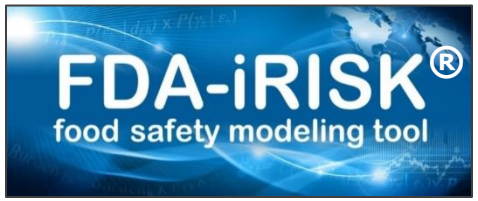
U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

FDA-iRISK® 5.0
A Comparative Risk Assessment Tool

March 12, 2026



Today's Speakers

Jane Van Doren, FDA

Yuhuan Chen, FDA

Greg Paoli, RSI

Acknowledgements:

- Kara Dean, FDA (moderator)
- JIFSAN staff (webinar support)

Purpose of Webinar

To introduce FDA-iRISK 5.0, enhanced version of FDA's publicly available food safety risk assessment tool.

Available at https://irisk.foodrisk.org.

Today's Presentation

- Overview of purpose of FDA-iRISK
- How FDA-iRISK works
  - New features in version 5.0
  - New case studies
- Demonstration and examples
- Summary

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 multiple external peer reviews of the underlying model structure and mathematical equations:**
  - focused on microbial and chemical risk assessments
  - focused on 2D simulation, streamlined sensitivity analysis, linkages, and shared access
  - the latest peer review focused on expanded linkages, flexible approach to defining diets, correlated consumption across life stages, and visualization

Enhancements in v5.0: New features released in FDA-iRISK 5.0 at https://irisk.foodrisk.org

FDA-iRISK Development: A Collaboration of Experts

- Peer reviews (I,II&III) experts from: Univ. Maryland, Univ. Florida, Technical Univ. Denmark, George Washington Univ. Med. Center, Johns Hopkins Bloomberg Sch. Public Health, Rutgers Robert Wood Johnson Med. School, Coleman Sci. Consulting, Exponent, Texas A&M Univ., CFIA, ANSES
- Peer reviews (IV&V) experts from: Technical Univ. Denmark, Statens Serum Inst. Denmark; ANSES, Exponent, Rutgers Univ.

- Beta-testing experts from: Rutgers Univ., Univ. Florida, Technical Univ. Denmark, ANSES/EFSA work group, BfR, Swedish National Food Agency, CFIA, Health Canada, Unilever, Nestle, USDA/FSIS

Purpose of FDA-iRISK: Why invest in risk assessment models/tools?

- Allows risk comparisons across many dimensions
- Predicts risks / compares burdens of illnesses for microbial and chemical hazards, as well as risks/benefits of dietary patterns
- Quantifies / compares effectiveness of interventions
- Separates/ quantifies impact of variability from that of uncertainty in outcomes of a risk assessment

Faster, user-friendly information for timely decisions

Purpose of FDA-iRISK: One of Important Risk Assessment Tools

- **Informs risk managers of where to look to:**
  e.g., prioritize risks and allocate resources effectively
- **Allows risk managers to evaluate effectiveness of interventions:**
  e.g., potential or equivalent control measures,
  contribution of compliance to risk management
- **Informs risk communicators in:**
  e.g., developing communication/outreach messages
  focusing on population sub-groups “at increased risk”

Inform Decisions

Recent Case Studies using FDA-iRISK

RESEARCH ARTICLE (https://doi.org/10.1371/journal.pone.0322948)

Rapid risk assessment to address emerging concerns of HPAI in raw and pasteurized milk

Yuhuan Chen[1], Kara J. Dean[1], Gavin J. Fenske[1], Sarah I. Murphy[1], Alexandra Gavelek[1], Régis Pouillot[2], Jane M. Van Doren[1]*, Sherri Dennis[1]

1 Human Foods Program, U.S. Food and Drug Administration, College Park, Maryland, United States of America, 2 Goldbelt C6, LLC, Chesapeake, Virginia, United States of America

* jane.vandoren@fda.hhs.gov

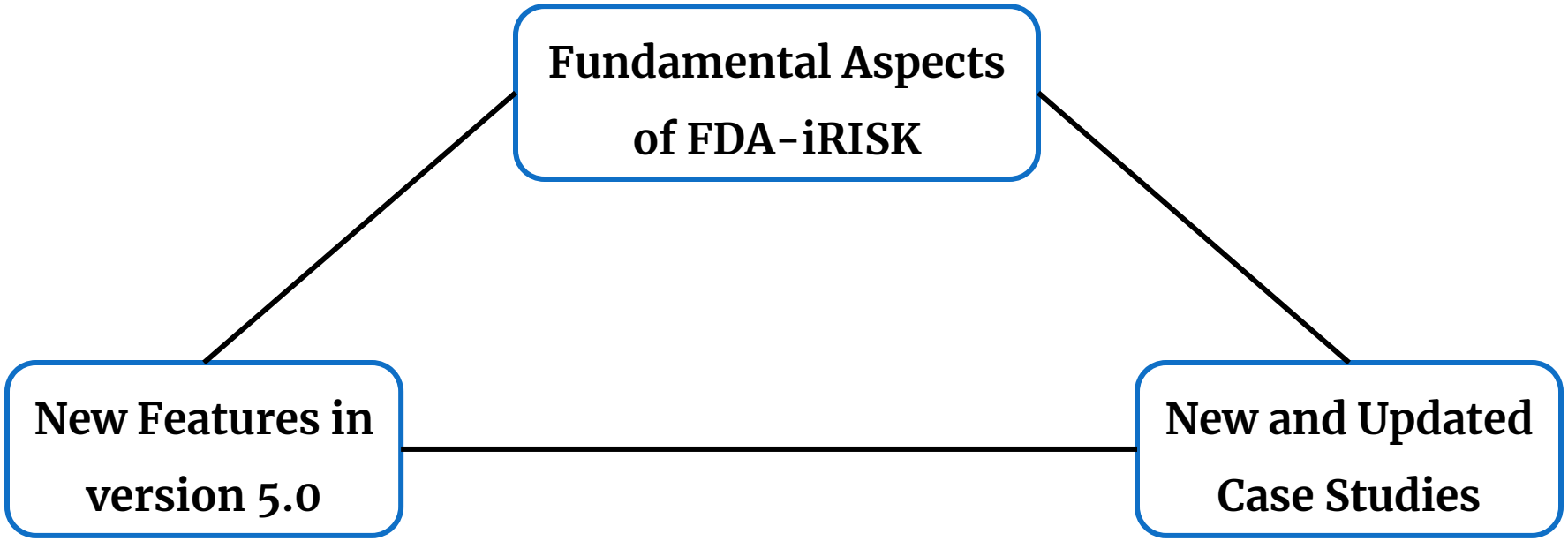
Research Paper (https://doi.org/10.1016/j.jfp.2025.100478)

Modeling the Impact of Between-lot and Within-lot Variability in *Listeria monocytogenes* Contamination on Risk Reduction From Sampling Ready-to-eat Foods

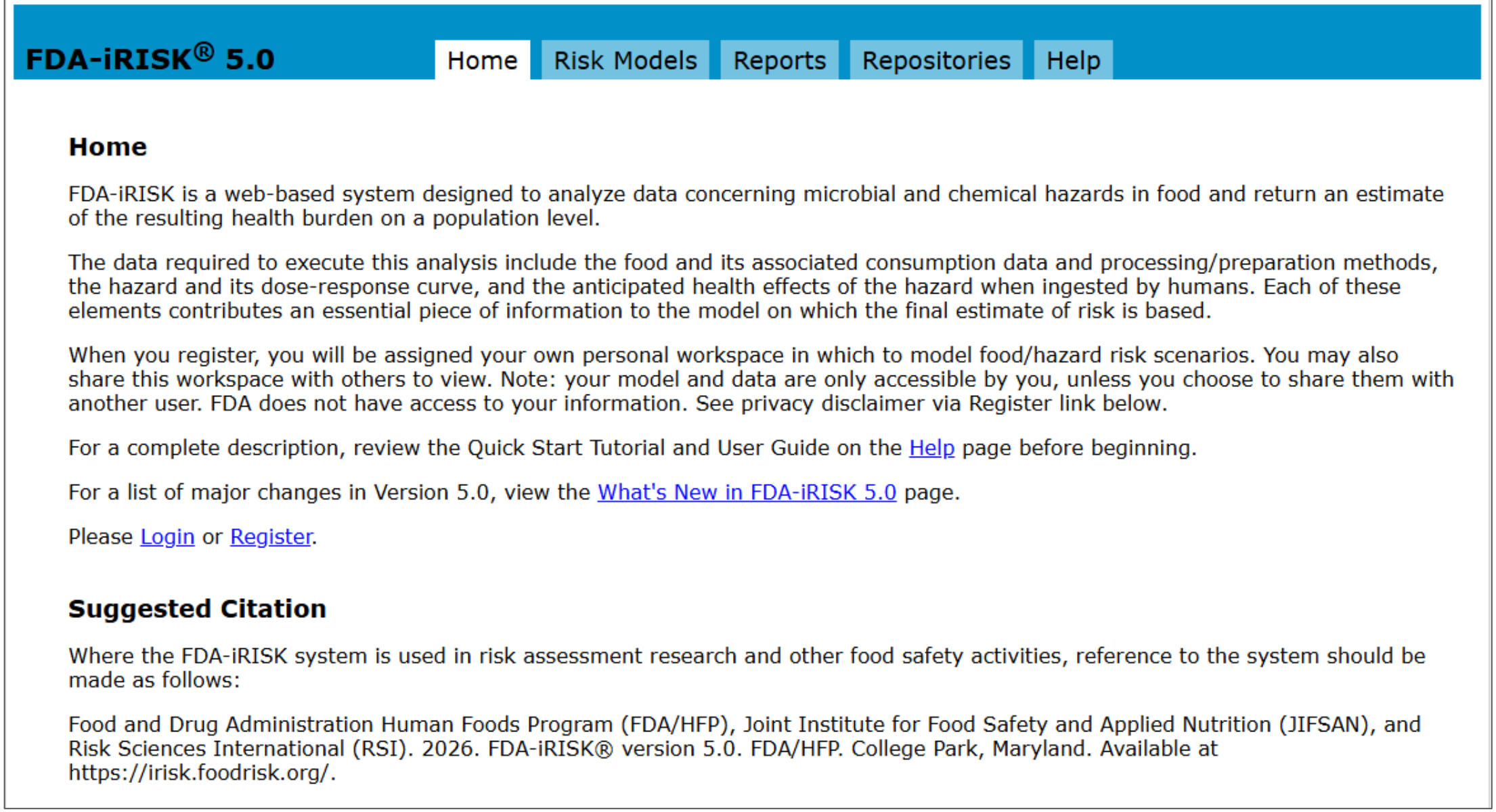
Yuhuan Chen [1,*], Régis Pouillot [2], Jane M. Van Doren [1]

[1] *Human Foods Program, U.S. Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, USA*
[2] *Consultant, 18 rue Mohamed Al Ghazi, Rabat 10170, Morocco*

How does FDA-iRISK work?



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



Fundamental Aspects of FDA-iRISK

- Provides a model framework, built-in functions, and data-entry templates
  - Enables users to enter data and build scenarios
- Directly connects data on probability and consequence through specification of a Risk Scenario (a risk assessment model)
  - Specific to food-hazard combinations
  - Describing key aspects and conditions of the hazard, the food, and the processing of the food as it relates to the fate of the hazard in the food.

What FDA-iRISK can do – Example: Rank Risks from Hazards in Single Food and Multiple Foods

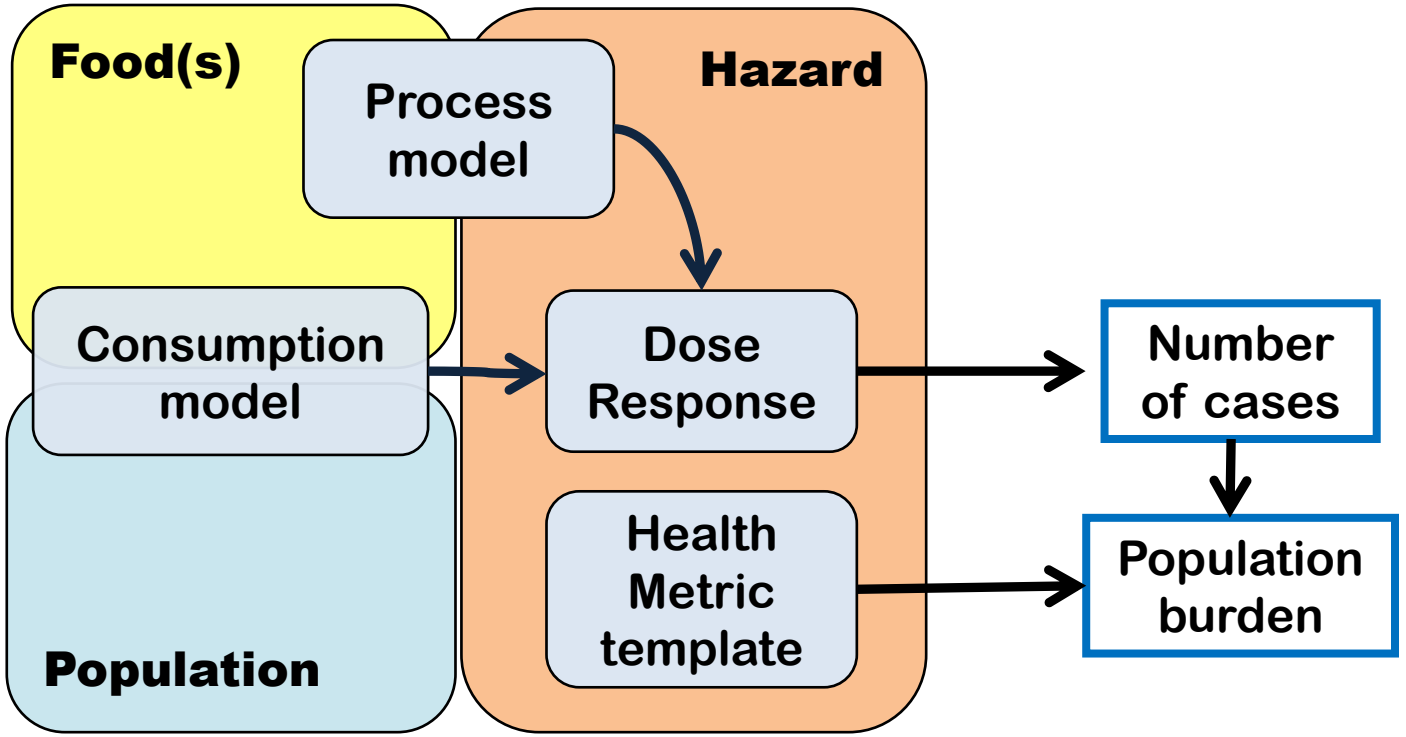
Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Illnesses	Mean Risk of Illness	Total DALYs per Year	DALYs Per EO or Consumer
06_L. monocytogenes in Cantaloupe (among 65+ subpopulation)	N/A	5.98E+8	73.8	1.24E-7	190	3.19E-7
08_Salmonella in peanut butter	N/A	1.70E+10	3280	1.93E-7	62.4	3.67E-9
07_L. monocytogenes in soft ripened cheese	N/A	1.89E+9	2.79	1.48E-9	15.7	8.27E-9
v5_05_Inorganic Arsenic in Multiple Foods: Apple Juice, Pear Juice, White Rice, Brown Rice	50	1.00E+6	0.802	8.02E-7	9.53	9.53E-6

Note: risk estimates based on data and assumptions made; for illustration purposes only.

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

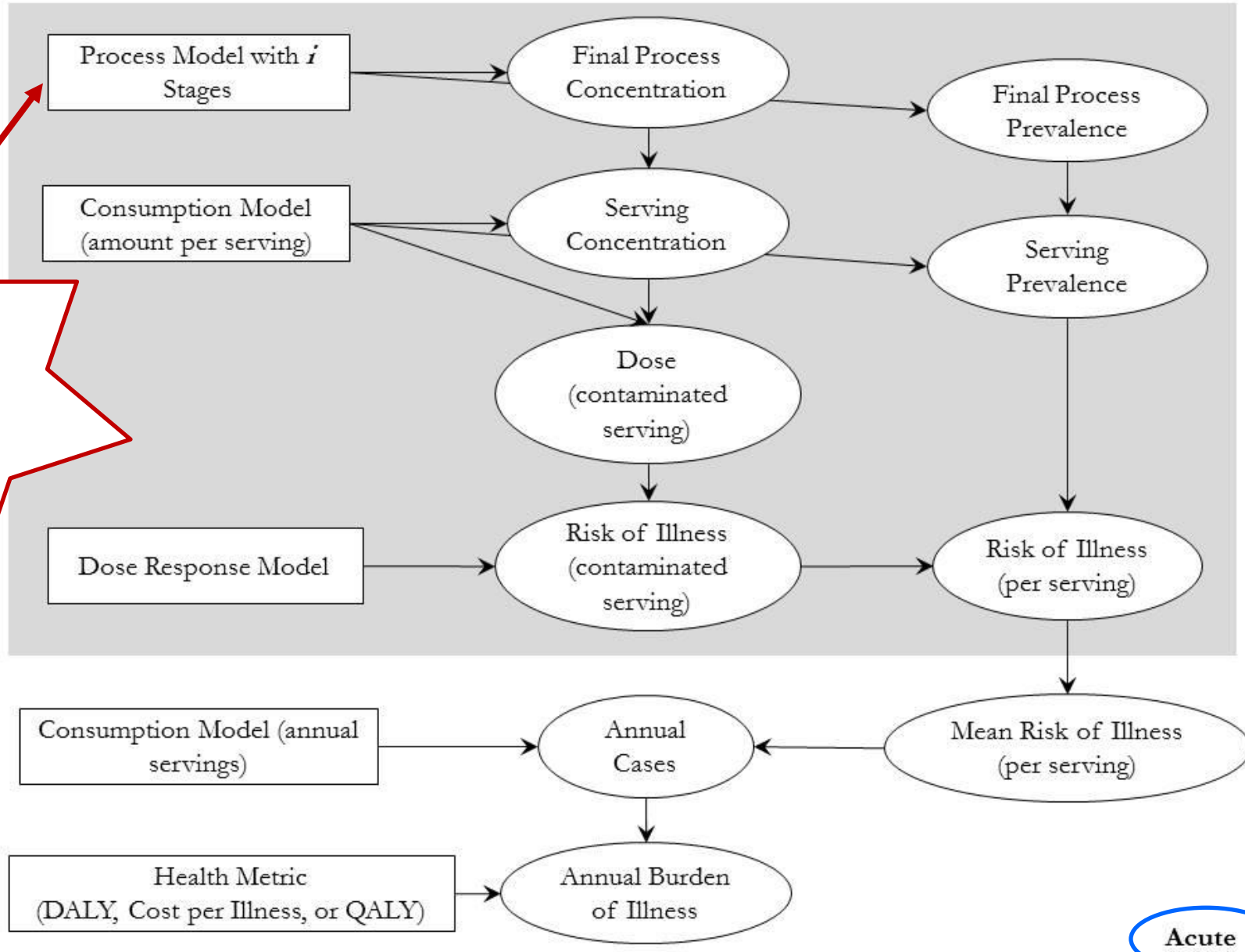
For acute exposure, option to estimate DALYs per Person per Year

Risk Scenarios (Risk Assessment Models) Developed in FDA-iRISK



(Built upon well-established risk assessment methodologies, consistent with Codex working principles. https://irisk.foodrisk.org/Documents/FDAiRISKTechnicalDocumentation.pdf)

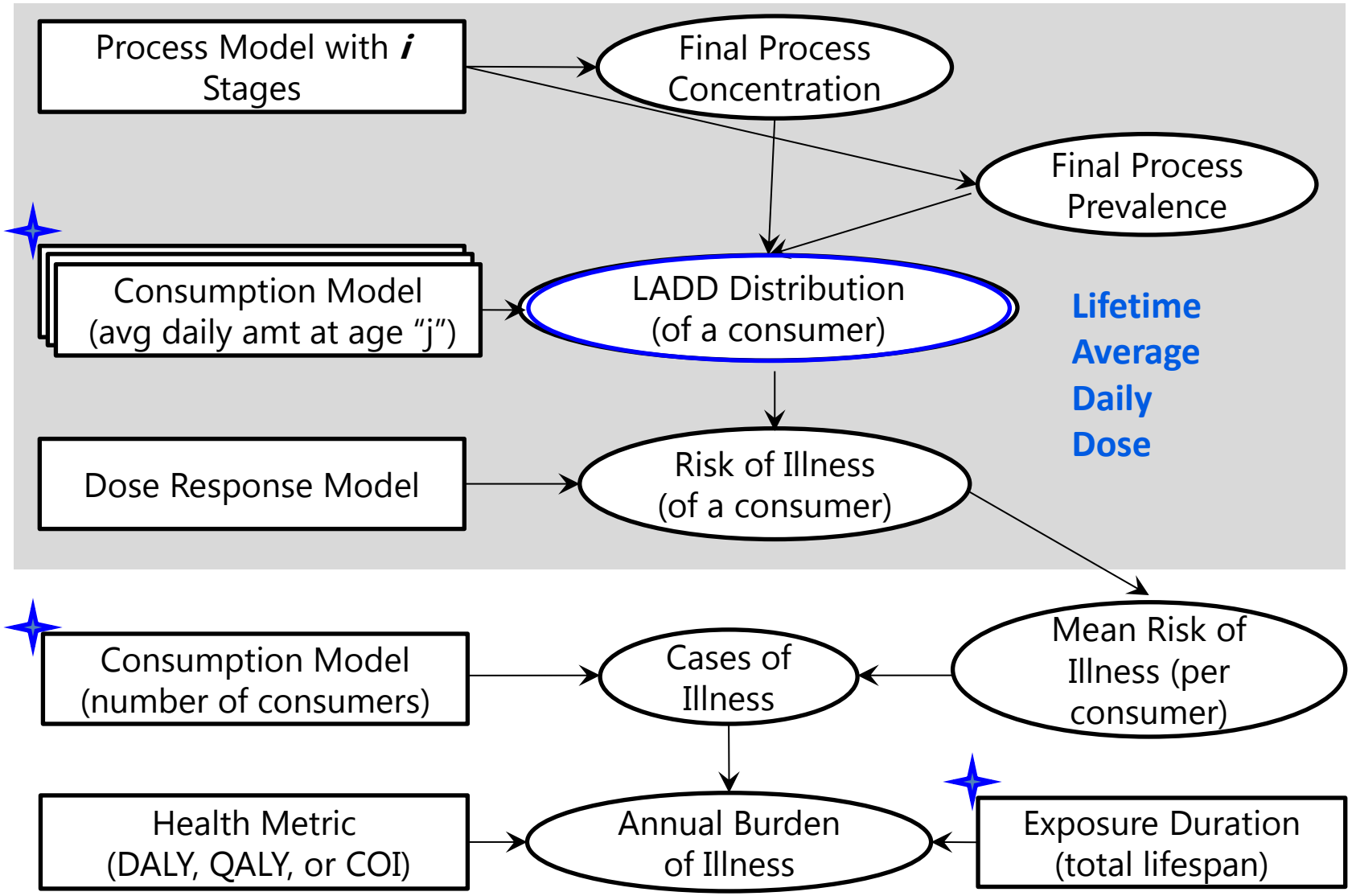
FDA-iRISK Model Structure (Microbial Hazards)



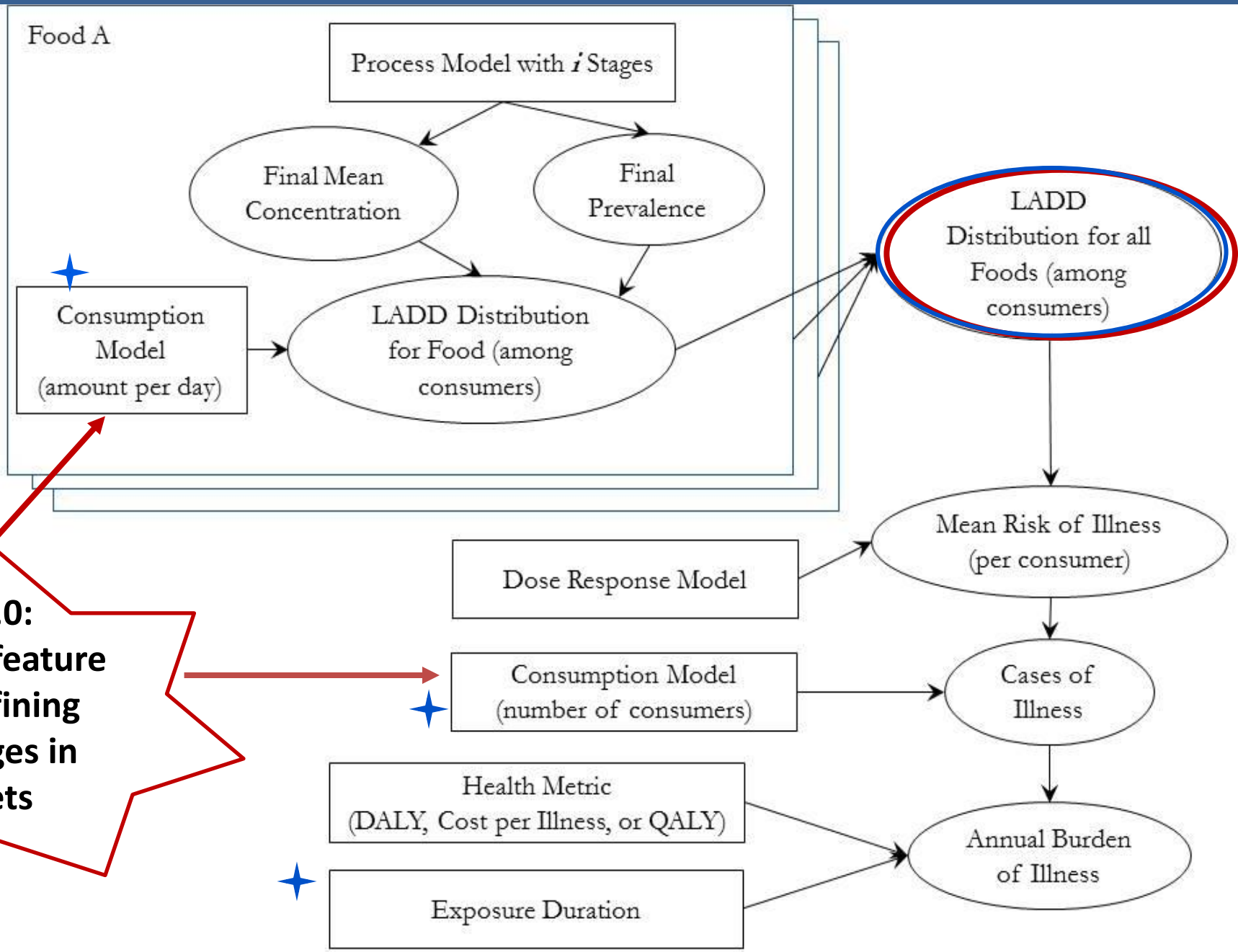
v5.0:
A new feature of linkage to external tools and databases

User inputs (data required)

FDA-iRISK Model Structure (Chronic Chemical Hazards)



FDA-iRISK Model Structure (Chronic Chemical Multifood)



v5.0: A new feature of defining changes in diets

Probabilistic Risk Assessment: Evaluating Convergence for Simulation

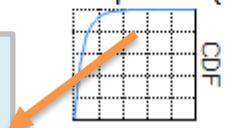
Appropriately evaluate rare event and right-skewed concentration distribution

Scenario Details for: 06_L. monocytogenes in Cantaloupe (among 65+ subpopulation)

Type:	Results Computed	Scenario Weight:	N/A
Hazard:	L. monocytogenes (Microbial Pathogen)	Metric Type:	DALY
Food:	Cantaloupe	Exposure Type:	Acute
Process Model:	L. monocytogenes in Cantaloupe	Converged:	Yes (by 264000 variability samples)
Consumption Model:	Cantaloupe Consumption 65+	Include Uncertainty:	No

Add Process Stage

Stage Name	Process Type	Definition
Handling at home	Increase by Addition	Triangular (Minimum: 0, Mode: 0.5, Maximum: 1) $\log_{10}$ cfu; Likelihood (5E-4)
Consumer Storage	Increase by Growth	Empirical (linear)



Amount of growth: overall 0.4-7.7 $\log_{10}$ CFU (0.8% probability 3.1-7.7 log, and 0.06% probability 5.0-7.7 log)

Report History | New Report | Simulation Settings

ls are required

lation setting set to view/edit from the list. Use
nty for risk estimates and ranking reports. The s
s set as selected first.

Select Set: Moderate Run (selected) | Load Set | Create New Set

Set Name: Moderate Run

Selected: True

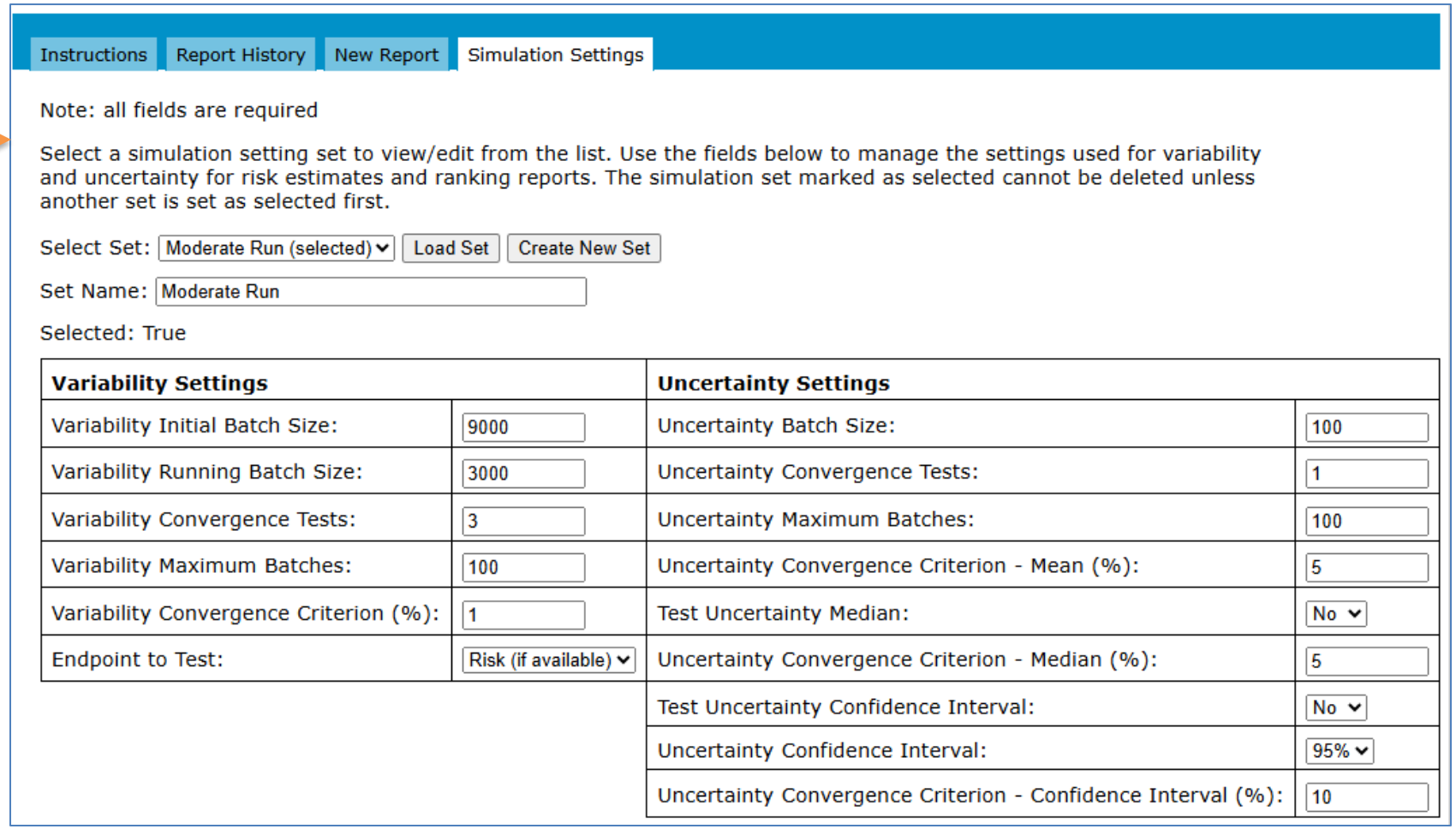
Variability Settings	
Variability Initial Batch Size:	9,000
Variability Running Batch Size:	3,000
Variability Convergence Tests:	3
Variability Maximum Batches:	100
Variability Convergence Criterion (%):	1
Endpoint to Test:	Risk (if available)

Note: estimates based on data and assumptions made; for illustration purposes only.

2D Monte Carlo Simulation in FDA-iRISK

Enables simultaneously and separately considering variability and uncertainty

- Simulation Settings (default settings)
- Settings are user-customizable **(advanced users)**; can define multiple sets of settings



Instructions | Report History | New Report | Simulation Settings

Note: all fields are required

Select a simulation setting set to view/edit from the list. Use the fields below to manage the settings used for variability and uncertainty for risk estimates and ranking reports. The simulation set marked as selected cannot be deleted unless another set is set as selected first.

Select Set: Moderate Run (selected) | Load Set | Create New Set

Set Name: Moderate Run

Selected: True

Variability Settings		**Uncertainty Settings**	
Variability Initial Batch Size:	9000	Uncertainty Batch Size:	100
Variability Running Batch Size:	3000	Uncertainty Convergence Tests:	1
Variability Convergence Tests:	3	Uncertainty Maximum Batches:	100
Variability Maximum Batches:	100	Uncertainty Convergence Criterion - Mean (%):	5
Variability Convergence Criterion (%):	1	Test Uncertainty Median:	No
Endpoint to Test:	Risk (if available)	Uncertainty Convergence Criterion - Median (%):	5
		Test Uncertainty Confidence Interval:	No
		Uncertainty Confidence Interval:	95%
		Uncertainty Convergence Criterion - Confidence Interval (%):	10

What v5.0 can do – example: Probabilistic Modeling of Uncertainty and Visualization

Risk estimates show uncertainty results in percentiles

Ranking Summary

All reported summary values are per lifecourse duration.

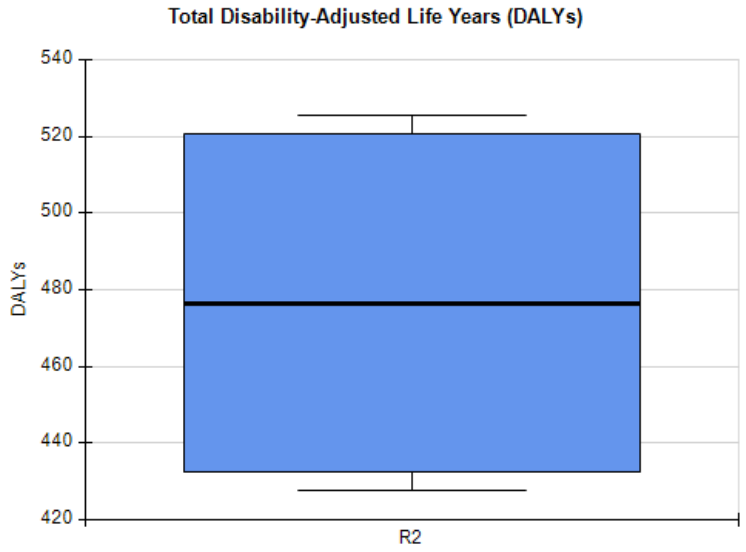
Scenario or Scenario Group
v5_05_Inorganic Arsenic in Apple Juice P Brown Rice (consumption correlation)

Chronic scenarios are NOT scaled by lifecou

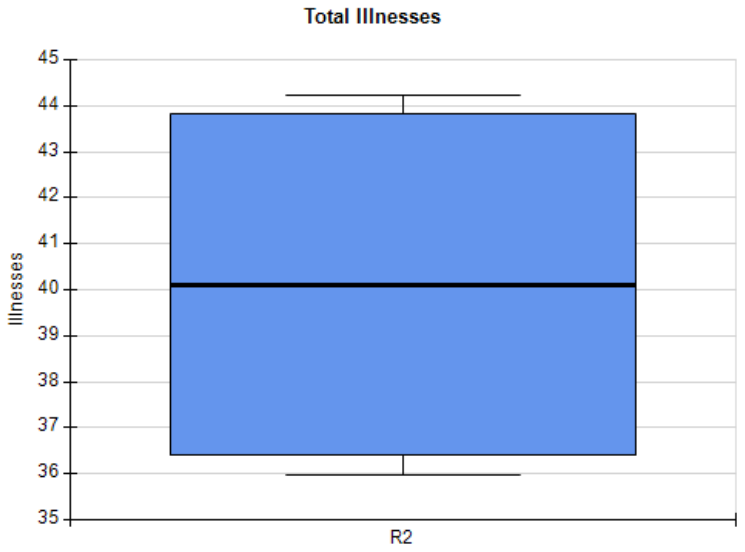
Scenario or Scenario Group
v5_05_Inorganic Arsenic in Apple Juice Brown Rice (consumption correlation)

Note: All chronic results have been compu
value for ranking. See the detailed results
duration of the lifecourse.

Uncertainty Results



5th and 95th percentiles (box), minimum and maximum values (whiskers), median (solid line), and mean (dotted line).



5th and 95th percentiles (box), minimum and maximum values (whiskers), median (solid line), and mean (dotted line).

Note: estimates based on data and assumptions made; for illustration purposes only.

New Features in FDA–iRISK 5.0

New Features added to FDA-iRISK 5.0

- Advanced modeling capacities
- Data importing and sharing
- Results visualizations
- Ease of utilizing model elements saved in repository

… in response to peer reviews and comments on long term development from peer reviews

New Features in FDA-iRISK 5.0

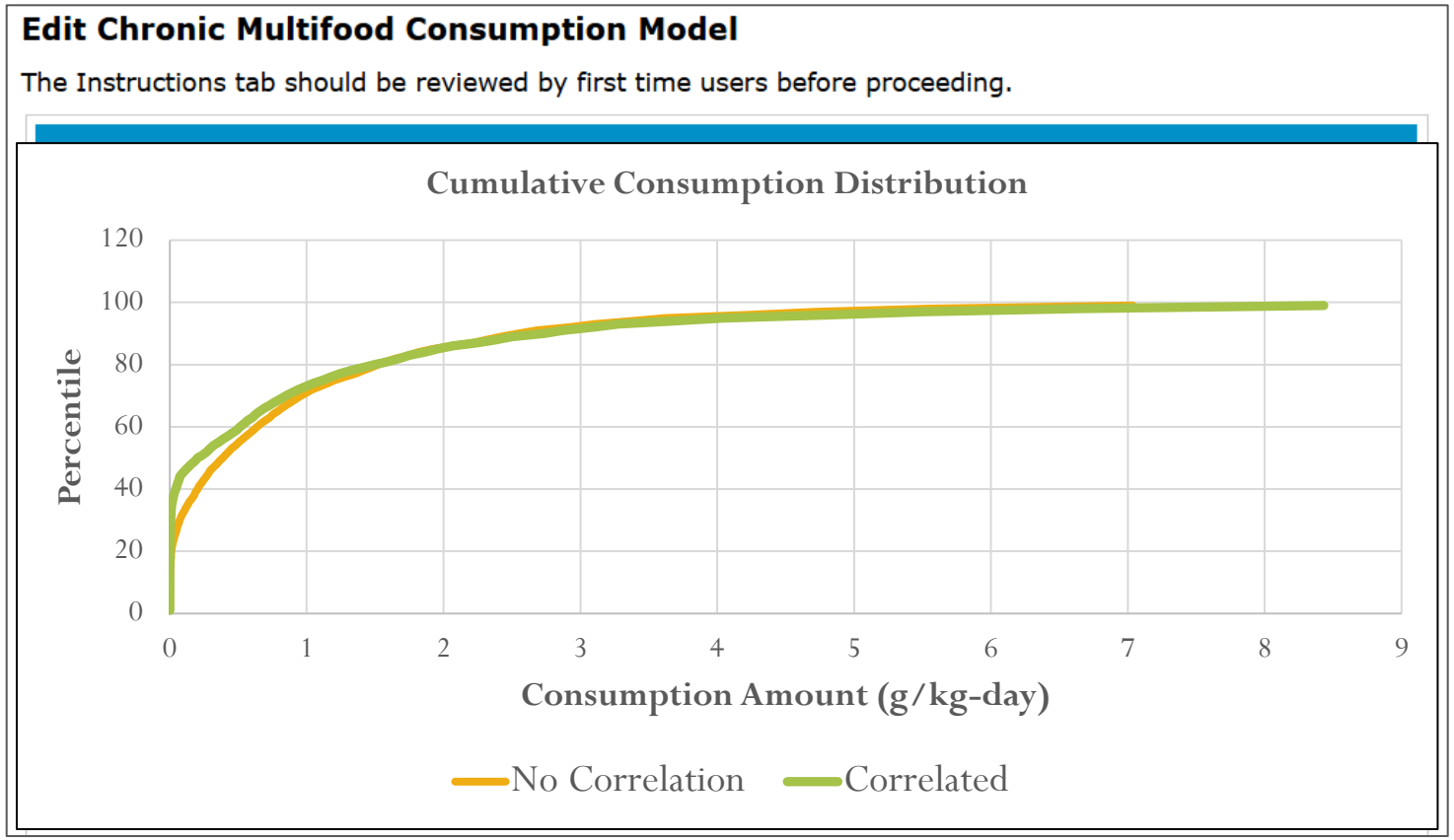
- Linkage to ComBase data and microbial growth or inactivation models
- Linkage to microbial sampling plan OC curve from FDA-OC App
- Import chronic multifood consumption models
- Correlation of consumption across life stages
- Chronic multifood consumption models parameterized by consumers-only distribution and percentage of consumers
- Expanded and more flexible approach to defining diets

- Streamlined sensitivity analysis parameterization, incl. for chronic multi-food multi-hazard scenarios
- Visualization of intermediate results: distribution of microbial concentrations across process stages
- Visualization of exposure estimates
- Visualization of risk estimates (e.g., illnesses and DALYs) for microbial and chronic chemical scenarios

And more…

Example 1:
Correlation of Consumption across Life Stages

- Option to use Rank (Spearman) correlation to align the consumption of individuals across their life stages
- Option to include or exclude at the scenario level



Example 2: Multifood Consumption Models Parameterization for Different Diets

- Define life stage consumption using two parameters:
  - the cumulative empirical consumption distribution
  - the percentage of consumers included in that distribution.
- Differentiate between the consumers-only (eaters) distribution and the per capita (eaters + non-eaters) distribution.
- Allows the user to define a different percentage under different diet patterns

Age and Sex (end age must be greater than start age):

Sex	Start: Year	Month	End: Year	Month
Both	0	0	70	11

Average Daily Consumption:

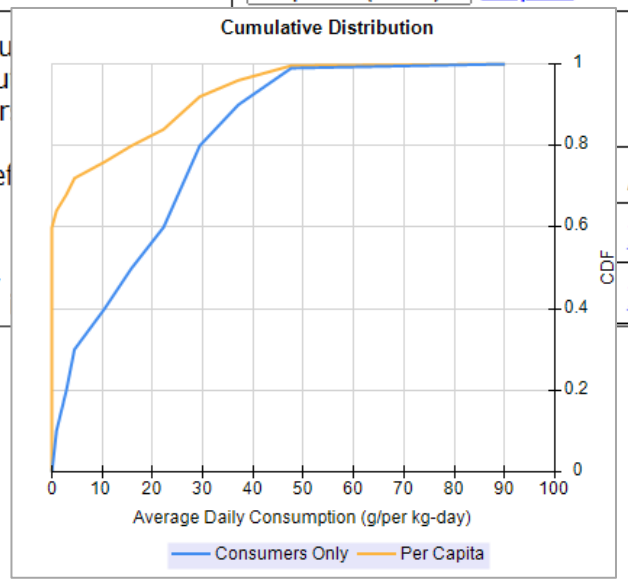
Units:	g per kg-day
Percentage of consumers included in the consumption distribution:	40 (%)
Distribution:	Empirical (linear) Import

The cumulative empirical distribu
linear) is used to enter a distribu
cumulative probability/value pair

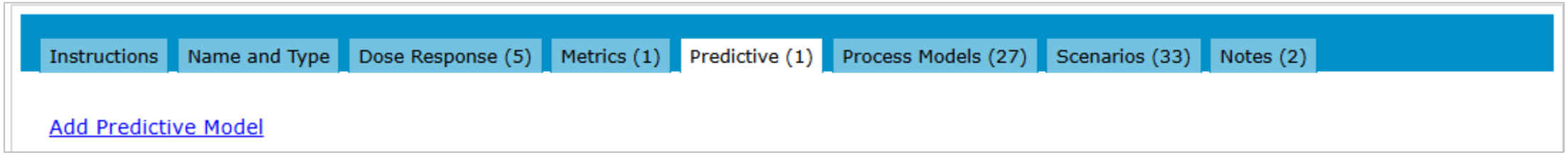
It may be entered as a table (def
textbox.

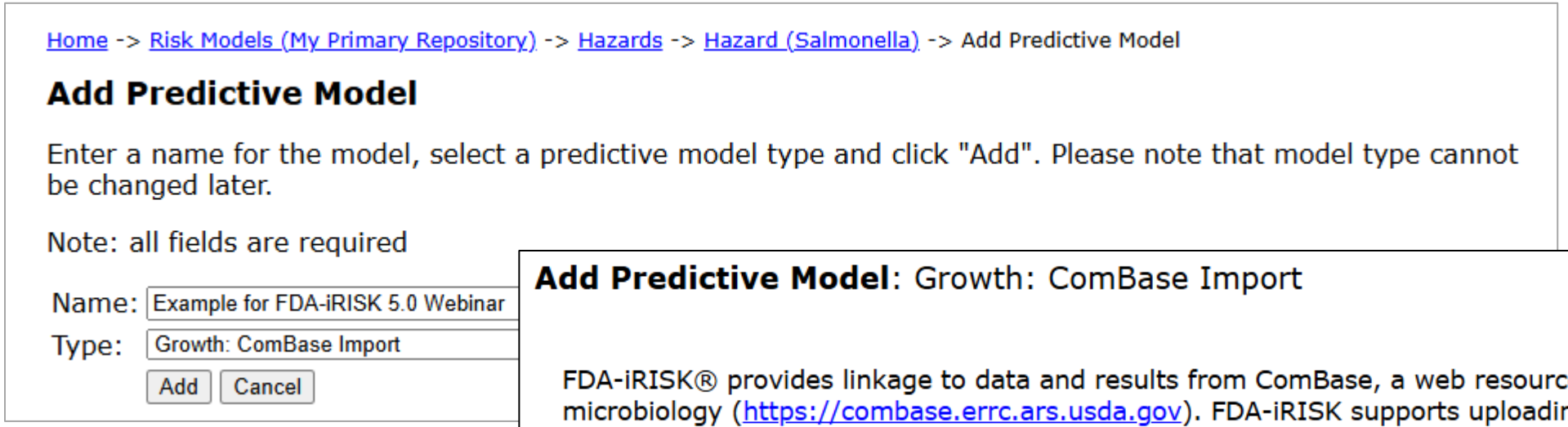
When entered as a table, insert,
rows as required. When entered

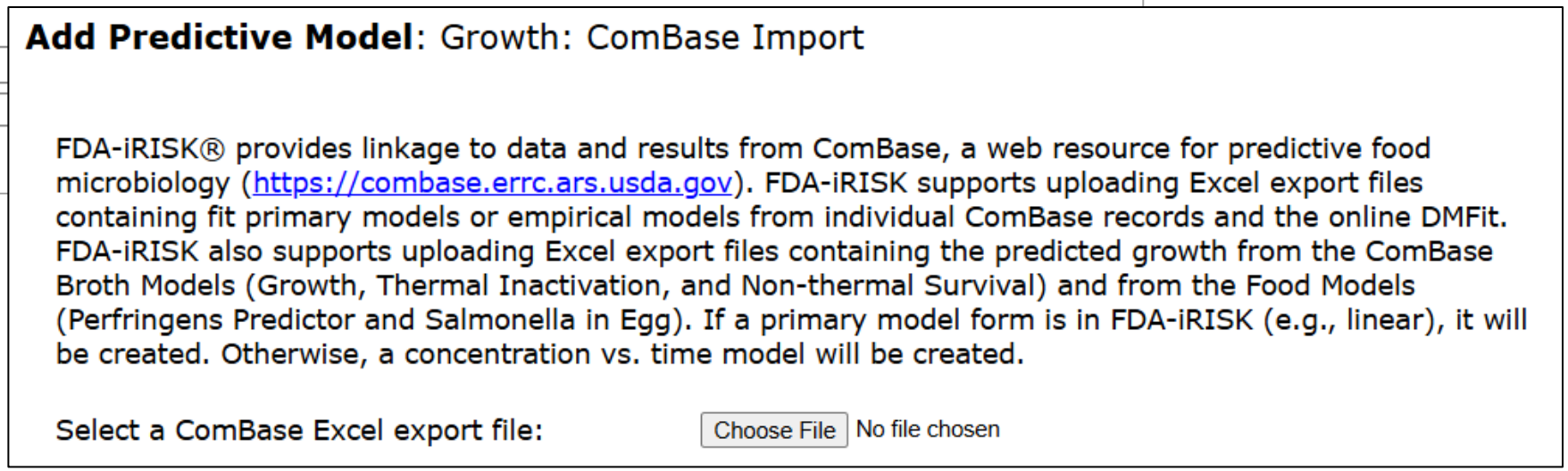
Actions
Insert Delete
Insert Delete



Example 3: Linkage between FDA-iRISK and ComBase







Example 3: Linkage between FDA-iRISK and ComBase Readily Creating a Range of Predictive Microbiology Models

Instructions | Name and Type | Dose Response (1) | Metrics (1) | Predictive (9) | Process Models (1) | Scenarios (1) | Notes (0)

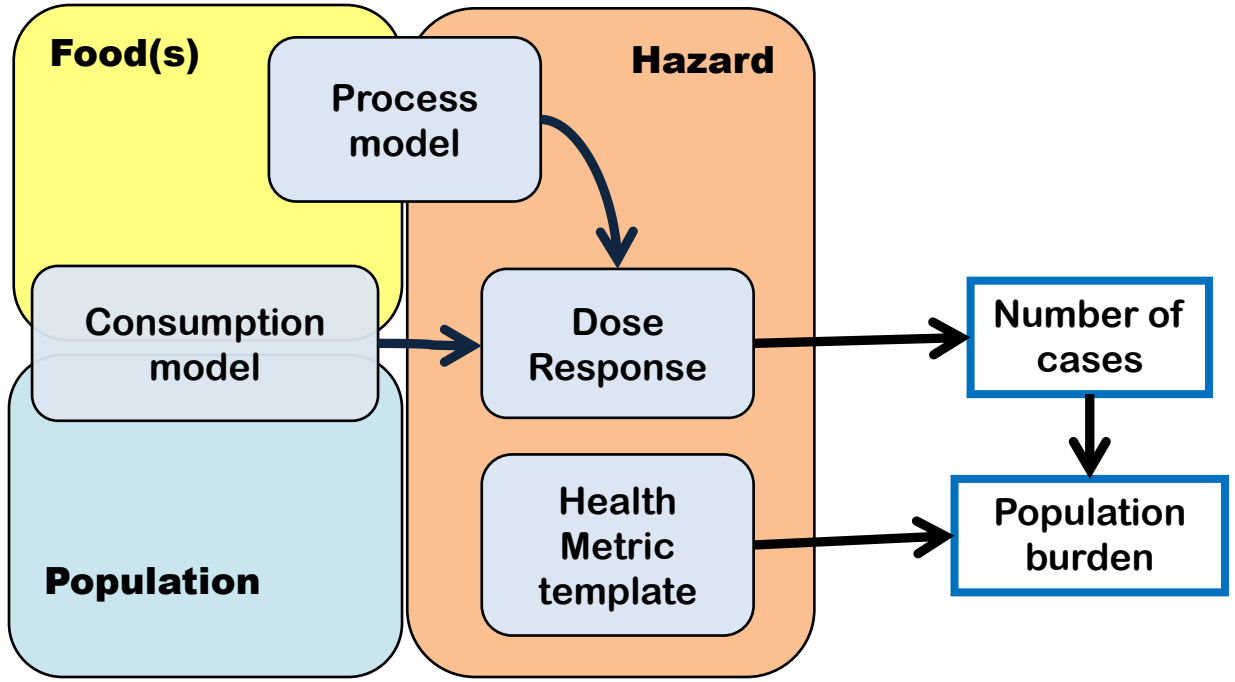
Add Predictive Model

When defining a predictive growth model in FDA-iRISK, the Minimum Growth Temperature represents the experimental minimum temperature observed and the Maximum Growth Temperature represents the experimental maximum temperature observed. FDA-iRISK will not compute growth for temperatures outside this range. See more details in the Technical Document section 3.1.

Model	Type	Actions
ComBase Broth Model - Growth	Growth: Concentration vs. Time	Edit Copy Delete
ComBase Broth Model - Non-Thermal Survival	Inactivation: Concentration vs. Time	Edit Copy Delete
ComBase DMFit Inactivation - Biphasic Model (no lag)	Inactivation: Concentration vs. Time	Edit Copy Delete
ComBase Food Model - Growth	Growth: Concentration vs. Time	Edit Copy Delete
ComBase Record Growth - Baranyi and Roberts Model (complete)	Growth: Primary Model - Baranyi and Roberts	Edit Copy Delete
ComBase Record Growth - Baranyi and Roberts Model (no asymptote)	Growth: Concentration vs. Time	Edit Copy Delete
ComBase Record Inactivation - Baranyi and Roberts Model (complete)	Inactivation: Concentration vs. Time	Edit Copy Delete
ComBase Record Inactivation - Baranyi and Roberts Model (no lag)	Inactivation: Concentration vs. Time	Edit Copy Delete
ComBase Record Inactivation - Linear	Inactivation: Primary Model	Edit Copy Delete

How FDA-iRISK can support risk-based thinking and preventive controls

- **Predictive microbiology modeling**
  - Growth, inactivation, etc.
- Before: Define initial prevalence and level, etc.
- After: Connect contamination in food to other components of a risk assessment



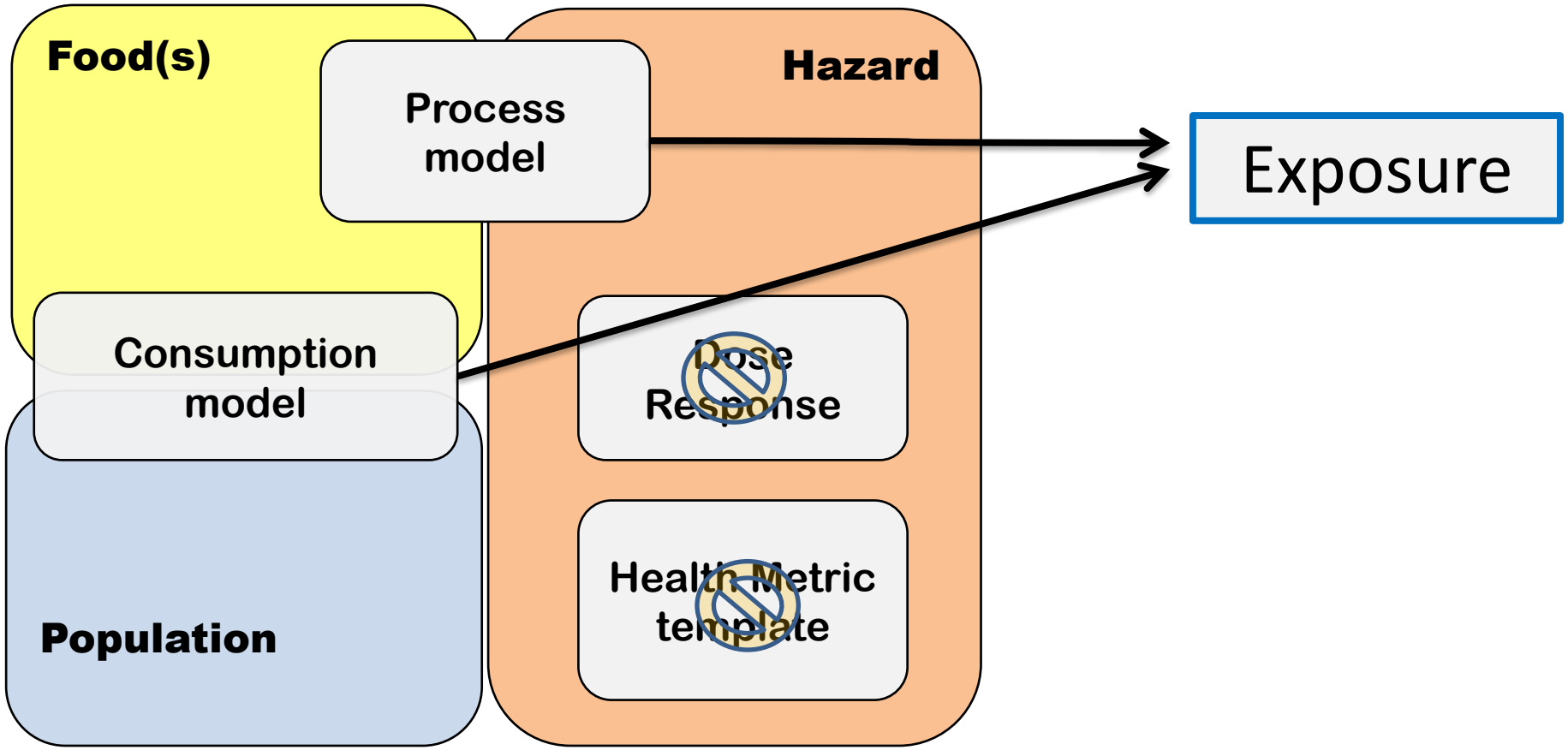
…Similar applications to risk-based control of chemical hazards.

New and Updated Cases Studies Utilizing FDA-iRISK 5.0

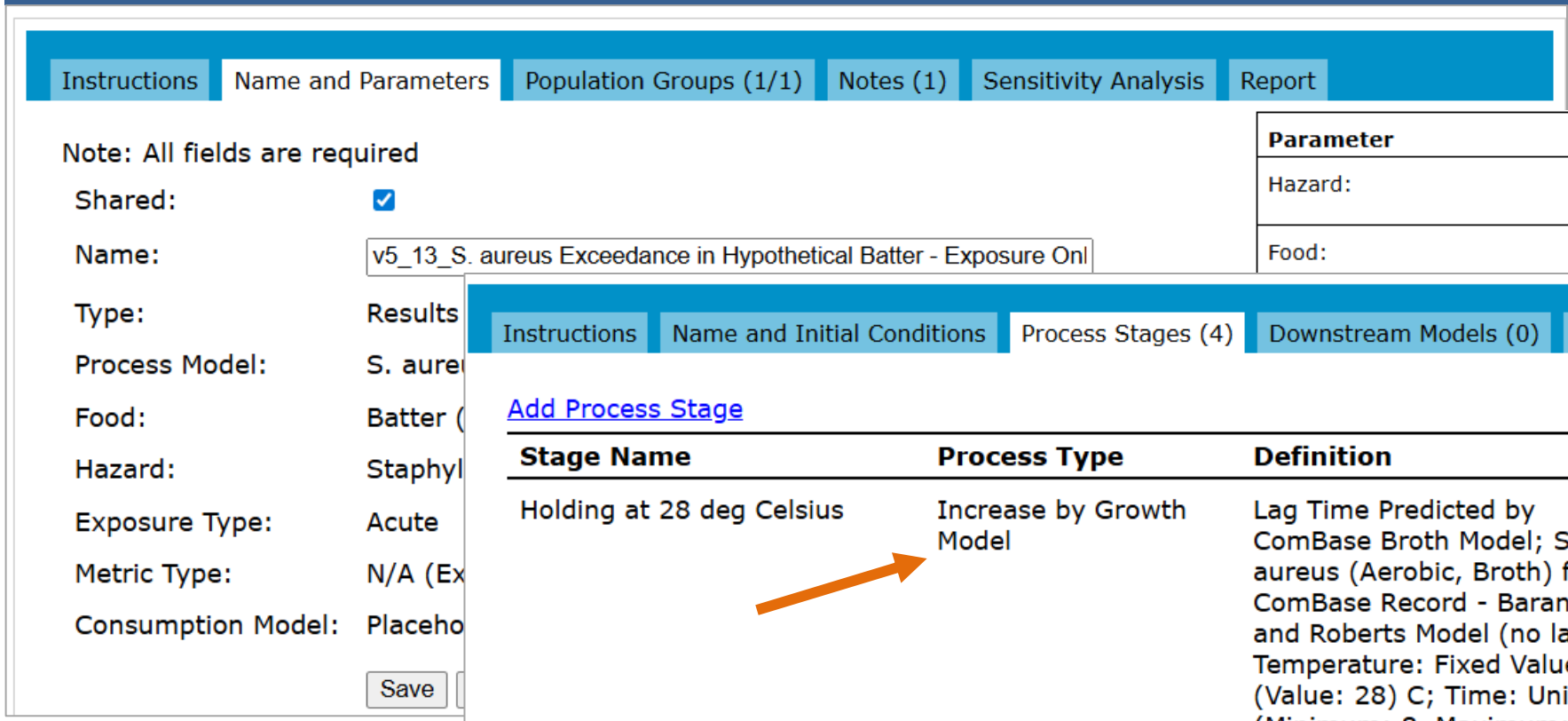
v5_05_Inorganic Arsenic in Apple Juice Pear Juice White Rice Brown Rice (consumption correlation) *(Multifood, Inorganic Arsenic, DALY, Chronic, Computed Multifood)*
v5_10_Manganese in Fruit & Vegetables (with dietary shift) *(Multifood, Manganese, DALY, Chronic, Computed Multifood)*
v5_11_Generic Scenario with Collage of Data and Model Imports from ComBase *(Generic Food, Generic Bacterial Pathogen, DALY, Acute, Computed)*

v5_12a_L. monocytogenes in RTE Foods with Impact of Sampling A *(RTE Foods, Listeria monocytogenes, DALY, Acute, Computed)*
v5_12b_L. monocytogenes in RTE Foods with Impact of Sampling B *(RTE Foods, Listeria monocytogenes, DALY, Acute, Computed)*
v5_12c_L. monocytogenes in RTE Foods with Impact of Sampling C *(RTE Foods, Listeria monocytogenes, DALY, Acute, Computed)*
v5_13_S. aureus Exceedance in Hypothetical Batter - Exposure Only *(Batter (hypothetical formulation), Staphylococcus aureus, No Metric - Exposure Only, Acute, Computed)*
v5_14_Generic Chemical Hazard in Diet *(Multifood, Generic Chemical Hazard, DALY, Chronic, Computed Multifood)*

Exposure Assessment Models in FDA-iRISK



Case Study 1: *S. aureus* Exceedance in Hypothetical Batter - Exposure Only



Parameter	Value	Uncertainty
Hazard:	Staphylococcus aureus	N/A
Food:	Batter (hypothetical	N/A

Instructions | Name and Initial Conditions | Process Stages (4) | Downstream Models (0) | Scenarios (1) | Notes (1)

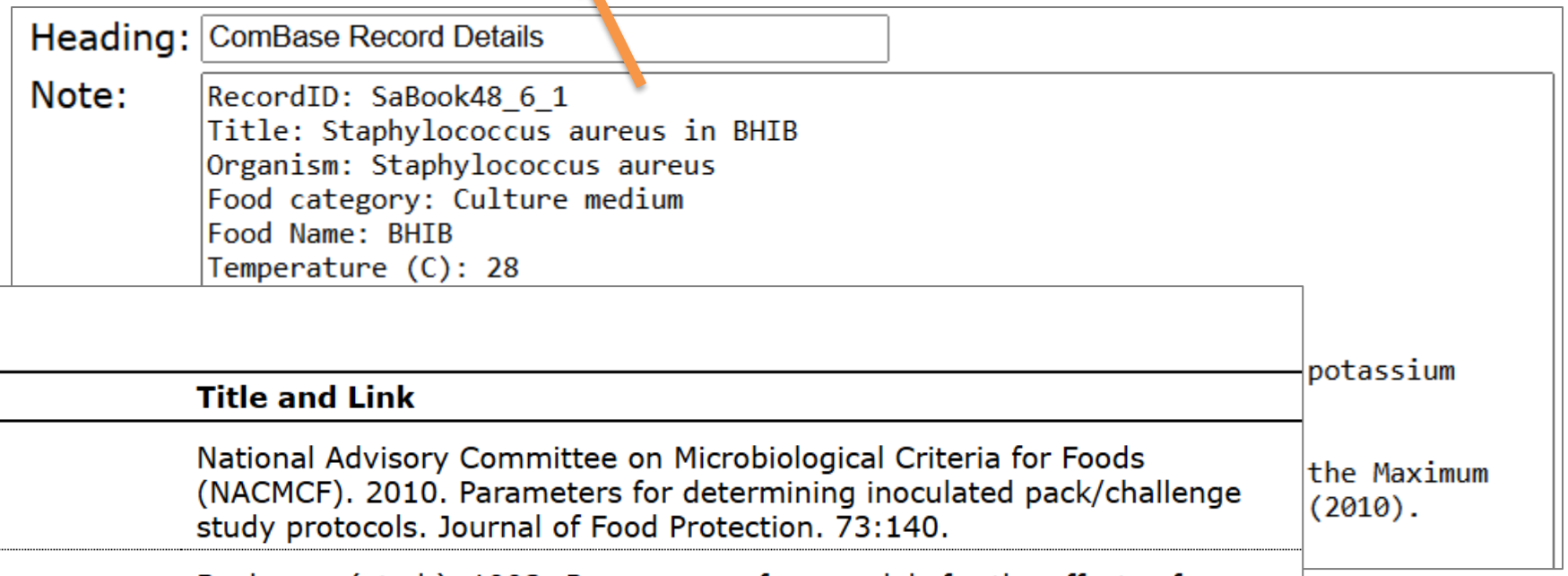
Add Process Stage

Stage Name	Process Type	Definition	Unit Size	Actions
Holding at 28 deg Celsius	Increase by Growth Model	Lag Time Predicted by ComBase Broth Model; S. aureus (Aerobic, Broth) from ComBase Record - Baranyi and Roberts Model (no lag); Temperature: Fixed Value (Value: 28) C; Time: Uniform (Minimum: 8, Maximum: 10) h	22700 g	Edit Copy Delete
Battering of Food Items	Partitioning	Triangular (Minimum: 25, Mode: 28, Maximum: 30) g	25.0 g - 30.0 g	Edit Copy Delete
Storage (Frozen)	No Change	Not applicable	25.0 g - 30.0 g	Edit Copy Delete
Threshold Exceedance Test	Threshold Exceedance Test	6 $\log_{10}$ cfu/g	25.0 g - 30.0 g	Edit Copy Delete

u: Uncertainty distribution defined for this parameter

Case Study 1: *S. aureus* Exceedance in Hypothetical Batter Using New Feature - Linkage to ComBase

Model	Type
Lag Time Predicted by ComBase Broth Model	Lag: Specified
S. aureus (Aerobic, Broth) from ComBase Record - Baranyi and Roberts Model (no lag)	Growth: Concentration vs. Time



References

Code	Title and Link
Ref01	National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 2010. Parameters for determining inoculated pack/challenge study protocols. Journal of Food Protection. 73:140.
SaBook48_6_1	Buchanan (et al.), 1993: Response surface models for the effects of temperature, pH, sodium chloride, and sodium nitrite on the aerobic and anaerobic growth of Staphylococcus aureus 196E. Journal of Food Safety 13: 159 - 175 https://combasebrowser.errc.ars.usda.gov/SearchDetails.aspx?combaseid=SaBook48_6_1

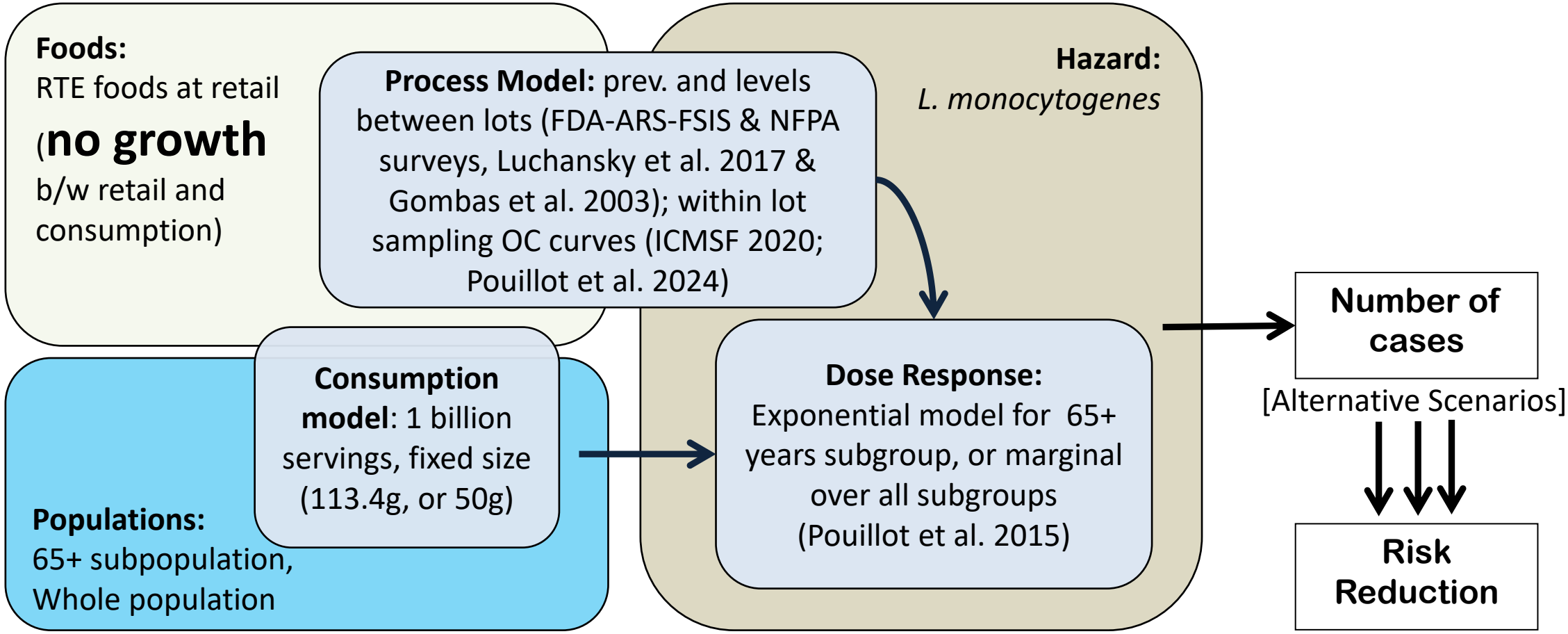
Case Study 1: *S. aureus* in Hypothetical Batter: Concentration Exceedance Test

Concentration Threshold Exceedance Results:

Scenario	Hazard	Food	Process Stage & Concentration Threshold Value	Proportion of Contaminated Food Units Exceeding Threshold	Proportion of All Food Units Exceeding Threshold
v5_13_S. aureus Exceedance in Hypothetical Batter - Exposure Only (Unmodified)	Staphylococcus aureus	Batter (hypothetical formulation)	Threshold Exceedance Test 6 log10 cfu/g	0.277	0.0111
Control Measure: Maximum Holding Time (8 hours)	Staphylococcus aureus	Batter (hypothetical formulation)	Threshold Exceedance Test 6 log10 cfu/g	0.0506	0.00202
Control Measure: Maximum Holding Time (6 hours)	Staphylococcus aureus	Batter (hypothetical formulation)	Threshold Exceedance Test 6 log10 cfu/g	0.00510	0.000204
Control Measure: Max Initial Level (2.0 log) and Max Holding Time (6 hours)	Staphylococcus aureus	Batter (hypothetical formulation)	Threshold Exceedance Test 6 log10 cfu/g	0.00	0.00

Note: estimates based on data and assumptions made; for illustration purposes only.

Case Study 2: Modeling the impact of variability in *L. monocytogenes* contamination on risk reduction from sampling RTE foods



Modeling the Impact of Between-lot and Within-lot Variability in *Listeria monocytogenes* Contamination on Risk Reduction From Sampling Ready-to-eat Foods (https://doi.org/10.1016/j.jfp.2025.100478)

We used FDA-iRISK for "rapid" risk assessment evaluating a wide range of scenarios to predict risk with and without sampling.

Table 1
Predicted cases per billion servings of no-growth RTE foods for the 65+ subpopulation with no test or test using FDA-iRISK and OC curves[a]

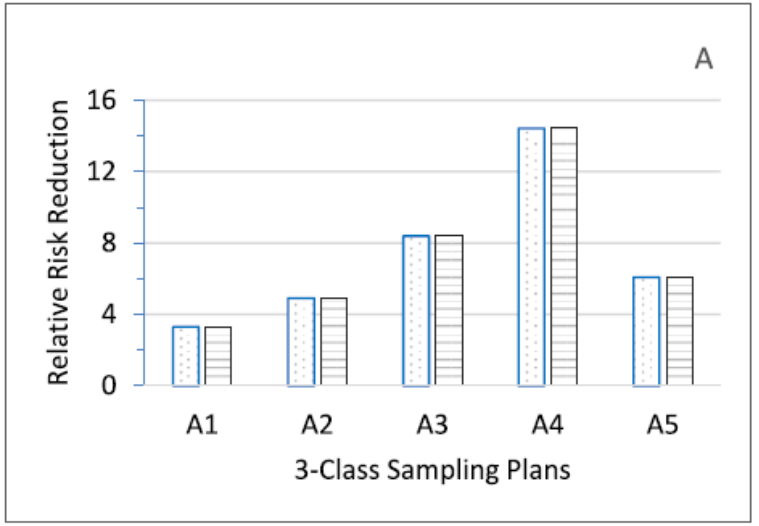
(A) Test using a 2-class plan

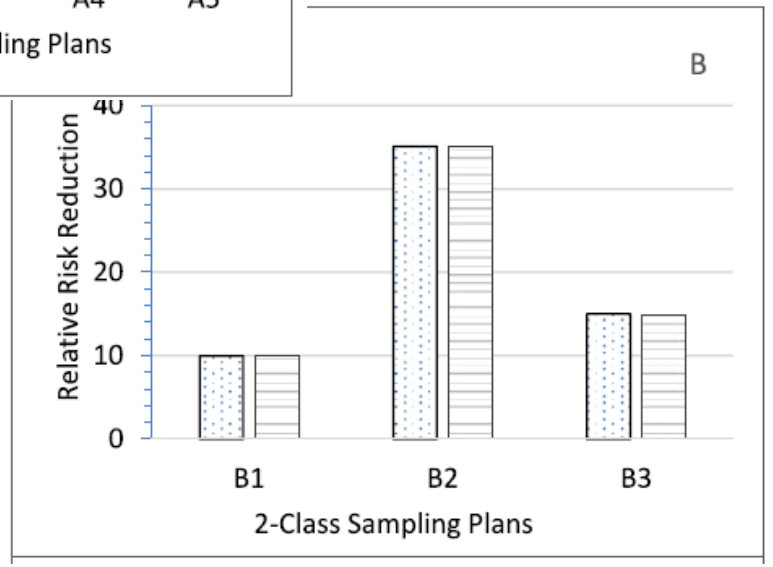
Test scenario and sampling plan	Predicted cases
No Test	0.698
$n = 5, m = 100$ CFU/g, $c = 0$	0.688
$n = 10, m = 0$ CFU/5 g, $c = 0$	0.0698
$n = 2, m = 0$ CFU/25 g, $c = 0$	0.126
$n = 5, m = 0$ CFU/25 g, $c = 0$	0.0464
$n = 10, m = 0$ CFU/25 g, $c = 0$	0.0198

(B) Test using a 3-class mixed plan

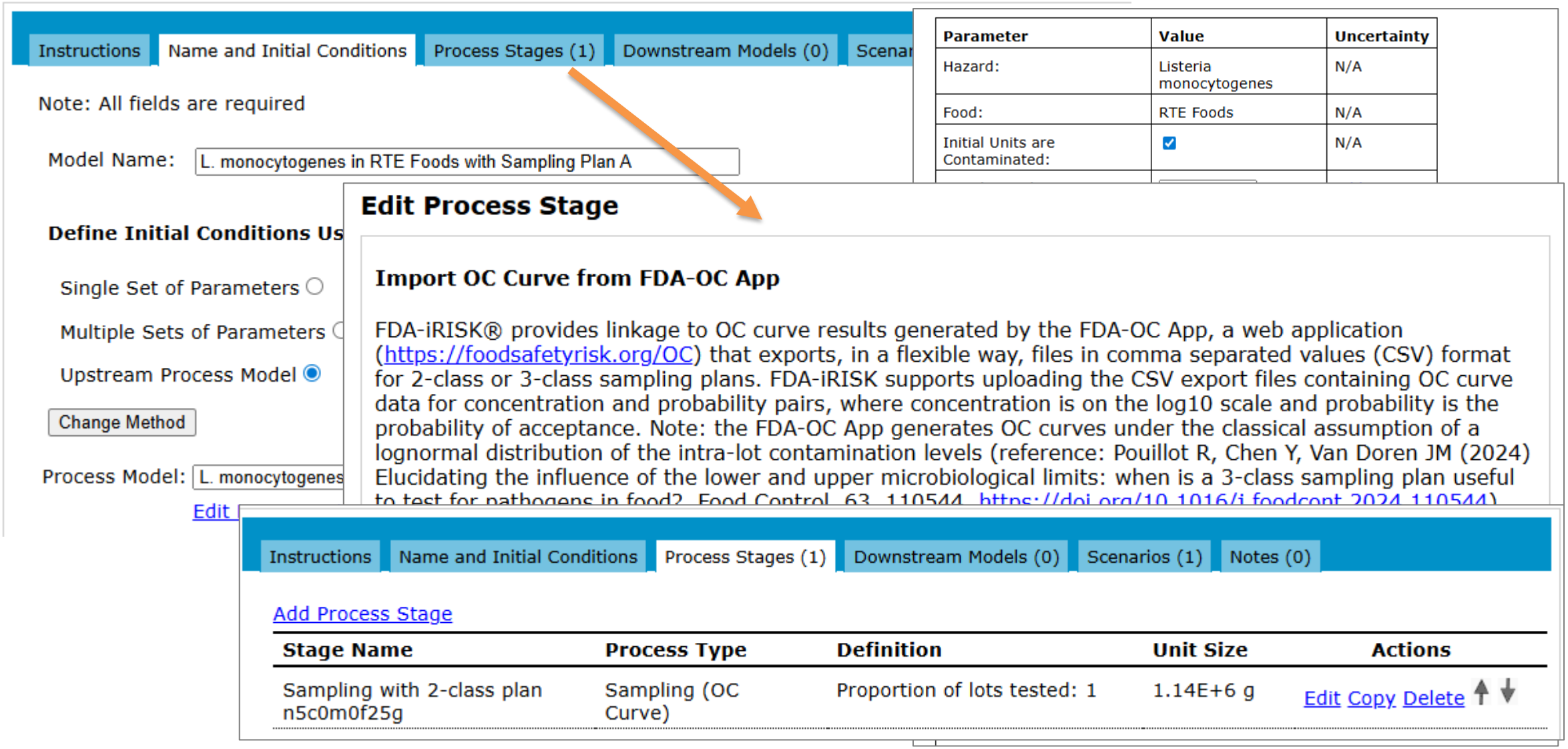
Test scenario and sampling plan	Predicted cases with test		
	$c = 3$	$c = 2$	$c = 1$
$M = 500$ CFU/g, $m = 0$ CFU/25 g, $n = 5$	0.318	0.204	0.115
$M = 100$ CFU/g, $m = 0$ CFU/25 g, $n = 5$	0.318	0.204	0.115
$M = 20$ CFU/g, $m = 0$ CFU/25 g, $n = 5$	0.317	0.204	0.115
$M = 10$ CFU/g, $m = 0$ CFU/25 g, $n = 5$	0.315	0.203	0.115

(C) Relative risk reduction after testing with a 2-class or 3-class mixed plan





Case Study 2: Utilizing v5.0 New Feature
Sample Linkage to Microbial Sampling Plan Outputs from FDA-OC App



How FDA-iRISK can support risk-based thinking: Impact of control measure; food does vs does not support pathogen growth

Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Illnesses	Mean Risk of Illness	Total DALYs per Year
06_L. monocytogenes in Cantaloupe (among 65+ subpopulation) (Unmodified)	N/A	5.98E+8	73.8	1.24E-7	190
Consumer Storage Step: No Growth	N/A	5.98E+8	0.0272	4.55E-11	0.0702

Growth vs. No-Growth: e.g., risk estimate differs by a factor of 2713

Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Illnesses	Mean Risk of Illness	Total DALYs per Year
v5_12a_L. monocytogenes in no-growth RTE Foods_No Testing	N/A	1.00E+9	0.703	7.03E-10	1.83
v5_12a_L. monocytogenes in RTE Foods with Impact of Sampling A (Unmodified)	N/A	1.00E+9	0.0466	4.66E-11	0.121

No-Test vs. Test All Lots: e.g., risk estimate differs by a factor of 15

Note: estimates based on data and assumptions made; for illustration purposes only.

Case Study 3: Sample Visualizations of Outputs from Process Model Concentration and Distribution of Concentrations (Final and Over Process Stages)

Instructions | Name and Parameters | Population Groups (1/1) | Notes (1) | Sensitivity Analysis | Report | Results

Optionally sort results by one of the underlined columns, click include beside the results of interest, then click the "Chart Selected Results" button to produce the charts.

Include	Key	Report Title
☑	R1	Sensitivity Analysis monocytogenes in C (among 65+ subpop Mar-2026 09:52:56
☑	R2	Sensitivity Analysis monocytogenes in C (among 65+ subpop Mar-2026 09:52:56

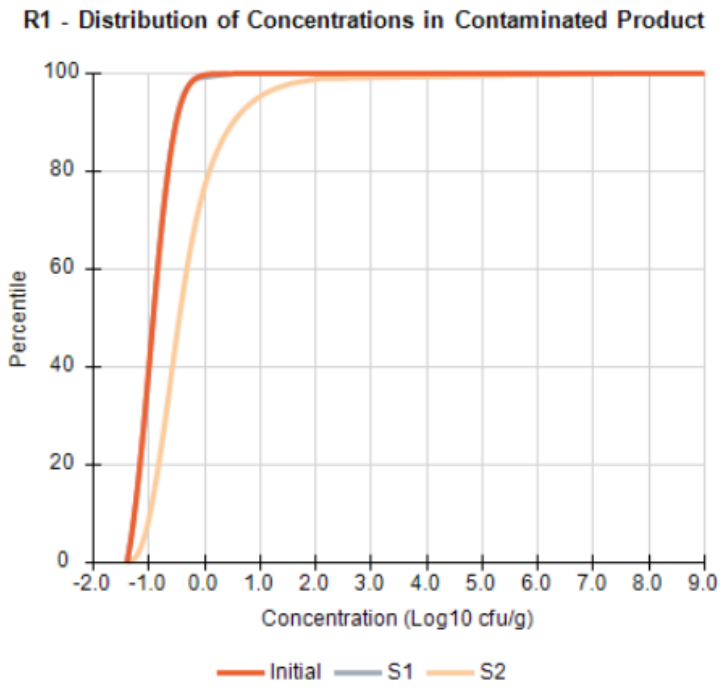
Generate: ☐ Health Metrics ☑ Final Concen

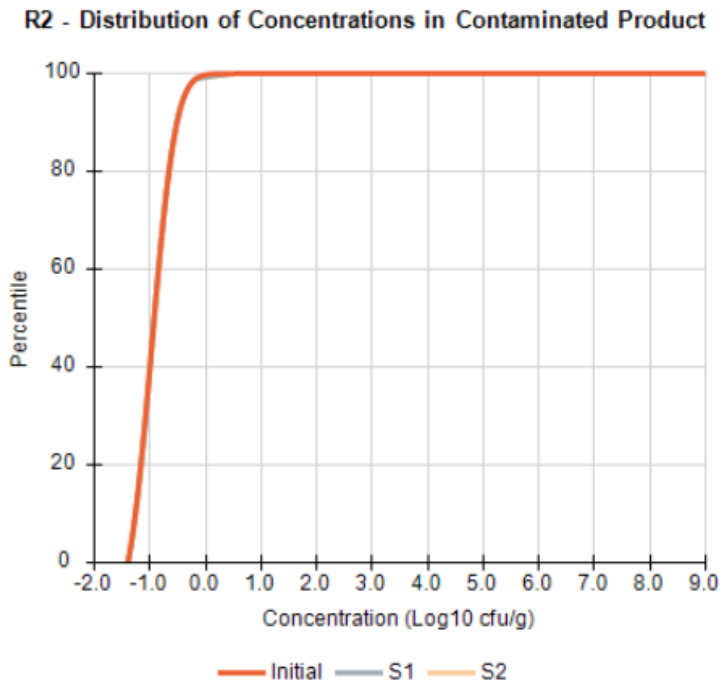
Chart Selected Results | Tabulate Selected Results

Final Concentration and Prevalence

Final Concentration (Arithmetic Mean) and Prevalence

Distribution of Final Concentrations in Contaminated Product





Note: estimates based on data and assumptions made; for illustration purposes only.

Case Study 4: v5_10 Mn in Fruit and Vegetables Scenario (updating process model)

Instructions | Name and Initial Conditions | Process Stages (0) | Downstream Models (0) | Scenarios (1) | Notes (1)

Note: All fields are required

Model Name: Manganese in Broccoli

Define Initial Conditions Using:

Single Set of Parameters ○

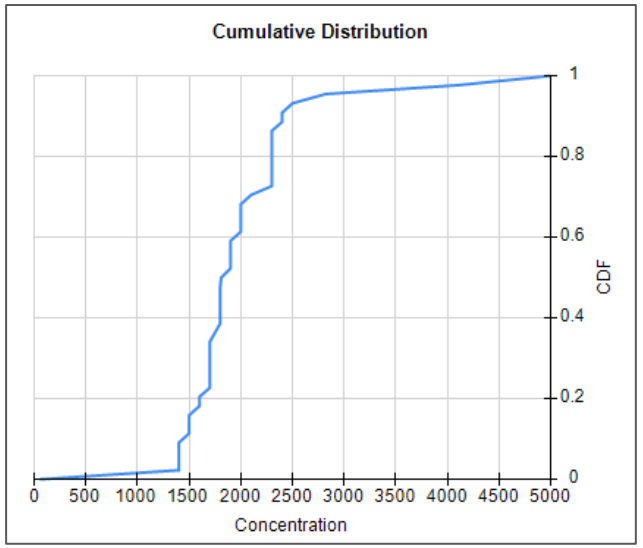
Upstream Process Model ○

Total Diet Study Data ◉

Change Method | Update TDS Data

Initial Contamination, Unit Size and Prevalence:

Parameter	Value	Uncertainty
Hazard:	Manganese	N/A
Food:	Broccoli	N/A



Heading: TDS Data used for initial conditions

Note:

```
Initial conditions set using Total Diet Study data for Manganese in Broccoli,
fresh/frozen, boiled (Food Code: 113) for years: 2017 - 2022, assuming non-detect
values have a concentration half the level of detection (LOD) and prevalence =1.
The LOD value is 100 ug/kg.

Data were downloaded (January 28, 2026) from the FDA Total Diet Study Interface
(TDSi). For details on the TDS methodology, see https://tdsi.fda.gov/.
```

Note: Contamination previously defined using 2003-2011 data:

Heading: Description (v4.2 Mn Multifood Scenario, 2021)

Note:

```
Initial conditions set using Total Diet Study data for Manganese in Broccoli,
fresh/frozen, boiled (Food Code: 113) for years: 2003 - 2011, assuming non-detect
values have a concentration half the level of detection (LOD) and prevalence = 1.
The LOD value is 0.3 mg/kg.

For details on the Total Diet Study see:
https://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184293.htm
```

v5_10_Mn Scenario: Sample Summary Table on Results Tab
Visualizations – Lifetime Average Daily Dose (LADD) and Risk Estimates

Edit Chronic Multifood Risk Scenario

The Instructions tab should be reviewed by first time users before proceeding.

Instructions | Name and Parameters | Consumption (12/12) | Dose Response (2/2) | Process Models | Diets | Notes (1) | Sensitivity | Report | Results

Optionally sort results by one of the underlined columns, click include beside the results of interest, then click the "Chart Selected Results" button to produce the charts.

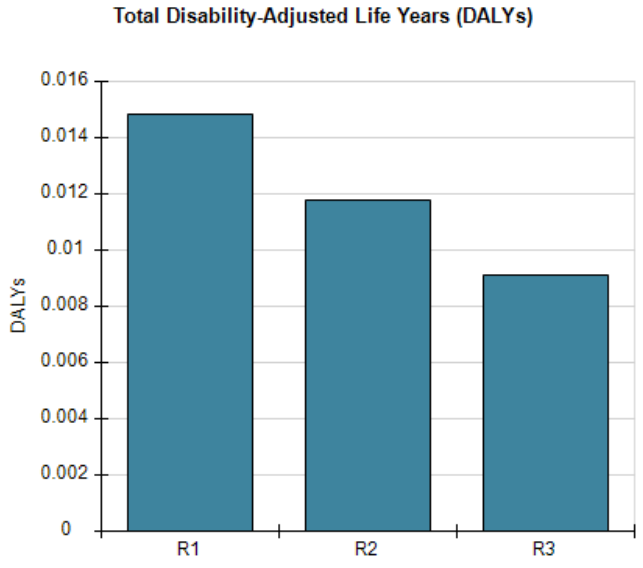
Include	Key ▲	Report Title	Details	Mean Risk of Illness	Illnesses	DALYs
☑	R1	Risk Estimate Report for v5_10_Manganese in Fruit & Vegetables (with dietary shift) (06-Mar-2026 11:13:12)	Variability Only; Diet: Fruit and Vegetable NHANES Diet, Shift: Baseline			
☑	R2	Risk Estimate Report for v5_10_Manganese in Fruit & Vegetables (with dietary shift) (06-Mar-2026 11:13:12)	Variability Only; Diet: Fruit and Vegetable NHANES Diet, Shift: 10% increase			
☑	R3	Risk Estimate Report for v5_10_Manganese in Fruit & Vegetables (with dietary shift) (06-Mar-2026 11:13:12)	Variability Only; Diet: Fruit and Vegetable NHANES Diet, Shift: 20% increase			
☐	R4	Risk Estimate Report for v5_10_Manganese in Fruit & Vegetables (with dietary shift) (06-Mar-2026 11:13:12)	Variability Only; Diet: Fruit and Vegetable NHANES Diet, Shift: Doubled Intake			

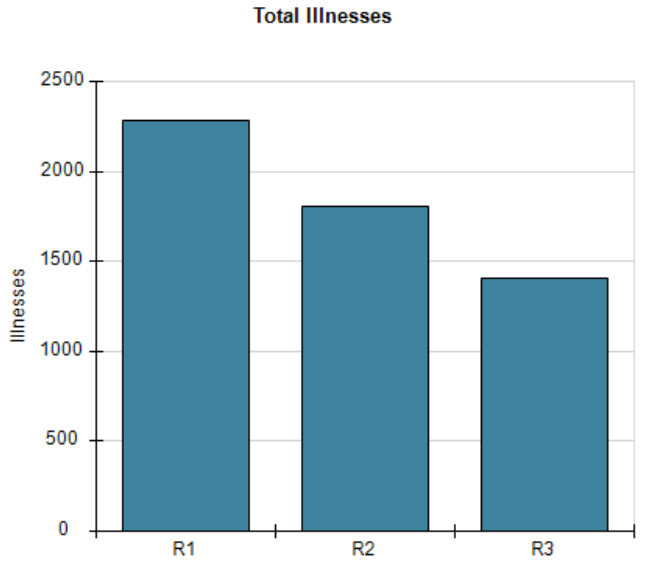
Generate: ☑ Health Metrics ☑ Final Concentration and Prevalence ☑ Process Model ☑ Lifetime Average Daily Dose

Chart Selected Results | Tabulate Selected Results

Exposure by Percentile (Variability Only)

Mean Results





Note: estimates based on data and assumptions made; for illustration purposes only.

Live Demonstration

Summary

Summary of FDA-iRISK Capacities

- FDA-iRISK can be leveraged to develop and implement simple to more complex risk scenarios transparently, reproducibly, and relatively rapidly.

Examples of FDA-iRISK Functionality:

- **Assess risks and interventions for:**
  - one hazard in different foods
  - multiple hazards in a single food
  - multiple food-hazard combinations
  - acute exposure to a hazard (microbial and chemical) and chronic exposure to one or multiple chemical hazards
- **Assess risks and health benefits from various dietary patterns**

Summary of FDA-iRISK Capacities

FDA-iRISK as a modeling tool plus …

- Facilitating broad access to a structured QRA methodology
- Improving risk assessment consistency and efficiency
  - Synergy among users, sharing data and results
- Enhancing knowledge organization
  - Users can accumulate and access risk scenarios and data in online repository, anytime.

… A tool for collaborations

Example Users of FDA-iRISK

- Who are *knowledgeable about the hazards, foods and processes they are describing*
  - Users may or may not be familiar with risk assessment methodology, particularly as it pertains to developing quantitative estimates of risk (may need training)
- Who are interested in a structured, mathematically rigorous tool that allows
  - New/developing professionals to quickly become capable of developing quantitative risk assessments
  - Experienced risk assessors to more quickly develop simple or complex risk assessments

Example Users of FDA-iRISK

- Direct users
  - Risk assessors
  - Food safety professionals with some risk modeling experience
  - A team of users with different expertise who collaborate
- Indirect users
  - Who are likely aware of the public health questions to be addressed
  - Who can put to practical use results generated from risk assessments

Acknowledgements

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FDA-iRISK 5.0
Further Information

Visit FoodRisk.org

https://www.foodrisk.org/resources/display/2

https://irisk.foodrisk.org

Visit FDA's Risk and Safety Assessments (Food) web page

https://www.fda.gov/food/science-research-food/risk-and-safety-assessments-food