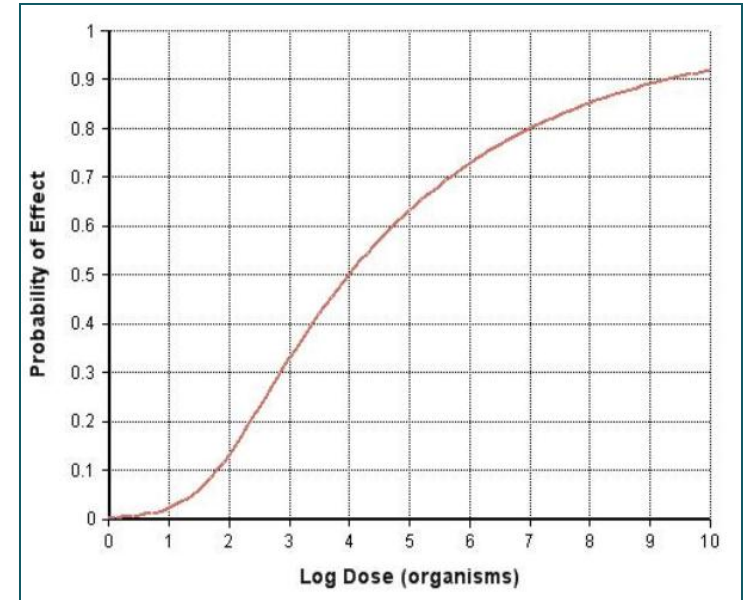- User selects one and populates it with parameters.

Health Impact Metrics

- **Disability Adjusted Life Years (DALY),**
  a commonly used metric

  - **Integrates info** on severity, duration of illness (burden of disease)

  - **Translates** # of illness cases & deaths **into common metric** (years of healthy life lost)

  - **Allows comparison** of burden of disease from microbial pathogens and chemical hazards (may have different illness severity and duration)

Examples – Health Outcomes

| Name and Type | Dose Response (1) | Metrics (1) | Process Models (4) | Scenarios (4) |

Name	Type	Value	**Add Hazard Metric**	
Salmonellosis general population (U.S., AIWH)	DALY	0.0188	Edit	Delete

Listeriosis in the Perinatal Population (RIVM)	DALY	13.8	Edit	Delete

- iRISK provides a template for each hazard

- User enters data on severity and duration of potential health outcomes of an illness, including relative frequency of each outcome. iRISK incorporates severity and duration in public-health metric (DALY)

Any questions about how iRISK works?

Send us a note on the chat line

Live Demonstration

Any questions about the Demonstration?

Send us a note on the chat line

# Summary

How is iRISK being used by FDA?

- Building a library of food-hazard risk scenarios
  - Evaluates effectiveness of interventions

- Using as a means for collaborating with other gov't agencies and organizations

- Communicating risk assessments to inform food safety decisions

Next Step: What is needed to further advance risk knowledge through iRISK?

- Collaboration and leveraging of resources – government, industry, and academic
  - May need third party to collect (redact) data
  - Encourage data sharing through iRISK web-portal

- Articulation of key risk management questions
  - So the "right" scenarios are developed, validated, and deployed

- Collection of data
  - Prevalence and enumeration data for specific hazards in specific commodities at specific points throughout the food supply chain
  - Understand variability and uncertainty for baseline "normal" and "outbreak"

Vision for iRISK

Data → Models → Interventions

→ iRISK User Community →
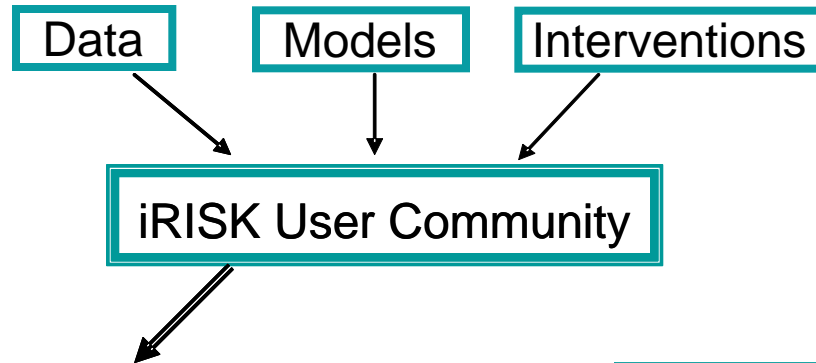
Centralized Knowledge Management:

Multiple stakeholders contribute to libraries of information that are:

- Consistent
- Documented
- Systematic
- Structured
- Quantitative

Result:

Leads to an improved understanding of risk in the food supply system by

- Ranking risks
- Comparing mitigation options
- Accumulating knowledge
- Enabling rapid predictions

Acknowledgements

We are grateful to the many experts who provided invaluable input and critique to assist in the development and refinement of the iRISK system, including members of the IFT expert panel, Risk Sciences International, RTI International, and external peer reviewers.

For further information about iRISK 1.0

Visit FoodRisk.org https://irisk.foodrisk.org

Visit FDA risk assessment web page
http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm