Welcome to the Webinar

FDA-iRISK® 2.0
A Comparative Risk Assessment Tool

March 11, 2015

Today's Speakers

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Acknowledgements:

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

Purpose of Webinar

To introduce FDA-iRISK 2.0, enhanced version of FDA's publicly available food safety risk assessment tool. Available at https://irisk.foodrisk.org.

Today's Presentation

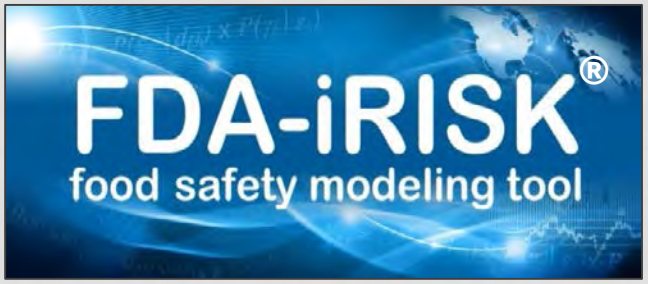
- Overview – purpose of FDA-iRISK
- How FDA-iRISK works
- New features in version 2.0
- Demonstration, examples
- Summary and Q&As

Overview – Purpose of FDA-iRISK

What is FDA-iRISK?

An interactive, Web-based system that enables users to relatively rapidly conduct fully quantitative, fully probabilistic risk assessments of food-safety hazards.

- underwent two external peer reviews of the underlying structure and mathematical equations:
  the first focused on microbial hazards,
  the second focused on chemical hazards.



Why is it important to have FDA-iRISK?

- Allows risk comparisons across many dimensions
  - Hazards, foods, processing/handling practices, population groups
- Predicts risks / compares burdens of illnesses for microbial and chemical hazards
  - Ranks them, e.g. 50 food-hazard pairs, based on a common metric
- Quantifies / compares effectiveness of interventions
  - Predicts reductions in risks and burdens

Faster, user-friendly information for timely decisions

FDA-iRISK – Novel Capacities

Existing Capacities v1.0:

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

Enhancements v2.0:

- **New features added to FDA-iRISK since the first launch**

What FDA-iRISK can do – Example: Rank Risks from Food-Hazard Pairs

Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Illnesses	Mean Risk of Illness	Total DALYs per Year	DALYs Per EO or Consumer
Salmonella in Peanut Butter	N/A	1.70E+10	3340	1.96E-7	63.4	3.73E-9
L. monocytogenes in soft ripened cheese	N/A	1.89E+9	3.36	1.77E-9	19.2	1.02E-8
Aflatoxin B1 in Tortilla Chips	77	2.50E+7	0.811	3.24E-8	15.7	6.30E-7
L. monocytogenes in Cantaloupe	N/A	5.98E+8	2.14	3.58E-9	5.51	9.23E-9
Inorganic Arsenic in Apple Juice	50	1.00E+6	0.105	1.05E-7	1.24	1.24E-6

Note: Risk estimates based on data and assumptions made; apple juice scenario based on draft FDA risk assessment.

Generate a full report, including a summary of risk estimates, ranking results, data, and rationale

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

FDA-iRISK Recent Developments: A Collaboration of Experts

Peer Review I
5 Experts from

- Univ. Florida
- Technical Univ. Denmark
- Univ. Maryland
- Coleman Sci. Consulting
- George Washington Univ. Med. Center

v2.0 Beta-testing
9 Experts from

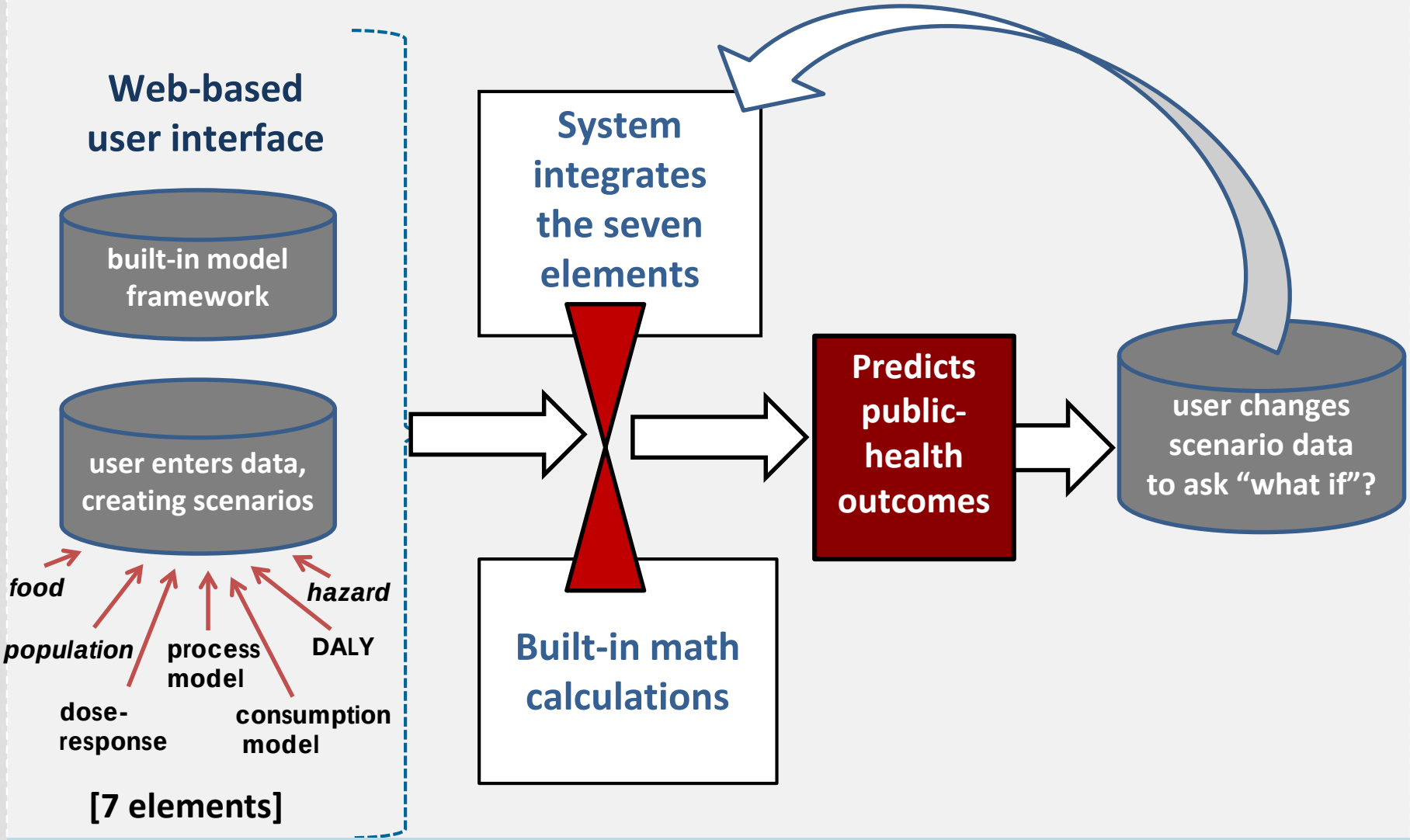
- Rutgers Univ.
- Univ. Florida
- Technical Univ. Denmark
- Health Canada
- ANSES/EFSA work group
- BfR
- Swedish National Food Agency
- Canadian Food Inspection Agency (CFIA)
- Unilever

Peer Review II
5 Experts from

- Technical Univ. Denmark
- Johns Hopkins Bloomberg Sch. Public Health
- Rutgers Robert Wood Johnson Med. School
- CFIA
- Exponent, Inc.

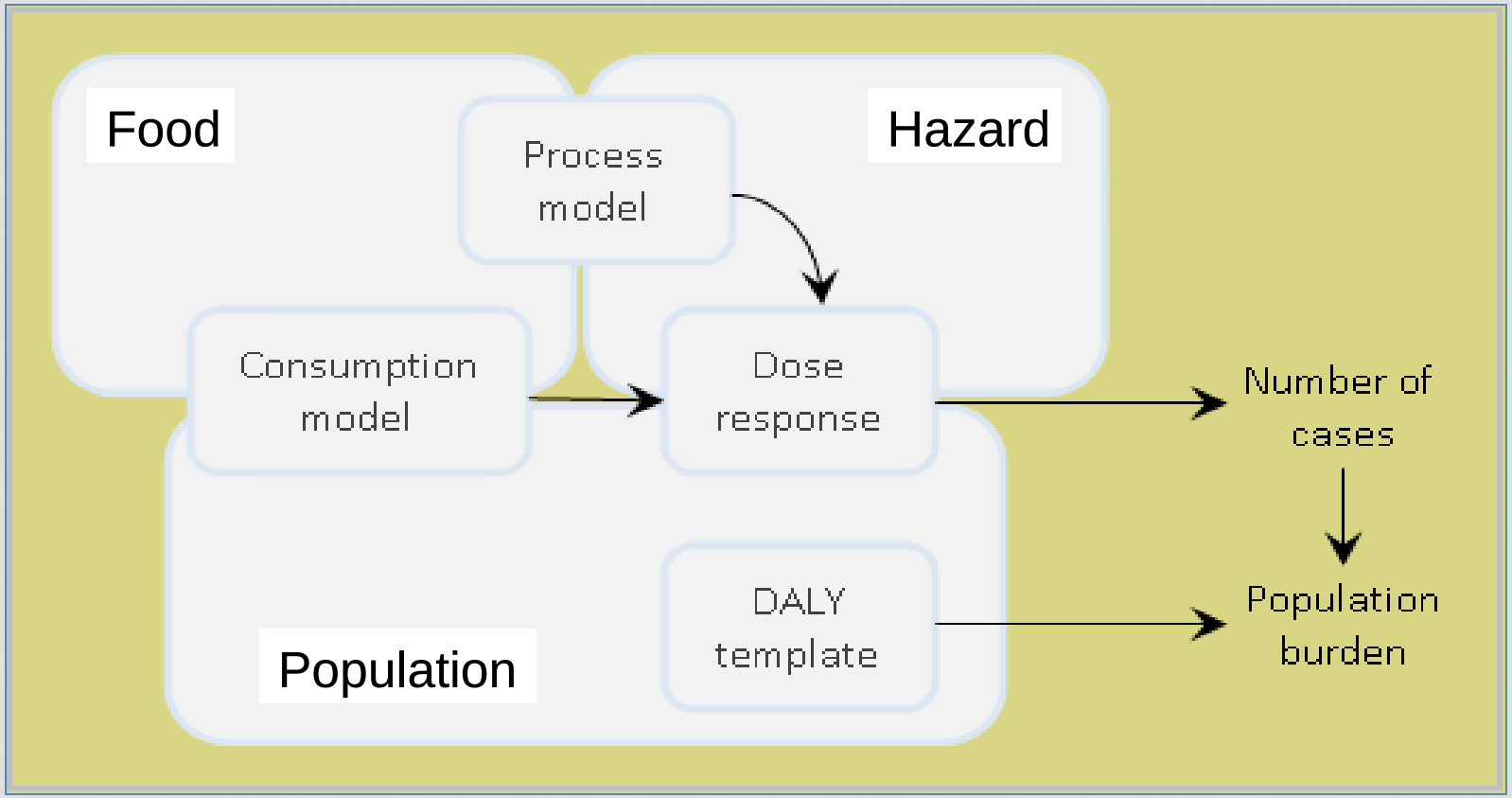
How does FDA-iRISK work?

How FDA-iRISK works

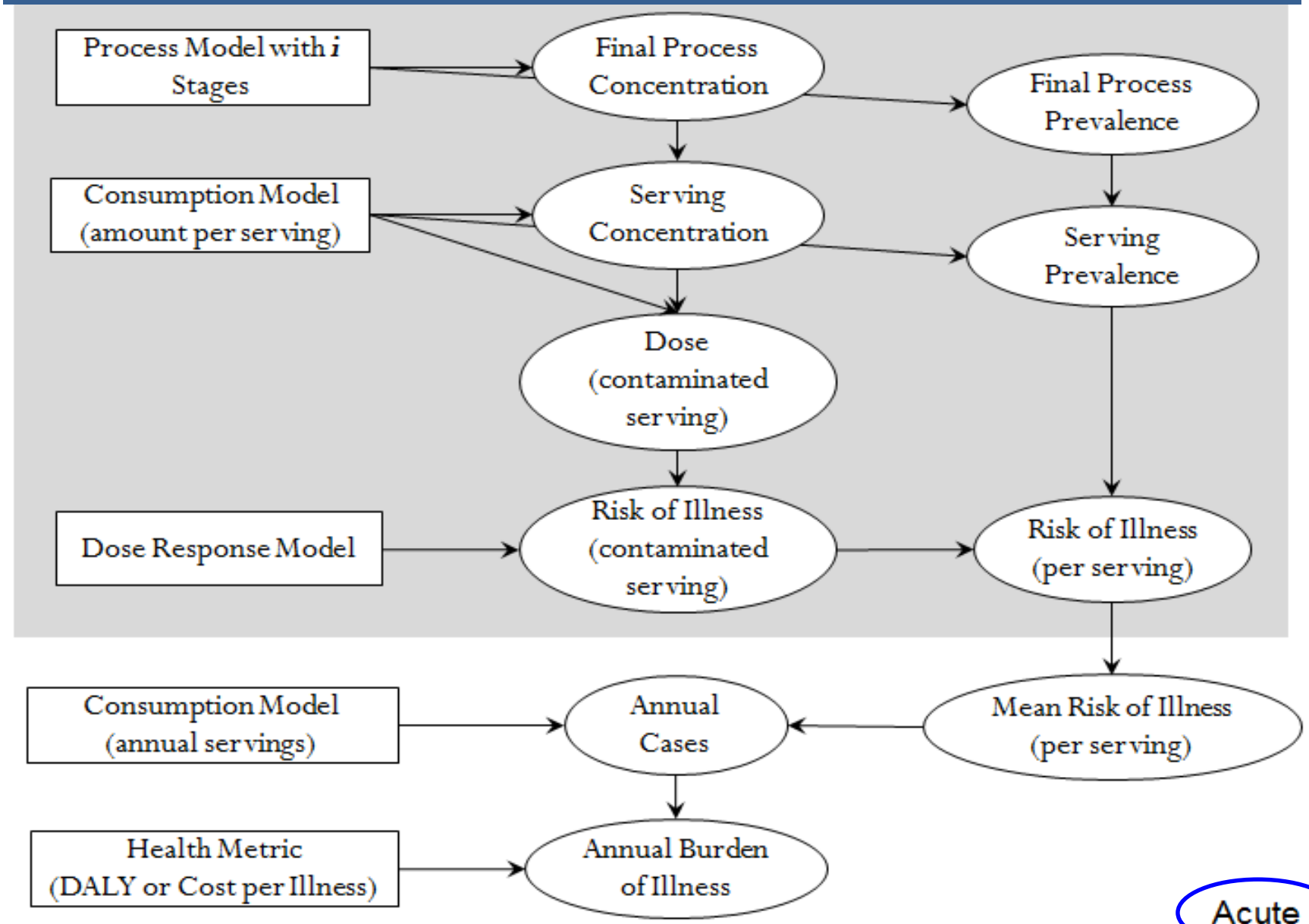


FDA-iRISK captures data from scenarios & outcomes to build a global picture of risks & interventions.

Relationship of the Seven Elements of a Risk Scenario (Risk Model) in FDA-iRISK

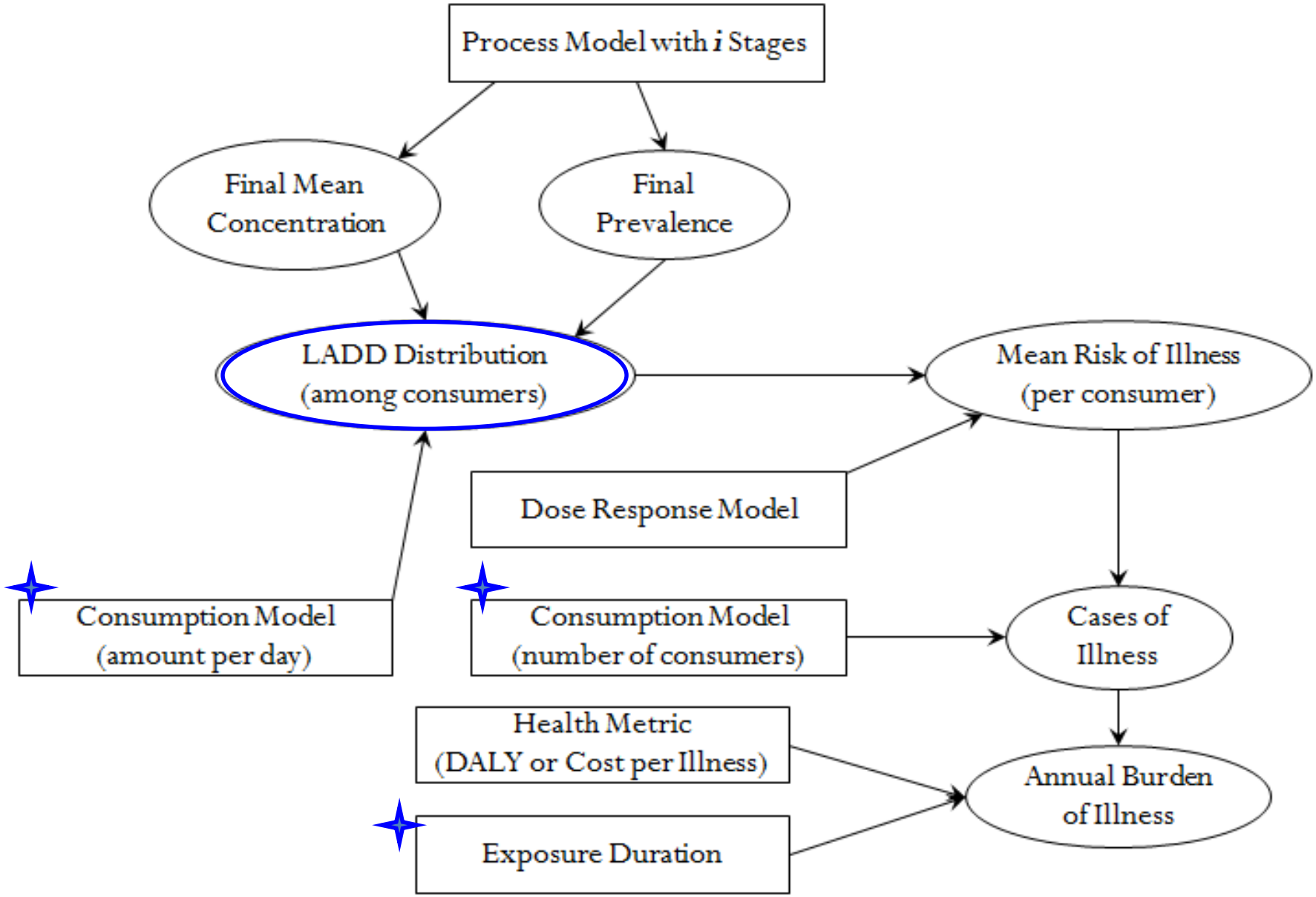


FDA-iRISK Model Structure (Microbial Hazards)



User inputs (data required)

FDA-iRISK Model Structure (Chronic Chemical Hazards)



Any questions about the overview and how FDA-iRISK works?

Send a note to the Q&A box

New Features in FDA-iRISK 2.0

Web Interface: Users Access, Create, Save and Share Scenarios

FDA-iRISK® 2.0 | Home | Models | Reports | Repositories | Help

Home

FDA-iRISK is a web-based system designed to analyze data concerning microbial and chemical hazards in food and return an estimate of the resulting health burden on a population level.

The data required to execute this analysis include the food and its associated consumption data and processing/preparation methods, the hazard and its dose-response curve, and the anticipated health effects of the hazard when ingested by humans. Each of these elements contributes an essential piece of information to the model on which the final estimate of risk is based.

When you register, you will be assigned your own personal workspace in which to model food/hazard risk scenarios. You may also share this workspace with others to view.

For a complete description, review the Quick Start Tutorial and User Guide on the Help page before beginning.

For a list of major changes from Version 1.0, view the What's New in FDA-iRISK 2.0 page.

Please Login or Register.

Suggested Citation

Where the FDA-iRISK system is used in risk assessment research and other food safety activities, reference to the system should be made as follows:

Food and Drug Administration Center for Food Safety and Applied Nutrition (FDA/CFSAN), Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and Risk Sciences International (RSI). 2015. FDA-iRISK version 2.0. FDA CFSAN. College Park, Maryland. Available at https://irisk.foodrisk.org/.

Major New Features added to FDA-iRISK 2.0

- Modeling Capacities
  - Key Computational Improvements
  - Other Computational Improvements
  - Sensitivity Analysis
- User Assistance
  - User Interface Enhancements
  - Upgrades to User Data Management
- Output Formats (PDF, Word, Excel) and Report Layout

… in response to 2nd peer review

Examples of User Input (Data)

Remember… once user defines food, hazard and population, further user input is required to populate

- **Process model**
  - Initial contamination (prevalence, level)
  - Production/processing/handling steps
- **Consumption patterns**
- **Dose-response relationship**
- **Health outcomes**

… i.e., last four elements represented by quantitative data in a **risk scenario**

Key Computational Improvements

- Improved treatment of rare events for "increase by addition" process type (in **process model**)
- Exposure-only scenarios (combine data from **process model** and **consumption patterns**)
- "Behind the scenes"
  - Stability analysis; parallel queuing

FDA-iRISK Process Model

- Provides a template for users to develop a process model with multiple steps, choose a process type, and populate the model with data
- Lists process types through which the hazard concentration and prevalence can change at various steps in food chains, such as:

  growth, inactivation, environmental contamination

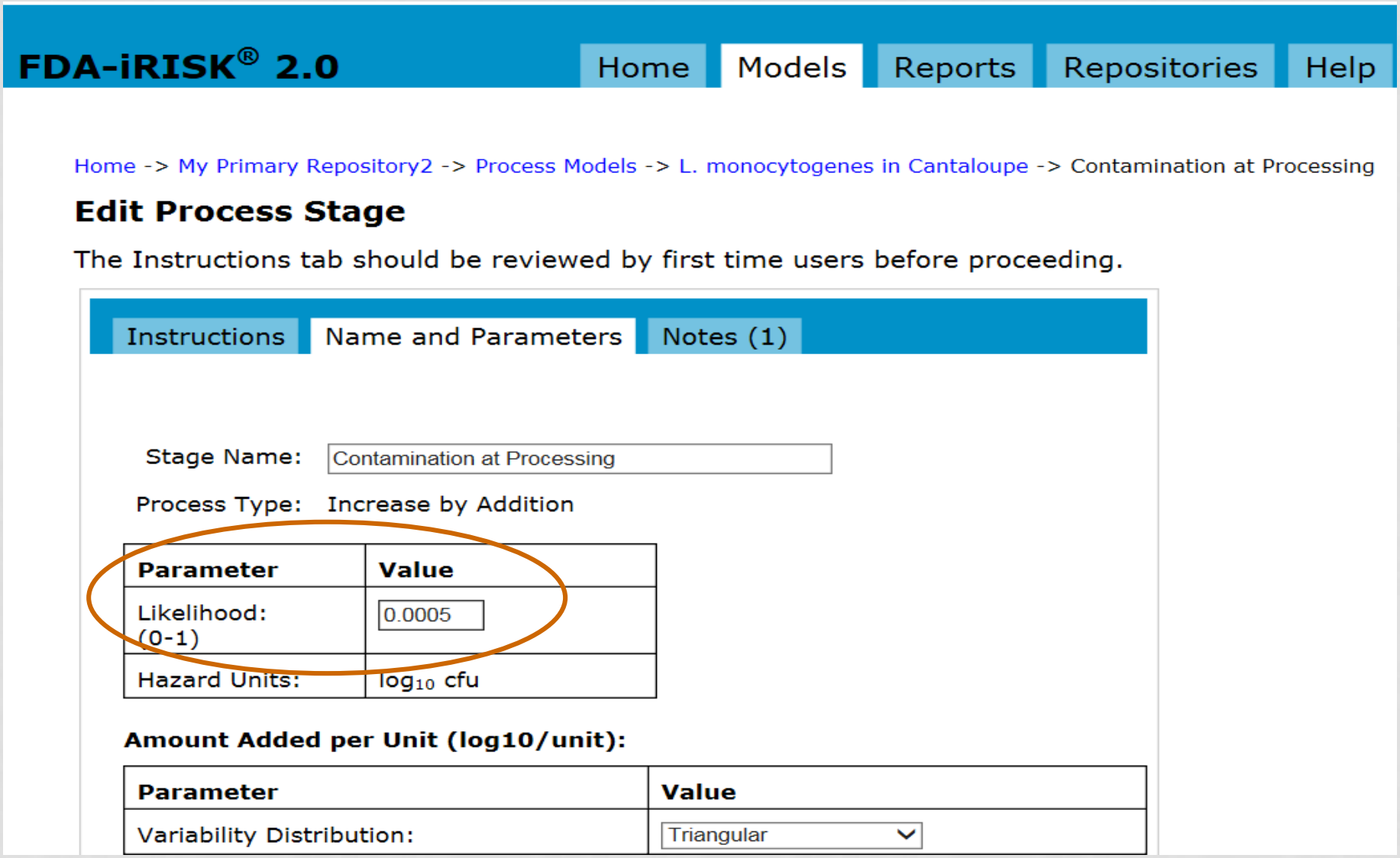
FDA-iRISK Process Model: "Process Types"

- **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

"Increase by Addition" now handles rare event additions

Process Model Example: Improved Treatment of Rare Events



Enable modeling likelihood <0.001

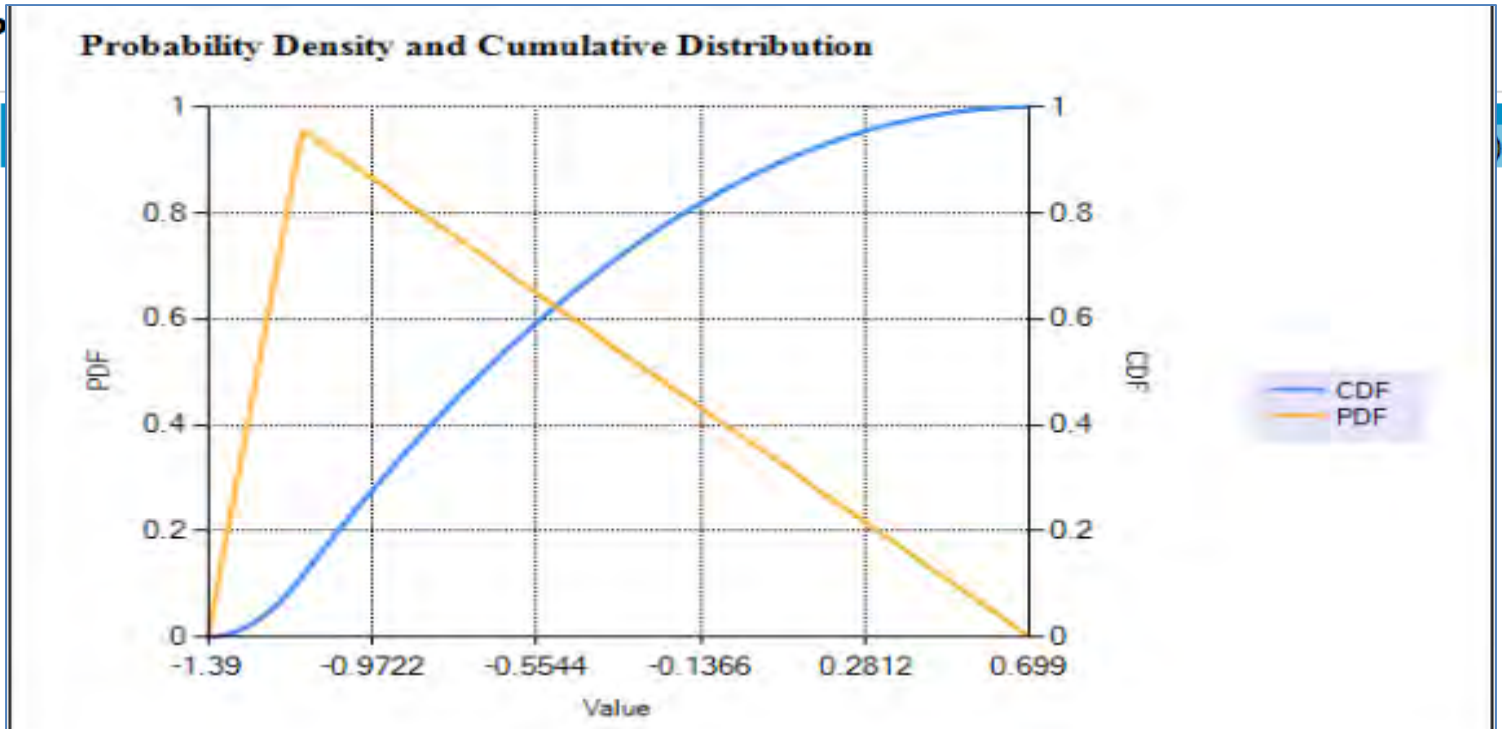
Other Computational Improvements

- Maximum population density (MPD) for microbial hazard (for **process model** initial contamination and as process type)
- Provide choices, g/day or g/kg-day as unit (for chronic **consumption patterns**)
- Toggle on/off “annual scaling” (for chronic **risk scenarios**)

Example: Setting MPD in Process Model

FDA-iRISK® 2.0 | Home | Models | Reports | Repositories | Help

Home -> irisk@foodrisk.org: Primary Repository -> Process Models -> L. monocytogenes in soft ripened cheese



Maximum Population Density (MPD):	
Restrict concentration to MPD:	True
Units:	log_{10} cfu / g
Value:	9

FDA-iRISK Process Model: "Process Types"

- **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

2. Increase by addition

3. Decrease

4. Pooling

5. Partitioning

6. Evaporation or Dilution

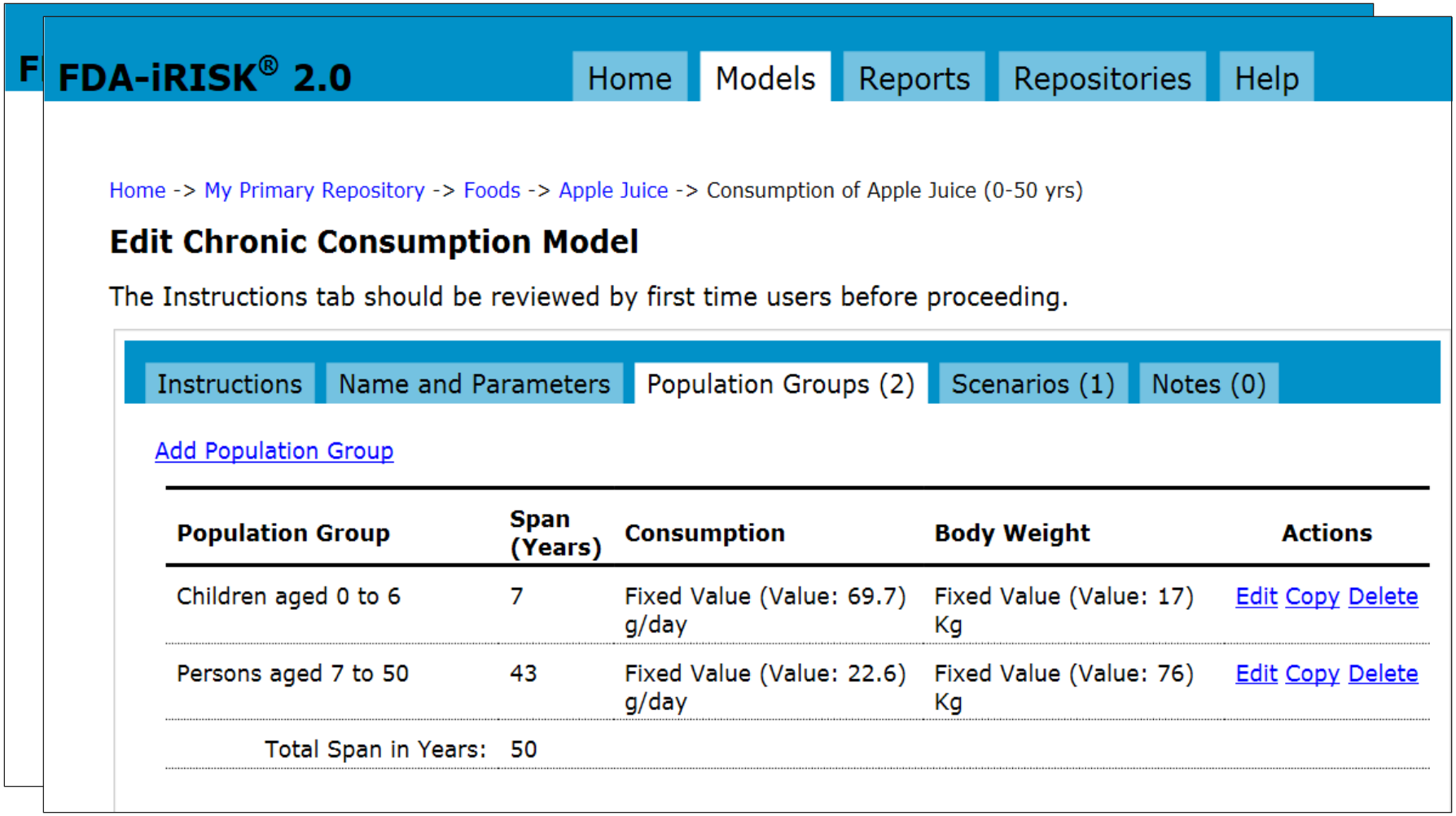
7. Redistribution (partial)

8. Redistribution (total)

9. No change

10. Set Maximum Population Density

Examples: Consumption Patterns

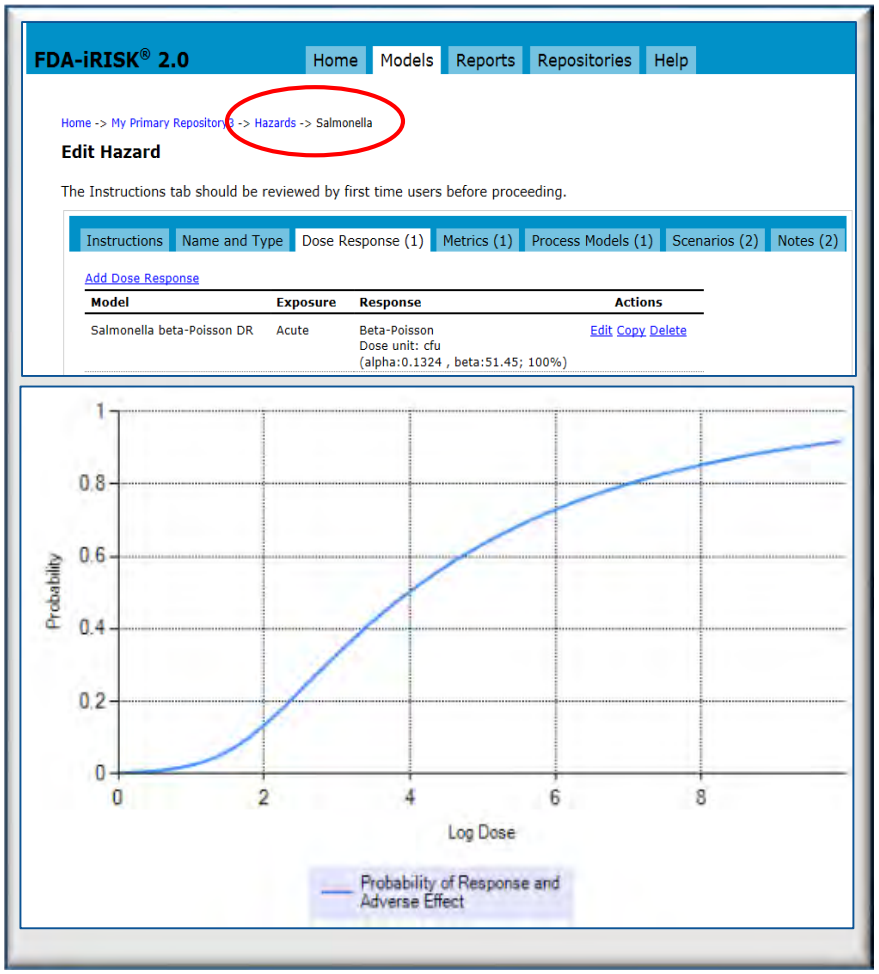


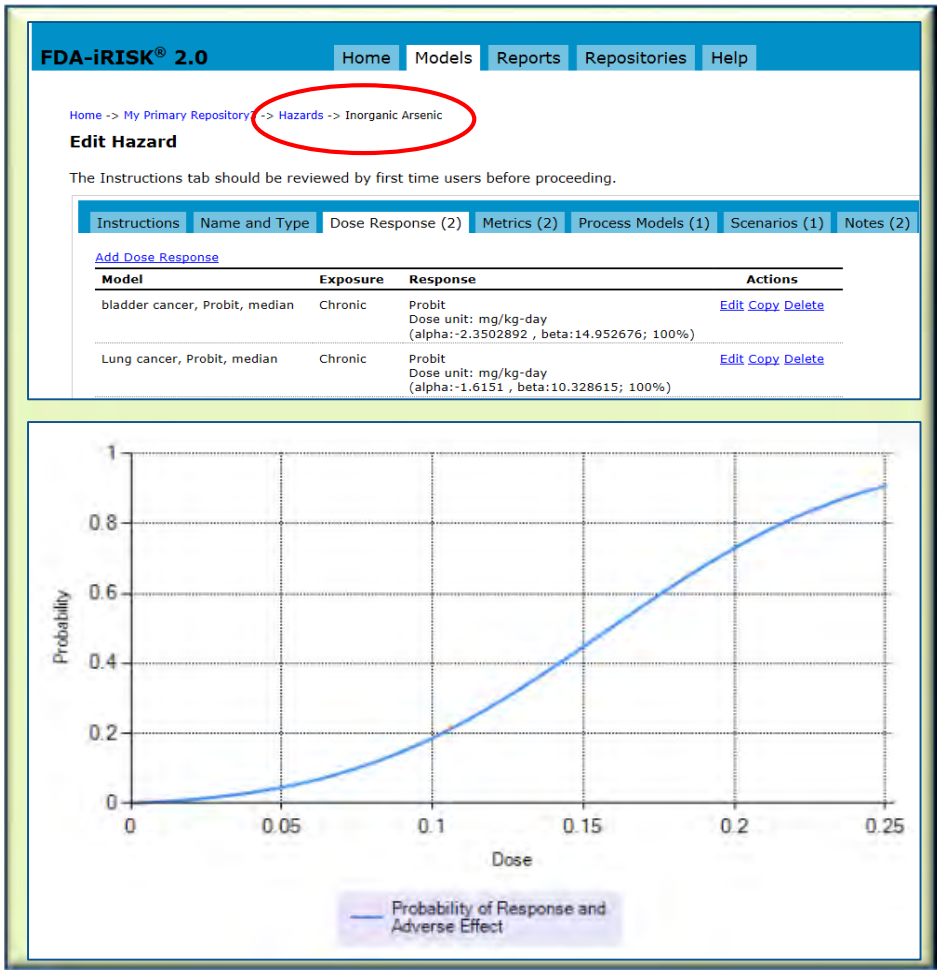
- FDA-iRISK provides templates for users to enter data, for acute exposure (e.g., eating occasions per year) or chronic exposure (e.g., amount per day in life stages) for population groups of interest.

More Computational Improvements

- Additional dose-response curves, e.g.
  - microbial/acute: Threshold Linear, Weibull
  - chemical/chronic: Log-Logistic, Probit, Restricted Weibull
- Additional distributions to characterize variability in contamination and consumption
- Updated treatment of beta-Poisson and exponential dose-response models (exact dose instead of mean dose)

Examples: Dose-Response Model





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

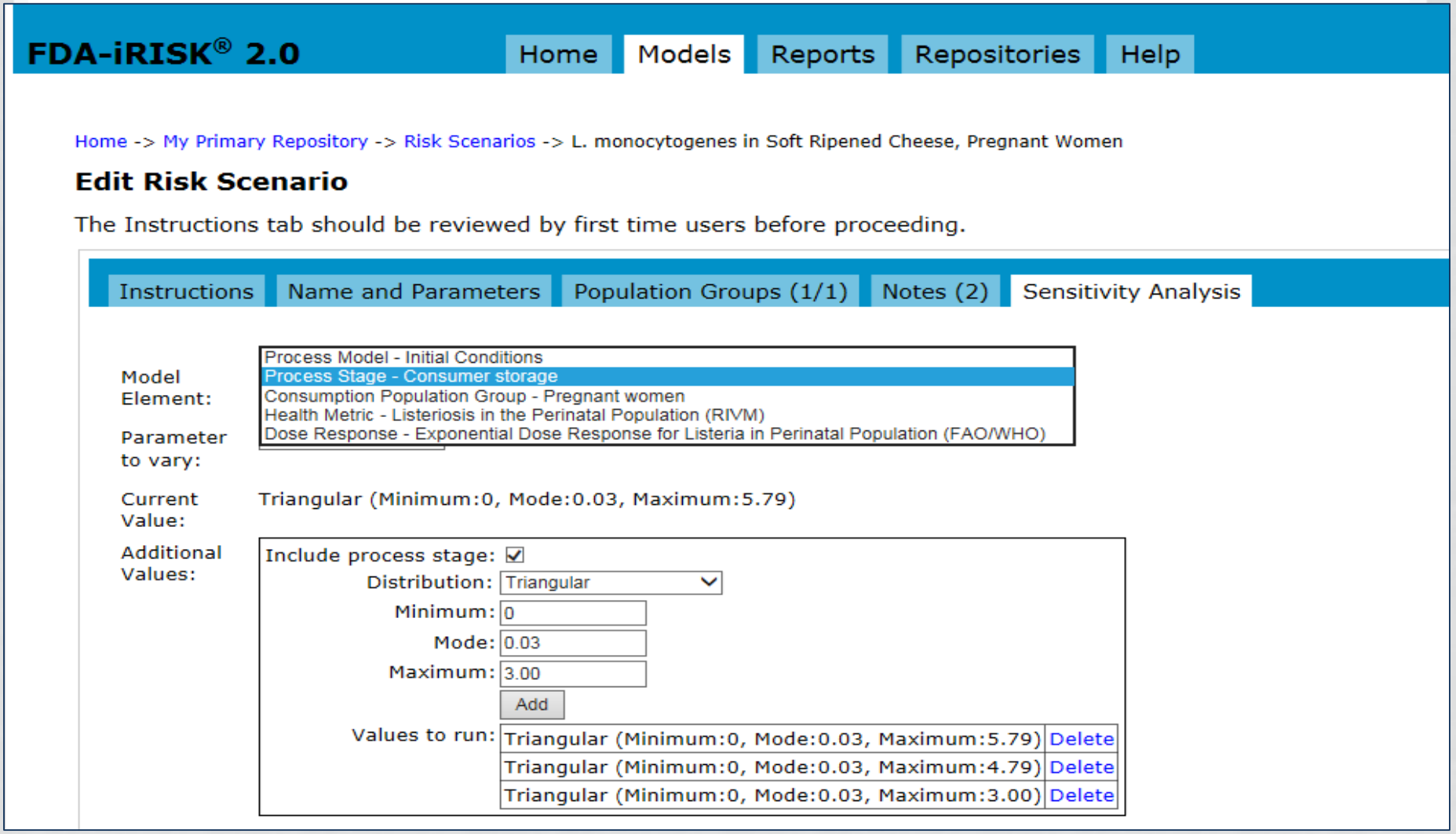
Ask FDA-iRISK – “what if”?

FDA-iRISK allows evaluation of alternative scenarios and specific interventions

- alternative scenarios for dose-response, consumption
- interventions applied at any step(s) of food production / manufacturing / handling, from farm to table

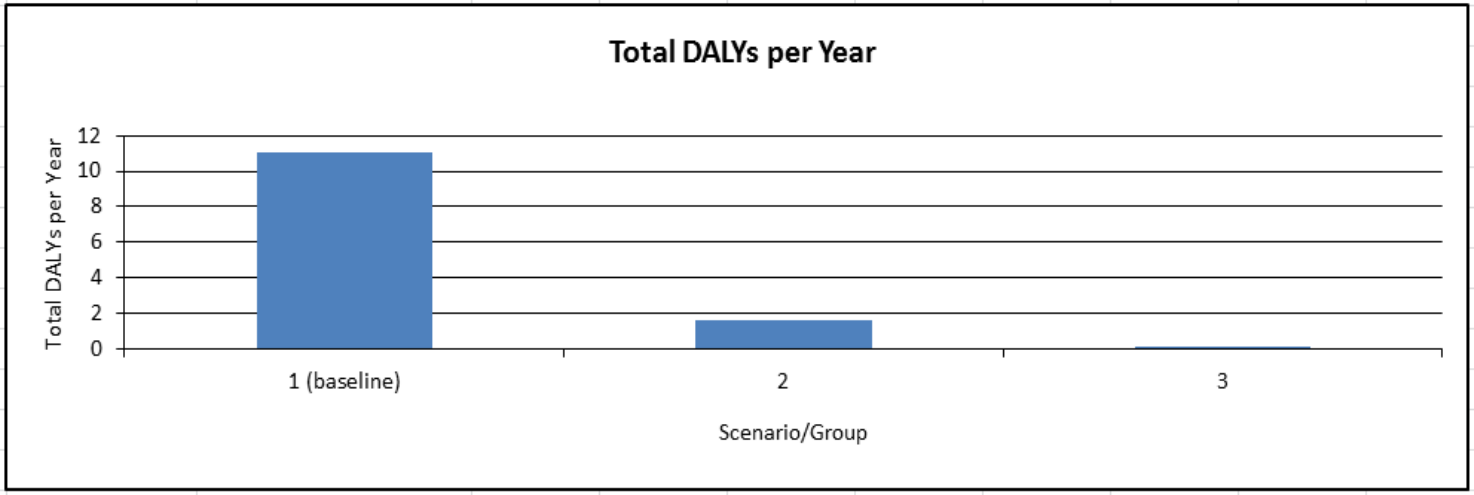
… using a baseline risk scenario

Major New Feature: Sensitivity Analysis



Sensitivity Analysis: Impact of Reducing the Extent of Growth on Burden of Listeriosis - *L. monocytogenes* in Soft Ripened Cheese

Sensitivity Analysis for L. monocytogenes in Soft Ripened Cheese, Pregnant Women



Scenario	Total DALYs per Year	Scenario Name
1 (baseline)	11.1	Process Stage Consumer storage Growth Amount: Triangular (Minimum:0, Mode:0.03, Maximum:5.79)
2	1.59	Process Stage Consumer storage Growth Amount: Triangular (Minimum:0, Mode:0.03, Maximum:4.79)
3	0.0627	Process Stage Consumer storage Growth Amount: Triangular (Minimum:0, Mode:0.03, Maximum:3.00)

User Interface Enhancements

- Additional validation of user inputs
- Plotting of dose-response models
- Plotting of distribution charts
- Improved sorting

Upgrades to User Data Management

- Multiple repositories per user
- Enhanced sharing of repositories
- Import and copy of:
  - Entire repositories
  - Individual model elements

Output Formats and Report Layout

- Word reports
- Excel reports
- Improved report layout
- Choices for risk ranking endpoint
  - DALYs
  - Illnesses
  - Mean risk per serving or per consumer

Live Demonstration

Any questions about the new features and demonstration?

Send a note to the Q&A box

Summary

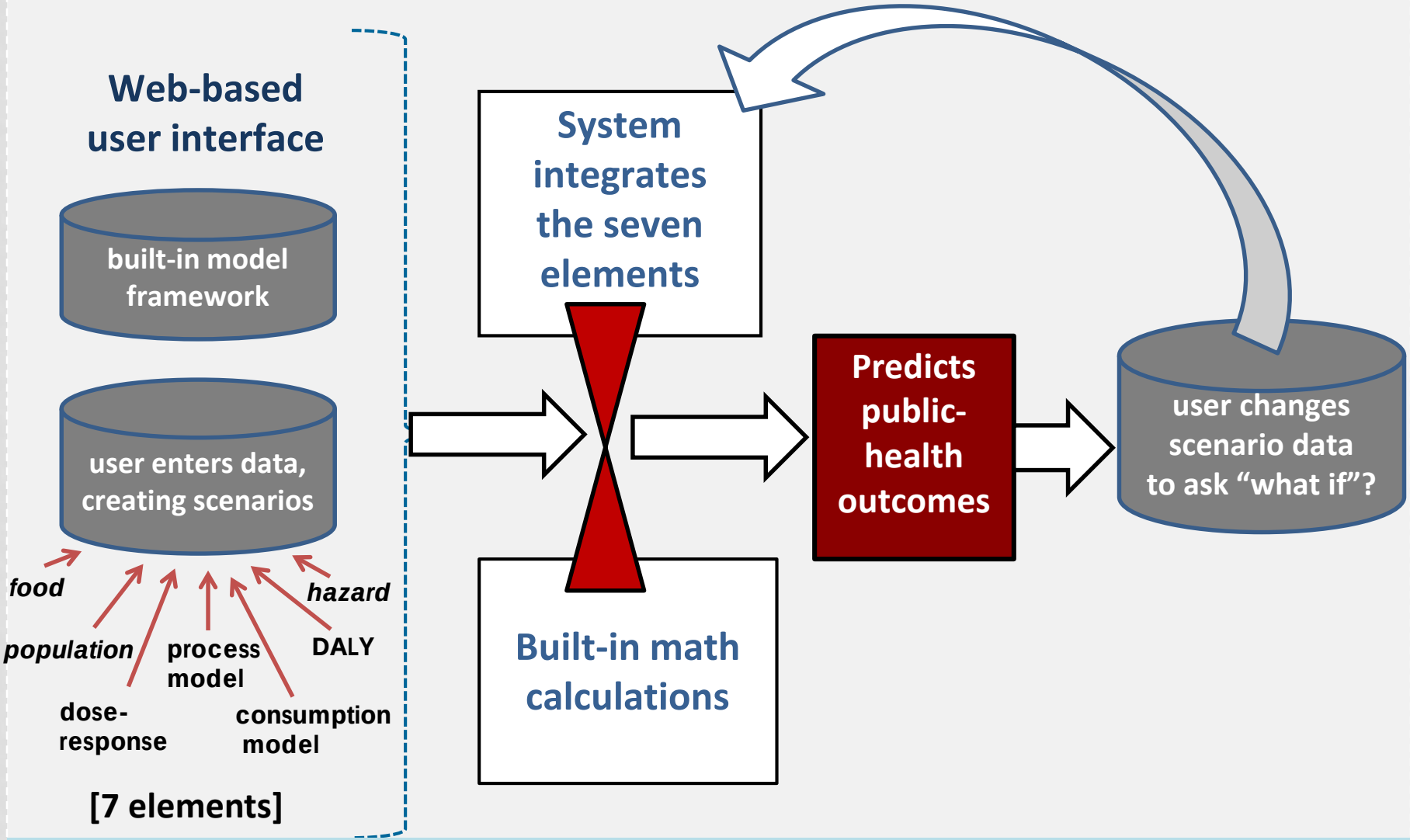
How is FDA-iRISK being used by FDA?

- Building new scenarios and expanding our library of data
  - e.g., *Salmonella* in shell eggs; chemical contaminants in produce
- Linking to external modules/tools to answer new questions
- Enhancing collaborations
  - e.g., with other federal agencies, other countries, private sector

What is Needed to Advance Risk Ranking Tools and their Applications?

- Collaboration and leveraging of resources – government, industry, and academic
  - Research agreements, third party to collect (redact) data
- Articulation of key risk management questions
  - So the "right" scenarios are developed, validated, and deployed
- Collection of data
  - Specific hazards/commodities at specific points throughout the food supply chain: prevalence, enumeration, transfer rate, growth, inactivation
  - Variability and uncertainty for baseline "normal" and "outbreak"

Summary: Overarching View of FDA-iRISK



FDA-iRISK captures data from scenarios & outcomes to build a global picture of risks & interventions.

Acknowledgements

We are grateful to the many experts who provided invaluable input and critique to assist in the development and refinement of the FDA-iRISK system, both v1.0 and v2.0, including Risk Sciences International, members of the IFT expert panel, RTI International, external peer reviewers, and beta-testing experts.

Further information about FDA-iRISK 2.0

Visit FoodRisk.org

http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/

https://irisk.foodrisk.org

Visit FDA risk assessment web page

http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm