FDA-iRISK® 4.2

Training Exercises Manual – Microbial Hazards

Training provided by:
Greg Paoli
Risk Sciences International

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Contents

Risk Scenarios for Microbial Hazards

This exercise provides two computed risk scenarios for acute microbial hazards.

- Scenario 1 - A single food-hazard pair in one population group
- Scenario 2 - A single food-hazard pair in three population groups

Scenario M1 - A Single Food-Hazard Pair in One Population Group

You are creating a computed scenario for *Salmonella*[1] spp. (nontyphoidal) in peanut butter that estimates the population health burden for a single food-hazard pair.

Complete the following tasks in your primary repository.

Task 1: Add the hazard, dose-response model, and a metric

Hazard

Add the hazard using the following specifications:

- **Name:** Salmonella
- **Type:** Microbial Pathogen
- **Default Unit:** cfu
- **Notes**[2]**:**

  1) *Heading:* Description
  Text: "Salmonella spp. have been detected in a number of low-moisture foods, including peanut butter (Scott et al., 2009). Salmonella outbreaks associated with low-moisture products have been reported worldwide (Scott et al., 2009). Illness is usually self-limiting but can lead to hospitalization and death. While salmonellosis may occur in healthy individuals, those most at risk are young children, pregnant women, older adults, and immunocompromised individuals (FDA, 2012)."

  2) *Heading:* References
  Text: Food and Drug Administration (FDA). 2012. Bad Bug Book - Foodborne Pathogenic Microorganisms and Natural Toxins, 2nd ed. Salmonella species, pp. 12-14;. Available at http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/default.htm. Accessed May 7, 2012.

  Scott, V. N., Y. Chen, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. A.

Smoot, S. Hood, J. Shebuski, and J. Banks. 2009. Control of Salmonella in low-moisture foods I: minimizing entry of Salmonella into a processing facility. Food Prot. Trends. 29:342-353.

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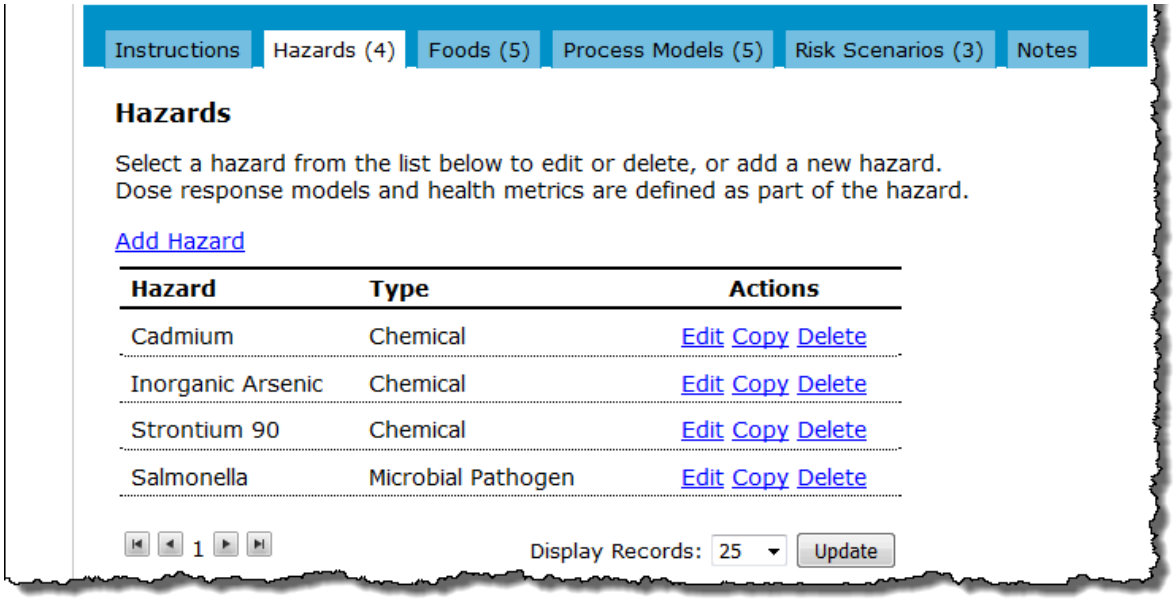
1. Note that italic font is currently not supported in the FDA-iRISK tool, itself. Therefore, the name of a microorganism, such as *Salmonella* or *Listeria monocytogenes*, displays in non-italic font both on the screen and when entered as text
2. A Notes tab is provided for each element where you are encouraged to include notes (i.e. descriptions, rationale, etc.).

When complete, the Hazards list on the Hazards tab should display as:

(*Tip:* To navigate to the Hazards tab, click the Hazards link in the breadcrumb at the top of the page.)



Dose-Response Model

Add the dose-response model using the following specifications:

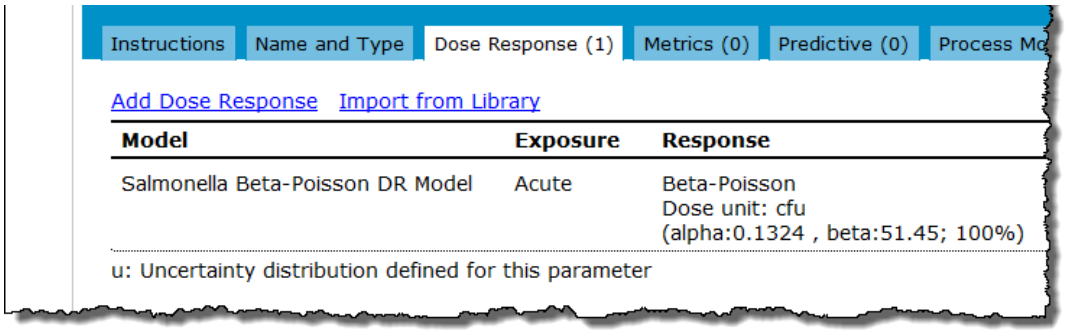
- **Name:** Salmonella Beta-Poisson DR Model
- **Response Type:** Beta-Poisson
- **Parameters:** Enter "0.1324" for alpha and "51.45" for beta. Since the assumption that the "response" side of the dose-response relationship will consist of clinical illness, leave the probability of adverse effect at 100%. *Note:* When entering a numerical value, you must use a period (.) to represent the decimal (e.g. 0.1324 and 51.45). Scientific notation is supported by FDA-iRISK (e.g. 0.1324 can also be expressed as 1.324E-01). Entering a comma (,) will result in an error. This requirement applies to any place where numerical values are defined, for example, when defining a dose-response relationship or a contamination distribution.
- **Notes:**

  1) *Heading:* Description
  Text: **"**Maximum Likelihood techniques were used by an expert panel (FAO/WHO, 2002; Table 3-16) to generate the best-fitting dose-response relationship using real world data including outbreak data. The best fit results were used to generate the expected values of parameters alpha and beta. The dose-response models were developed using illness as an endpoint (FAO/WHO, 2002)."

  2) *Heading:* References
  Text: "Food and Agriculture Organization of the United Nations, World Health Organization (FAO/WHO). 2002. Risk assessments of Salmonella in eggs and broiler chickens. Technical report. Microbiological Risk Assessment Series 2. FAO/WHO. Rome. Available at http://www.fao.org/food/food-safety-quality/scientific- advice/jemra/

risk-assessments/salmonella0/en/. Accessed May 7, 2012."

When complete, the Dose Response list on the Dose Response tab (click Salmonella in the breadcrumb) should display as:

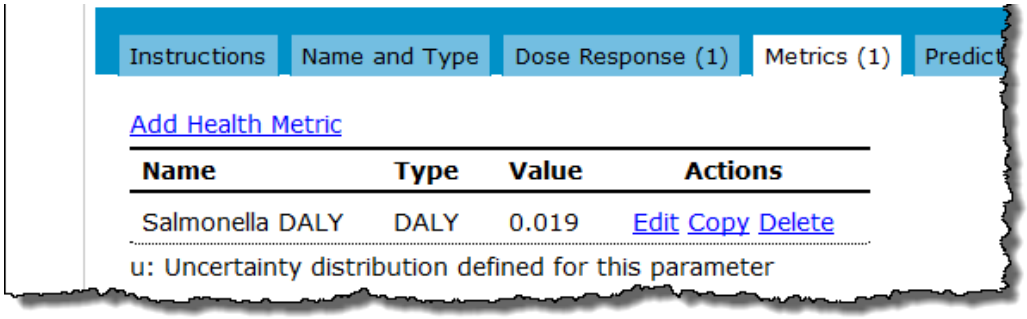


Metric

Add the metric using the following specifications:

- **Name:** Salmonella DALY
- **Type:** DALY
- **Value:** 0.019
- **Uncertainty:** none (do not click "Add")

When complete, the Metrics list on the Metrics tab should display as:



Task 2: Add the food and its consumption pattern in the population group

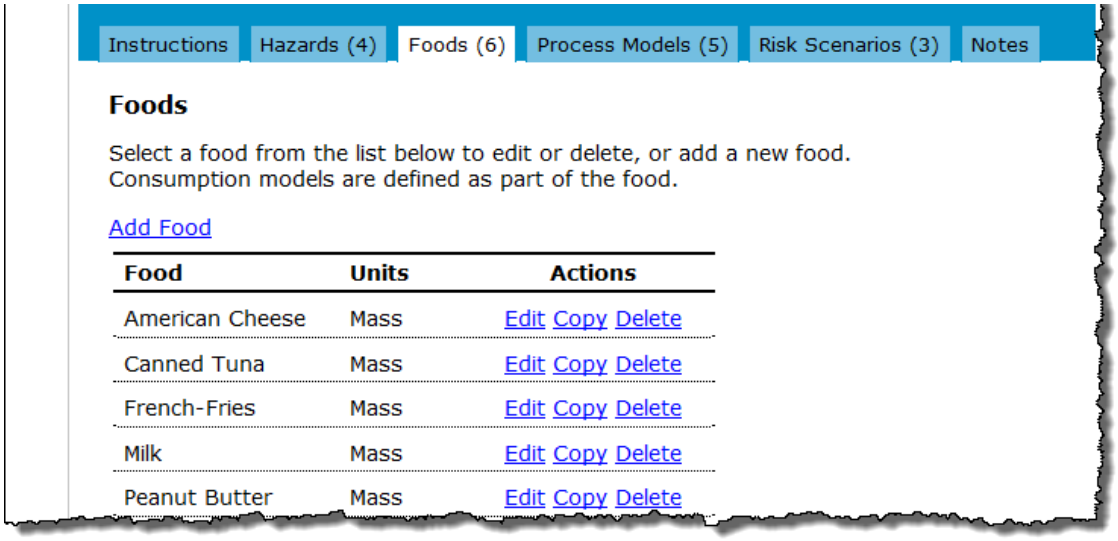
Food

Add the food using the following specifications:

- **Name:** Peanut Butter
- **Measured using:** Mass

When complete, the Foods list on the Foods tab should display as:

(*Tip:* To navigate to the Foods tab, click the Foods link in the breadcrumb at the top of the page.)

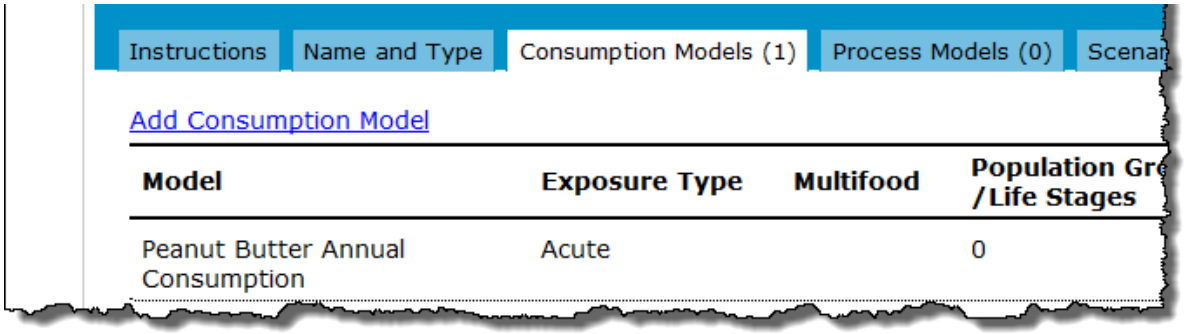


Consumption Model

Add the consumption model using the following specifications:

- **Name:** Peanut Butter Annual Consumption
- **Exposure Type:** Acute

When complete, the Consumption Model list on the Consumption Models tab should display as:

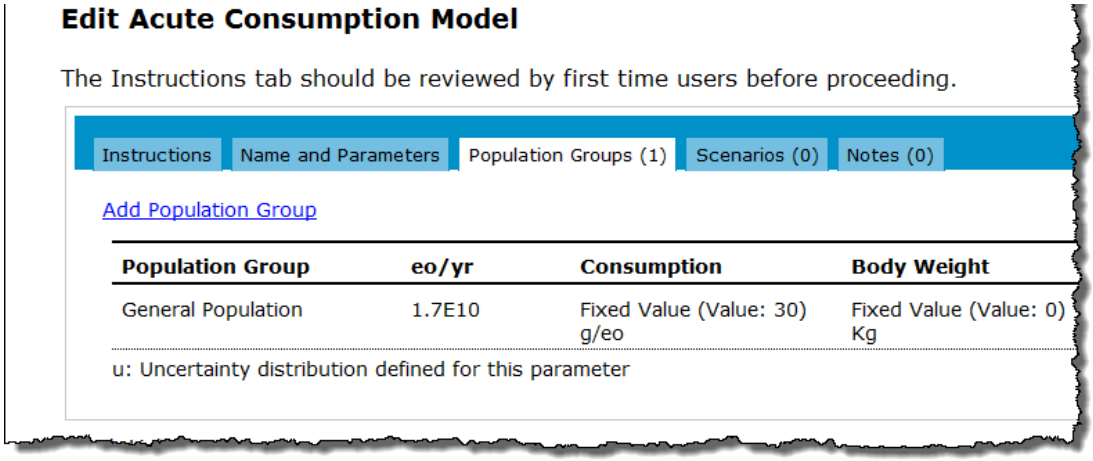


Population Group

Add the population group using the following specifications:

- **Name:** General Population
- **Eating Occasions per year:** 1.7E10 (i.e. 17 billion)
- **Amount per Eating Occasion - Unit:** g
- **Amount per Eating Occasion - Variability Distribution:** Fixed Value
- **Amount per Eating Occasion - Value:** 30
- **Body Weight:** Can be left at "0" for this scenario because body weight is not considered in a risk scenario for a microbial hazard.

When complete, the Population Groups list on the Population Groups tab should display as:



Task 3: Add the process model

Now that you have created the hazard and food elements for the risk scenario, you need to create a process model. Add a process model using the following specifications:

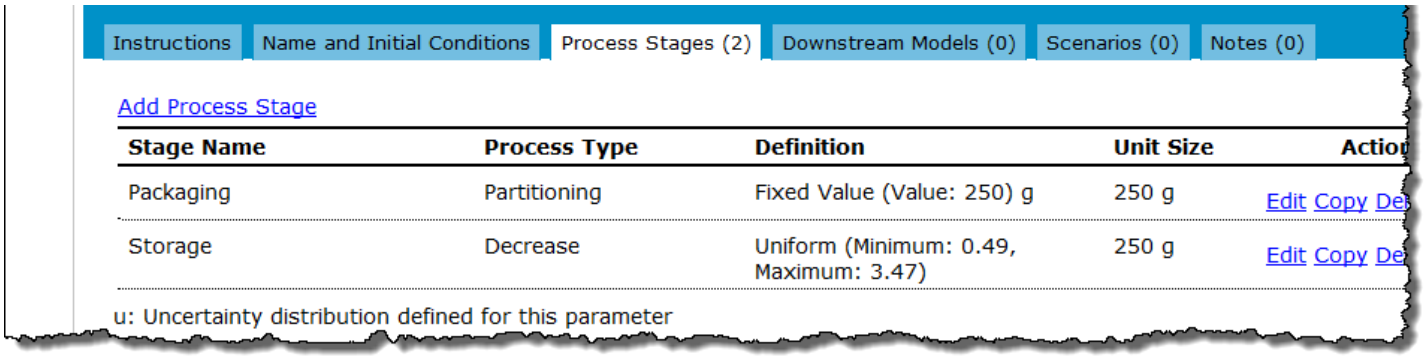
- **Name:** Salmonella in Peanut Butter
- **Hazard:** Salmonella
- **Food:** Peanut Butter
- **Initial Conditions:** The initial concentration must describe the concentration among contaminated units only, and must result in at least one cfu per unit mass defined. The prevalence value must represent the proportion of contaminated units of the unit mass specified.
- **Define Initial Conditions Using:** "Single Set of Parameters"
  Leave the box indicating that some initial units are contaminated checked. Set the unit mass to "6.85E3" and the units to "kg" for the initial unit size. Set the initial prevalence at "5.5E-6". Change the variability distribution option for concentration to "Uniform" distribution. After the page reloads, enter a minimum value of "-1.52" and a maximum value of "2.55". Note that this is on the log scale. Leave the units for concentration as "Log10 cfu/g". Leave the maximum population density as "9 log10 cfu/g". (Tip: Click the Save button to remain on the Edit Process Model page.)

Add process stages to the process model using the following specifications:

Process Stage Name	Specifications
Packaging	**Process Type:** Partitioning **Food Units:** g **Final Unit Size:** 250

Storage	**Process Type:** Decrease **Variability Distribution:** Uniform **Minimum:** 0.49 **Maximum:** 3.47

The Process Stages list on the Process Stages tab should display as:



Task 4: Add the risk scenario

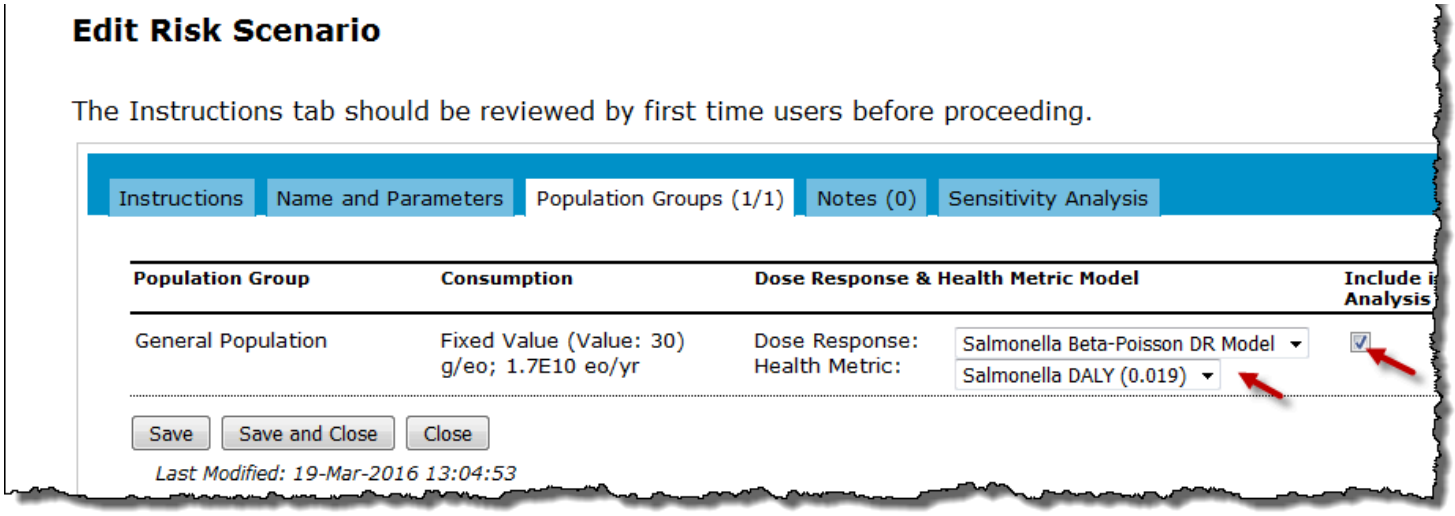
You have now defined all required elements for this risk scenario. Next, you will create the computed risk scenario for a single hazard and single food called “Salmonella in Peanut Butter”.

The Type is “Computed using FDA-iRISK model for single hazard and single food”

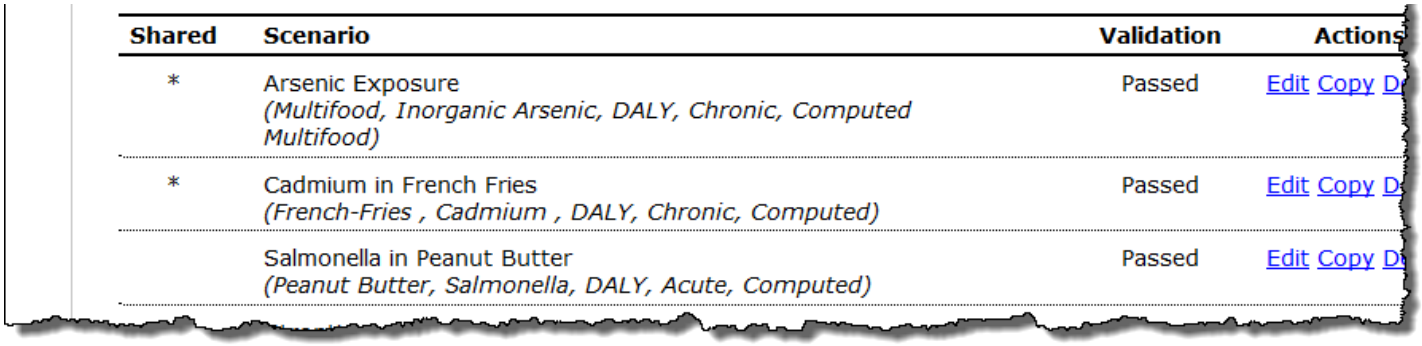
Leave the “Exposure only” box clear.

Hint: Computed risk scenarios must be linked to the food, hazard, dose-response, metric, consumption model, and process model.

Finally, you will select the “General Population” population group to include in the analysis. (This is required in order to create and generate the Risk Estimates and Scenario Ranking report.) Be sure to confirm that the correct Dose-Response model and Heath Metric are selected for the population group.



When complete, the Risk Scenarios list on the Risk Scenarios tab should display as:

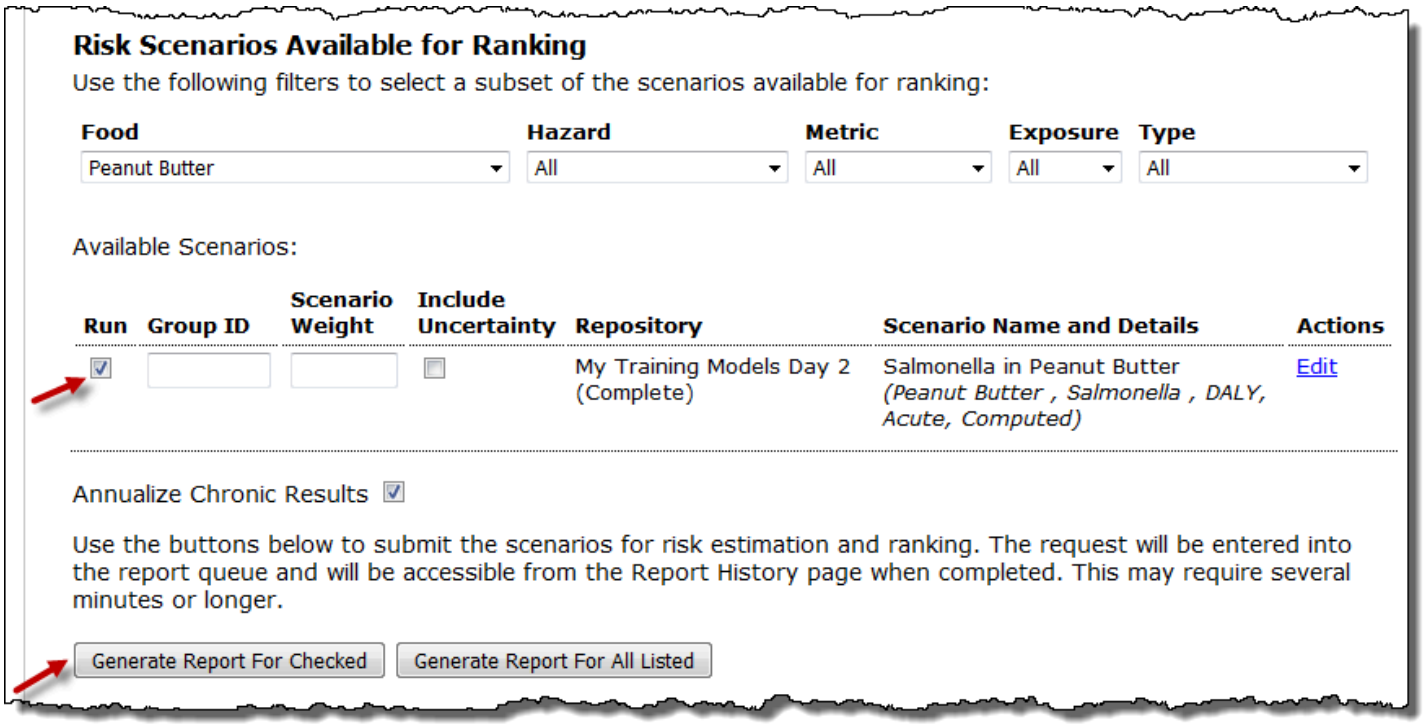


Task 5: Create and generate the Risk Estimates and Scenario Ranking report

You will create a Risk Estimates and Scenario Ranking report called, “FDA-iRISK Ranking for Salmonella in Peanut Butter” for the risk scenario that you’ve just created. (While this report only contains one scenario, it uses the generic ranking system to present results based on annual burden.)

Hint: Click the Reports tab on the main tab bar at the top of the page and choose to Create a “Risk Estimates and Scenario Ranking” Report Type.

Select the Run check box to the left of the scenario and then generate the report.



Task 6: Review the Risk Estimates and Scenario Ranking report

On the Report History tab of the Reports page, click the “Refresh Lists” button until your report disappears from the list of Pending Reports and appears in the list of Completed Reports.

Finally, view your detailed report in PDF format (check the “Details” and “Notes” boxes before clicking on “View PDF”) and compare it with the results shown below.

The report's cover page includes the report title, the abstract (if provided), and the disclaimer. The summary of the rankings starts on the second page. In this case, there is only one scenario:

Report Title: FDA-iRISK Ranking for Salmonella in Peanut Butter

Ranking Summary

All reported summary values are per year. For chronic scenarios, results for the total lifecourse have been divided by the lifecourse duration (e.g. 70 years) specified for the life stages included in the scenario.

Scenario or Scenario Group	Total DALYs per Year	Uncertainty Results
Salmonella in Peanut Butter	62.4	N/A

Note: All chronic results have been computed by dividing the total for the lifecourse by the duration of the lifecourse in years to provide a yearly value for ranking. See the detailed results sections for the complete lifecourse results, or multiply the values shown in this summary by the duration of the lifecourse.

The report summary is followed by an ungrouped ranking summary with additional details. That is, it shows the rankings by individual scenario in descending order.

Report Title: FDA-iRISK Ranking for Salmonella in Peanut Butter

Ranking Summary for Risk Scenarios (Ungrouped)

All reported summary values are per year. For chronic scenarios, results for the total lifecourse have been divided by the lifecourse duration (e.g. 70 years) specified for the population groups included in the scenario.

Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Illnesses	Mean Risk of Illness	Total DALYs per Year	DALYs Per EO or Consumer	Total DALYs per Year (Weighted)
Salmonella in Peanut Butter	N/A	1.70E+10	3280	1.93E-7	62.4	3.67E-9	62.4

Note: All chronic results have been computed by dividing the total for the lifecourse by the duration of the lifecourse in years to provide a yearly value for ranking. See the detailed results sections for the complete lifecourse results, or multiply the values shown in this summary by the duration of the lifecourse.

Several results are provided in the summary sections. All are per year values unless the “Annualize Chronic Results” option was unselected.

- **Lifecourse Duration** Applies to chronic chemical hazard scenarios and is the total lifespan considered by the scenario (e.g. 70 years).
- **Eating Occasions or # Consumers** “Eating occasions**”** is used for acute hazards and is the total for all population groups provided. “# Consumers” applies to chronic chemical hazard scenarios.
- **Total Illnesses** The total number of illnesses generated for the scenario.
- **Mean Risk of Illness** The total number of illnesses divided by the number of eating occasions (or consumers).

- **Total DALYs per Year** As this is a DALY metric scenario, the total number of DALYs is for the year.
- **DALYs per Eating Occasion or Consumer** The DALYs divided by the number of eating occasions (or consumers).
- **Weighted DALYs** These may differ from Total DALYs per Year If a scenario weight was added.

If you selected the Details check box on the Report History page, the next set of pages provides a scenario-by- scenario summary. The first section summarizes the scenario. It re-states the elements contained in the scenario, as well as indicating whether the Monte Carlo simulation converged or not. If the model converged, it reports the number of iterations used.

Scenario Details for: Salmonella in Peanut Butter

Type:	Results Computed	Scenario Weight:	N/A
Hazard:	Salmonella (Microbial Pathogen)	Metric Type:	DALY
Food:	Peanut Butter	Exposure Type:	Acute
Process Model:	Salmonella in Peanut Butter	Converged:	Yes (by 18000 variability samples)
Consumption Model:	Peanut Butter Annual Consumption	Include Uncertainty:	No

The next section summarizes changes in concentration and prevalence as the food and hazard move through the process model.

Process Model: Salmonella in Peanut Butter

	Initial Conditions	Model Outputs*
Prevalence:	5.5E-6	**4.19E-6**
Concentration:	Uniform (Units: log10 cfu/g) Minimum: -1.52 Maximum: 2.55 Computed Mean: 1.58 log10 cfu/g	**0.352 log10 cfu/g**
Unit Mass:	Fixed Value (kg) Value: 6850	**250 g**

* Final prevalence and Prevalence-Weighted mean concentration

Process Stages for Salmonella in Peanut Butter :

Process Stage	Process Type	Definition	Concentration (log10 cfu/g)	Prevalence
Packaging	Partitioning	Fixed Value (g) Value: 250	1.58	5.50E-6
Storage	Decrease	Uniform Minimum: 0.49 Maximum: 3.47	0.352	4.19E-6

The initial values provided are repeated, and final values reported. As well, the concentration and prevalence are reported for the end of each process stage.

The next section summarizes the risk estimates generated for the population group as a result of the final concentration and prevalence, as well as serving size (amount consumed). The definitions for the population group is presented first, followed by the results.

Result Summary

Mean Exposure: See population groups

Total Number of Illnesses: 3280

Total DALY/Year: 62.4

Population Group Definitions:

Population Group	Consumption	Dose Response	Health Metric
General Population	Eating Occasions: 1.7E10 eo/yr Per Eating Occasion: Fixed Value (Units: g/eo) Value: 30	Salmonella Beta-Poisson DR Beta-Poisson (Dose unit: cfu) alpha: 0.1324 beta: 51.45 Probability of adverse effect: 100%	Salmonella DALY (0.019 DALYs)

Population Group Results:

Population Group	Mean Dose* (units)	Mean** Prevalence in Servings	Mean Probability of Illness	Number of Illnesses per year	Total Metric Per Year (DALYs)
General Population	91.8	3.08E-6	1.93E-7	3280	62.4

* Mean dose per Contaminated serving

** Proportion of contaminated servings

If the scenario contained more than one population group, each would be summarized separately.

Finally, if you selected the Notes check box on the Report History page, any non-private notes associated with the scenario and its elements would be included at the end of the scenario's summary.

Scenario M2 - A Single Food-Hazard Pair in Three Population Groups

You are creating a computed scenario for *Listeria monocytogenes* in soft ripened cheese that estimates the health burden for three population groups (each with its own dose-response model, DALY metric, and consumption data) for a single food-hazard pair.

Complete the following tasks in your primary repository.

Task 1: Add the hazard, dose-response model, and a metric

Hazard

Add the hazard using the following specifications:

- **Name:** L. monocytogenes
- **Type:** Microbial Pathogen
- **Default Unit:** cfu

Dose-Response Model

Add the following distinct dose-response models for acute exposures to the L. monocytogenes hazard:

Name	Response Type	r-Value	Probability of Adverse Effect
Adults 60+ DR	Exponential	8.39E-12	100
Intermediate Aged (5-59) DR	Exponential	5.34E-14	100
Perinatal DR	Exponential	4.51E-11	100

When complete, the Dose Response list should display as:

Model	Exposure	Response	Actions
Adults 60+ DR	Acute	Exponential Dose unit: cfu (r:8.39E-12; 100%)	Edit Copy Delete
Intermediate Aged (5-59) DR	Acute	Exponential Dose unit: cfu (r:5.34E-14; 100%)	Edit Copy Delete
Perinatal DR	Acute	Exponential Dose unit: cfu (r:4.51E-11; 100%)	Edit Copy Delete

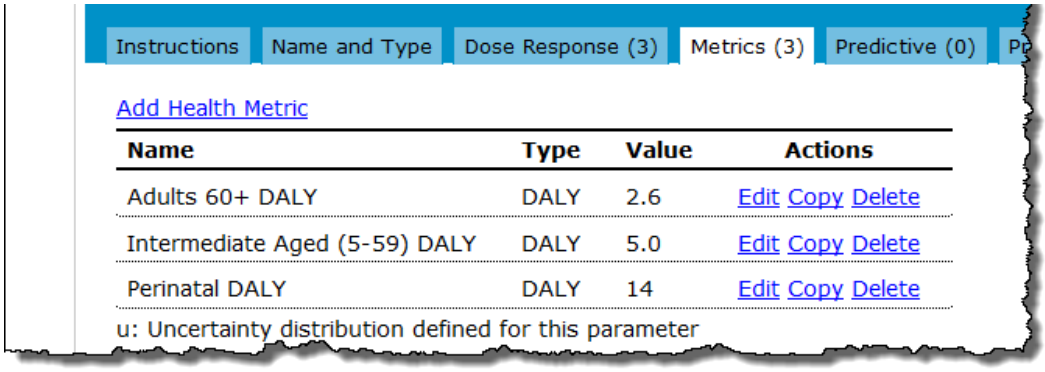
u: Uncertainty distribution defined for this parameter

Metric

Add the following metrics to the L. monocytogenes hazard:

Name	Type	Value
Adults 60+ DALY	DALY	2.6
Intermediate Aged (5-59) DALY	DALY	5.0
Perinatal DALY	DALY	14

When complete, the Metric list should display as:



Task 2: Add the food and its consumption pattern in the population groups

Food

Add the food using the following specifications:

- **Name:** Soft Ripened Cheese
- **Measured using:** Mass

Consumption Model

Add the consumption model using the following specifications:

- **Name:** Total Consumption of Soft Ripened Cheese
- **Exposure Type:** Acute

Population Groups

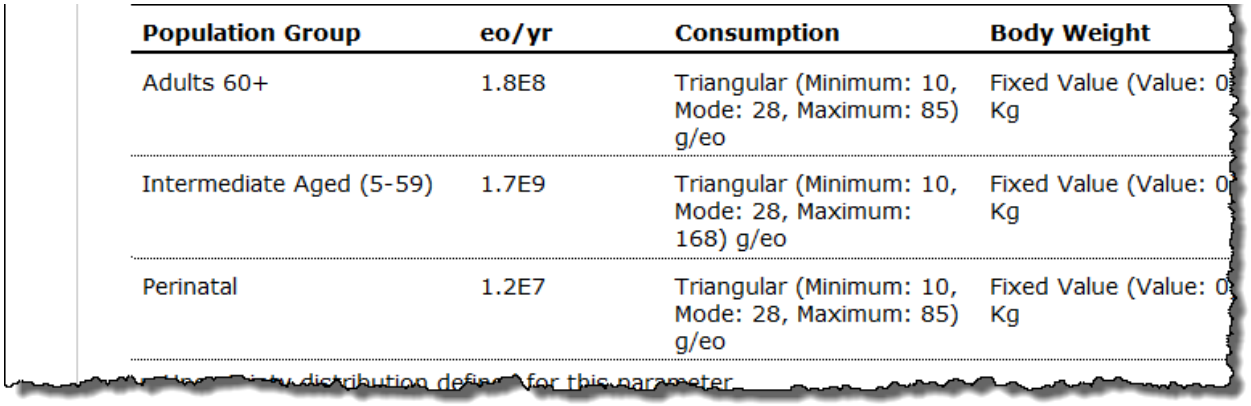
Add the following population groups with the following parameters:

Name	Eating occasions per	Amount per eating occasion	Body Weight

	year	(in grams)	
Adults 60+	1.8E+08	Triangular(10,28,85)	Fixed Value: 0
Intermediate Aged (5-59)	1.7E+09	Triangular(10,28,168)	Fixed Value: 0
Perinatal	1.2E+07	Triangular(10,28,85)	Fixed Value: 0

You may omit the Body Weight and Correlation fields.

When complete, the Population Groups list on the Population Groups tab should display as:



Population Group	eo/yr	Consumption	Body Weight
Adults 60+	1.8E8	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo	Fixed Value (Value: 0 Kg
Intermediate Aged (5-59)	1.7E9	Triangular (Minimum: 10, Mode: 28, Maximum: 168) g/eo	Fixed Value (Value: 0 Kg
Perinatal	1.2E7	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo	Fixed Value (Value: 0 Kg

Task 3: Add the process model

Add a process model using the following specifications:

- **Name:** L. monocytogenes in soft ripened cheese
- **Hazard:** L. monocytogenes
- **Food:** Soft Ripened Cheese
- **Define Initial Conditions Using:** "Single Set of Parameters"
- **Initial Conditions:** Leave the box indicating that some initial units are contaminated checked. Set the initial unit mass as "227 g", and set the initial prevalence as "0.0104". Set the initial concentration as "Triangular (- 1.39, -1.15, 0.699) log10 cfu/g". Leave the maximum population density to "9 log cfu/g". Save the changes.

Add process stages to the process model using the following specifications:

Process Stage Name	Specifications
Consumer Storage	**Process Type:** Increase by Growth **Variability Distribution:** Triangular **Minimum:** 0 **Mode:** 0.03 **Maximum:** 5.79

Task 4: Add the risk scenario

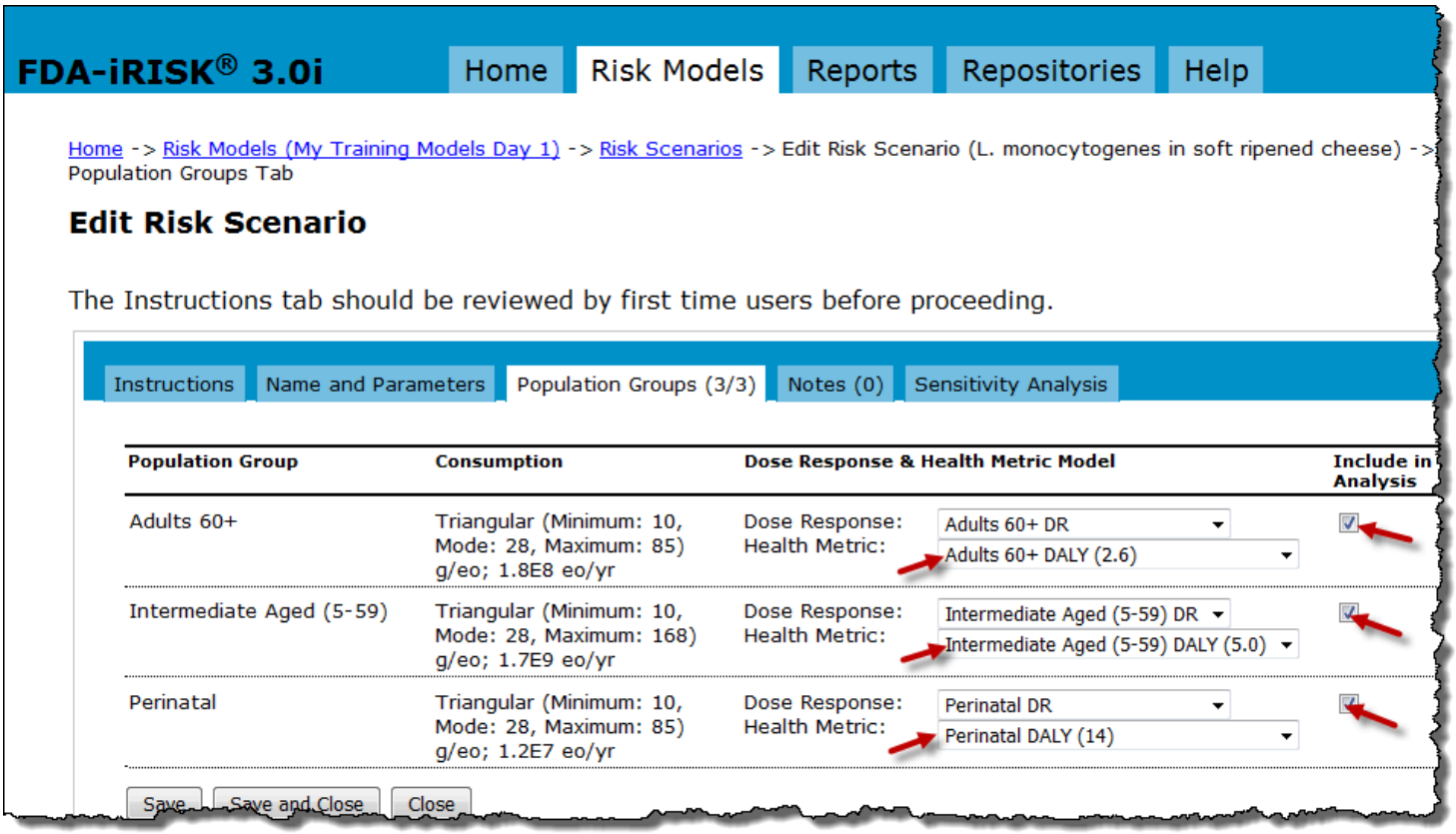
You have now defined all required elements for this risk scenario. Next, you will create the computed risk scenario for single hazard and single food called “L. monocytogenes in soft ripened cheese”.

Hint: Computed risk scenarios must be linked to the food, hazard, dose-response, metric, consumption model, and process model.

The Type is “Computed using FDA-iRISK model for single hazard and single food”

Leave the “Exposure only” box clear.

Finally, you will select the population groups to include in the analysis. Use the following specifications. Be sure to match the population groups with the appropriate dose-response model and metric.



Task 5: Create and generate the Risk Estimates and Scenario Ranking report

You will create a Risk Estimates and Scenario Ranking report called, “Ranking Report for Salmonella and L. monocytogenes” for both risk scenarios that you created in this exercise.

Hint: Click the Reports tab on the main tab bar at the top of the page and choose to Create a “Risk

Estimates and Scenario Ranking" Report Type.

Select the Run check box to the left of both scenarios (Salmonella in Peanut Butter and L. monocytogenes in soft ripened cheese) and then generate the report.

Confirm the appropriate repository is "checked" in the "List scenarios for" field below the Report Abstract field.

Task 6: Review the Risk Estimates and Scenario Ranking report

On the Report History tab of the Reports page, click the "Refresh Lists" button until your report disappears from the list of Pending Reports and appears in the list of Completed Reports.

Finally, view your detailed report in PDF format (check the "Details" and "Notes" boxes before clicking on "View PDF") and compare it with the results shown below.

This report contains two scenarios, ranking in descending order by total DALYs per

year.

Ranking Summary

All reported summary values are per year. For chronic scenarios, results for the total lifecourse have been divided by the lifecourse duration (e.g. 70 years) specified for the life stages included in the scenario.

Scenario or Scenario Group	Total DALYs per Year	Uncertainty Results
Salmonella in Peanut Butter	62.4	N/A
L. monocytogenes in soft ripened cheese	15.7	N/A

Ranking Summary for Risk Scenarios (Ungrouped)

All reported summary values are per year. For chronic scenarios, results for the total lifecourse have been divided by the lifecourse duration (e.g. 70 years) specified for the population groups included in the scenario.

Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Illnesses	Mean Risk of Illness	Total DALYs per Year	DALYs Per EO or Consumer	Total DALYs per Year (Weighted)
Salmonella in Peanut Butter	N/A	1.70E+10	3280	1.93E-7	62.4	3.67E-9	62.4
L. monocytogenes in soft ripened cheese	N/A	1.89E+9	2.79	1.48E-9	15.7	8.27E-9	15.7

The details section contains complete details for both scenarios, sorted alphabetically by name.

In the results section for the soft ripened cheese scenario, the report breaks out the results for each population group:

Population Group	Consumption	Dose Response	Health Metric
Adults 60+	Eating Occasions: 1.8E8 eo/yr Per Eating Occasion: Triangular (Units: g/eo) Minimum: 10 Mode: 28 Maximum: 85	Adults 60+ DR Exponential (Dose unit: cfu) r: 8.39E-12 Probability of adverse effect: 100%	Adults 60+ DALY (2.6 DALYs)
Intermediate Aged (5-59)	Eating Occasions: 1.7E9 eo/yr Per Eating Occasion: Triangular (Units: g/eo) Minimum: 10 Mode: 28 Maximum: 168	Intermediate Aged (5-59) DR Exponential (Dose unit: cfu) r: 5.34E-14 Probability of adverse effect: 100%	Intermediate Aged (5-59) DALY (5.0 DALYs)
Correlation Option: No Correlation			
Perinatal	Eating Occasions: 1.2E7 eo/yr Per Eating Occasion: Triangular (Units: g/eo) Minimum: 10 Mode: 28 Maximum: 85	Perinatal DR Exponential (Dose unit: cfu) r: 4.51E-11 Probability of adverse effect: 100%	Perinatal DALY (14 DALYs)
Correlation Option: No Correlation			

Population Group Results:

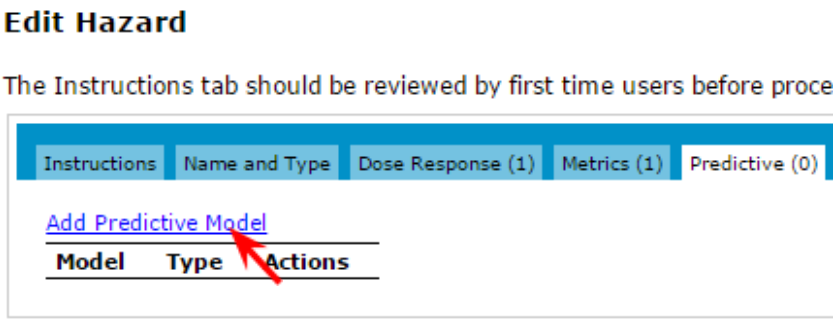
Population Group	Mean Dose* (units)	Mean** Prevalence in Servings	Mean Probability of Illness	Number of Illnesses per year	Total Metric Per Year (DALYs)
Adults 60+	1.21E+5	0.0104	1.06E-8	1.90	4.94
Intermediate Aged (5-59)	2.09E+5	0.0104	1.16E-10	0.197	0.986
Perinatal	1.24E+5	0.0104	5.79E-8	0.695	9.73

* Mean dose per Contaminated serving

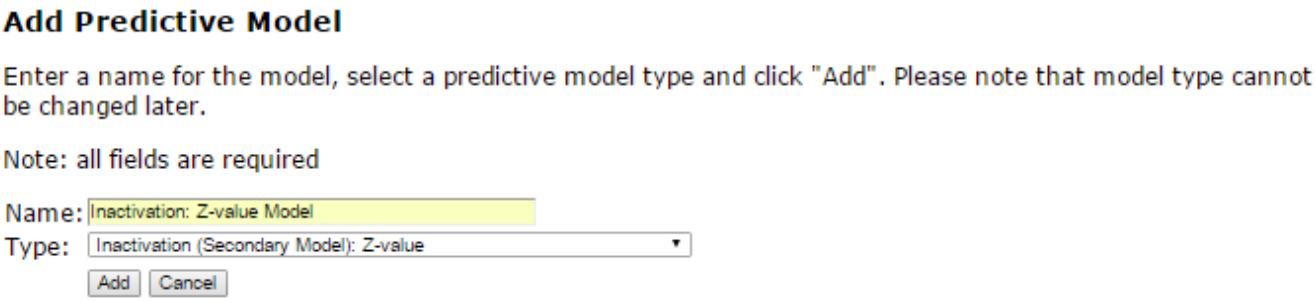
** Proportion of contaminated servings

Exercise PM1: Predictive Models

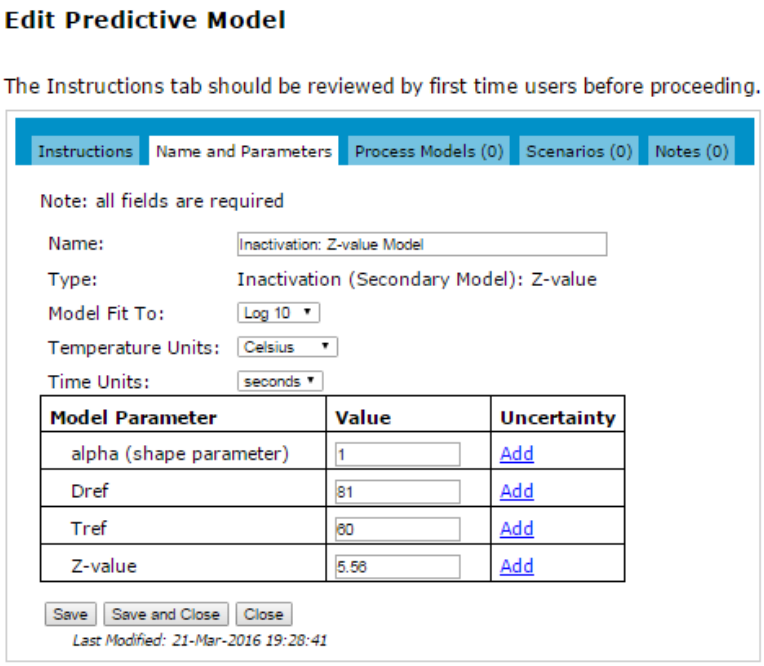
This example will walk the user through building a predictive inactivation model for *Salmonella*. The example requires that the user has previously imported and modified the '*Salmonella* in Peanut Butter' scenario. To begin, click to edit *Salmonella* under the Hazards tab. Then click on the 'Predictive' tab, and click "Add Predictive Model".



Name the model: "Inactivation: Z-value Model", and select 'Inactivation (Secondary Model): Z-value' as the Type. Click Add.

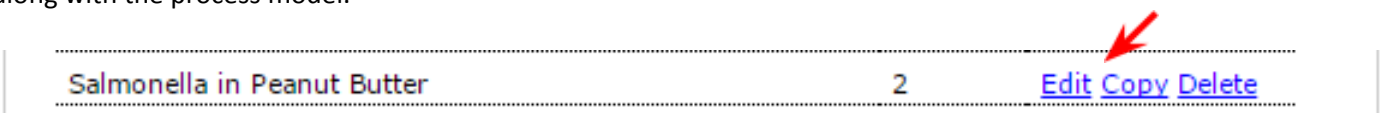


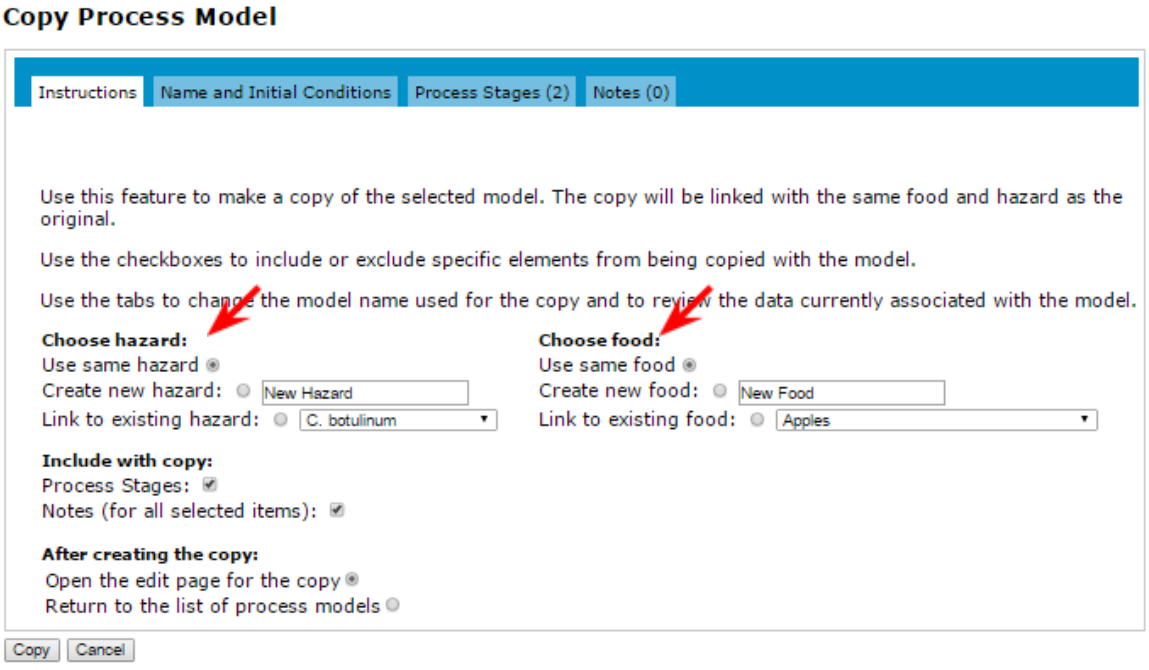
Add the following parameters to the Z-value inactivation model (make sure to change the time unit to seconds):



Save and close.

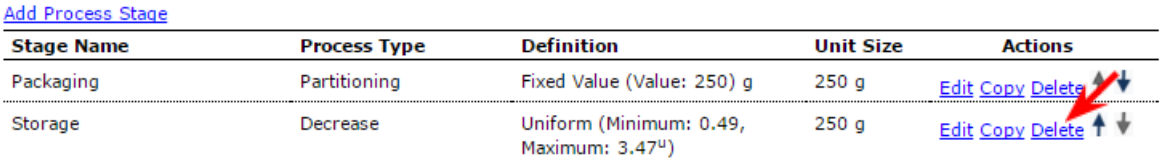
Copy the existing "*Salmonella* in Peanut Butter" Process Model. Make sure to use the same Hazard Model and Food go along with the process model.



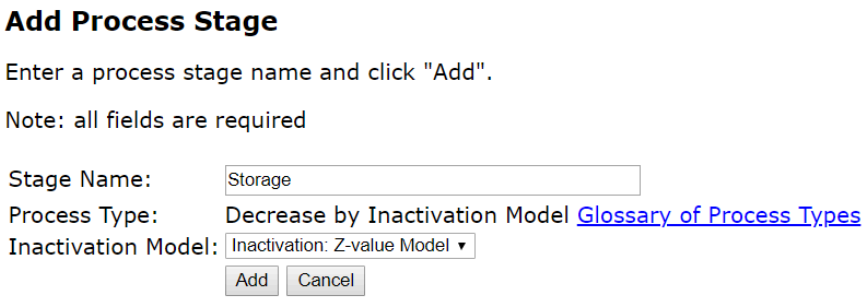


Change the name of the process model to "*Salmonella* in Peanut Butter (Predictive Inactivation)". The initial conditions will remain the same as the original "*Salmonella* in Peanut Butter" process model.

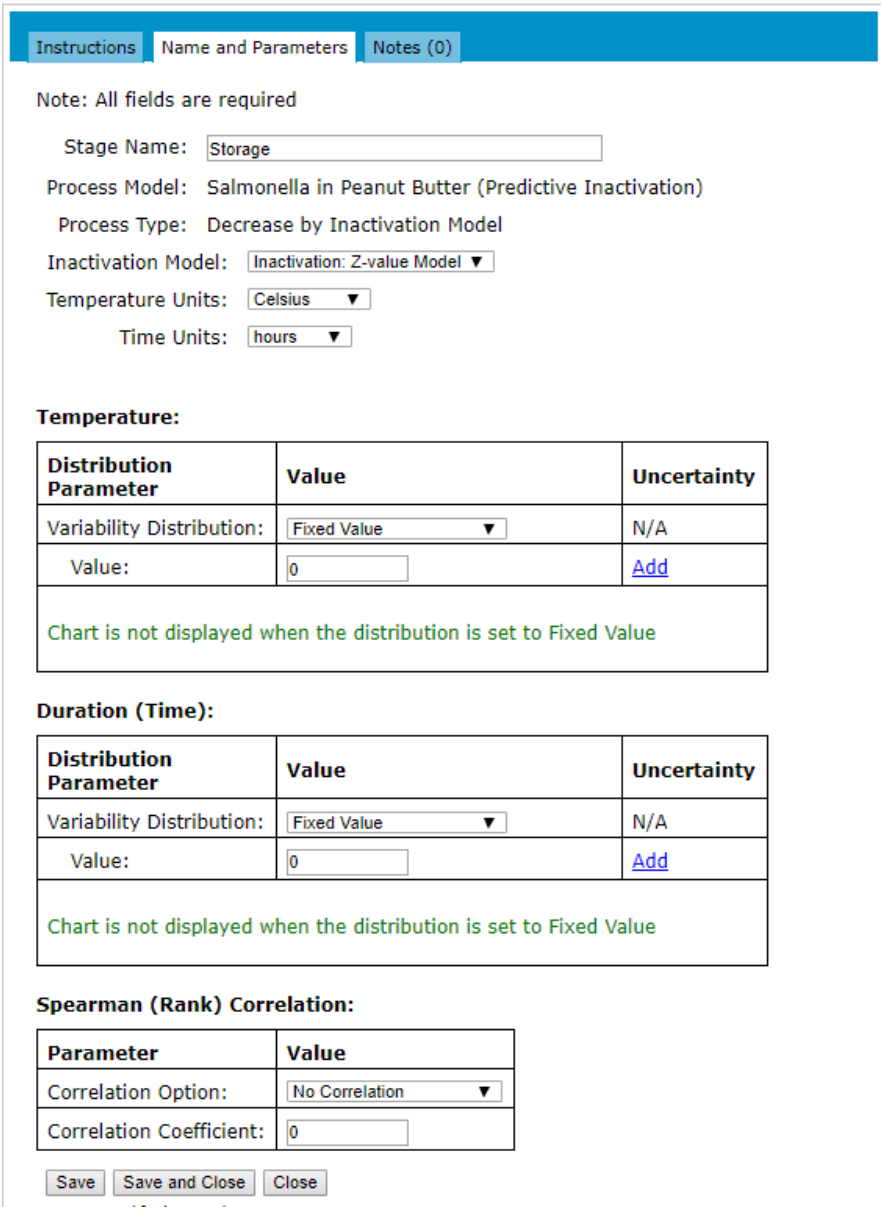
Delete the existing 'Storage' process stage.



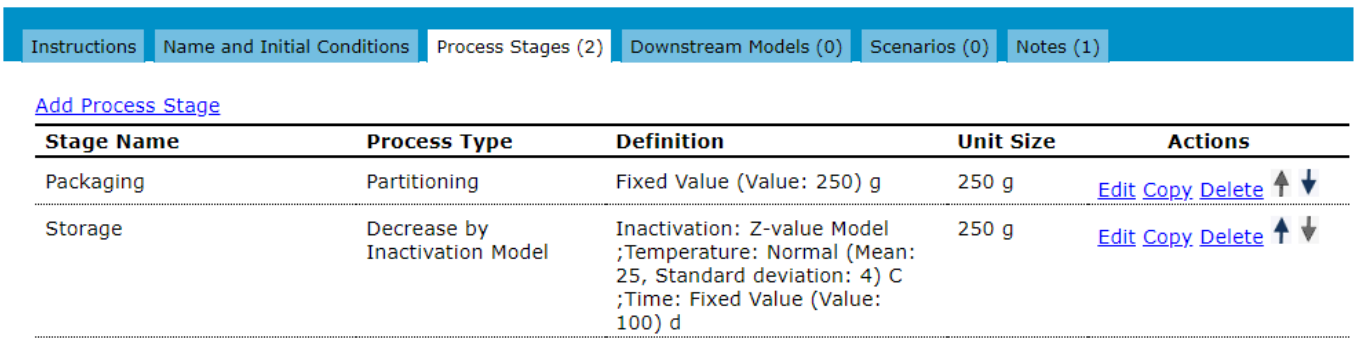
Add a new process stage. Select the 'Decrease by Inactivation Model' process stage type. Select the 'Inactivation: Z-value Model' predictive model from the dropdown menu.



The following screen will appear:



You will estimate the storage time of peanut butter to be 100 days at a normally distributed mean of 25°C, standard deviation 4°C (note: time and temperature do not represent actual values for peanut butter storage).
Hint: make sure to check the **Time Units** and change it from "hours" to "days". Enter appropriate parameters into the input boxes. No Spearman (Rank) Correlation is used in this exercise. Save and close the process stage.



Create a scenario for *Salmonella* in Peanut Butter (Predictive Model). Reset the simulation settings to default.

Generate a report for "*Salmonella* in Peanut Butter (Predictive)", and the original "*Salmonella* in Peanut Butter" scenarios.

Risk Scenarios Available for Ranking

Available Scenarios:

Run	Group ID	Scenario Weight	Include Uncertainty	Repository	Scenario Name and Details	Actions
☑			n/a	My irisk@foodrisk.org_IAFP Workshop2019	Salmonella in Peanut Butter *(Peanut Butter, Salmonella, DALY, Acute, Computed)*	Edit
☐			n/a	My irisk@foodrisk.org_IAFP Workshop2019	Salmonella in Peanut Butter – Specified *(Peanut Butter, Salmonella, DALY, Acute, Specified)*	Edit
☑			n/a	My irisk@foodrisk.org_IAFP Workshop2019	Salmonella in Peanut Butter (Predictive) *(Peanut Butter, Salmonella, DALY, Acute, Computed)*	Edit

Predictive model results are shown in the process stages section of the report.

Ranking Summary

All reported summary values are per year. For chronic scenarios, results for the total lifecourse have been divided by the lifecourse duration (e.g. 70 years) specified for the life stages included in the scenario.

Scenario or Scenario Group	Total DALYs per Year	Uncertainty Results
Salmonella in Peanut Butter (Predictive)	288	N/A
Salmonella in Peanut Butter	62.4	N/A

Process Stages for Salmonella in Peanut Butter (Predictive Inactivation):

Process Stage	Process Type	Definition	Concentration (log10 cfu/g)	Prevalence
Packaging	Partitioning	Fixed Value (g) Value: 250	1.58	5.50E-6
Storage	Decrease by Inactivation Model	Inactivation Model: Inactivation: Z-value Model Temperature: Normal (C) Mean: 25 Standard deviation: 4 Time: Fixed Value (d) Value: 100 Correlation Option: No Correlation; Correlation Coefficient: 0	1.47	5.44E-6

Exercise SA1: Sensitivity Analysis

You will create and run a sensitivity analysis report for a risk scenario.

You can select one or more sensitivity analysis sets to compare against the baseline risk scenario. FDA-iRISK computes the results for each alternative set of values independently.

Note: You can change a parameter set in any one of the four model elements in the risk scenario under evaluation: process model, consumption model, dose response model, and health metric. For this exercise, you will focus on control measures applied in the process model.

Run Sensitivity Analysis

1. Navigate to the Risk Scenarios page.

2. Click the **Edit** link to the right of the risk scenario where you want to run sensitivity analysis (e.g., Salmonella in Peanut Butter (Predictive)).

3. Click on the Sensitivity Tab.

4. Create three sensitivity sets:

- In the first sensitivity set, decrease the mean storage time.
- In the second, decrease the mean temperature.
- In the third, decrease time and temperature both by the same amount as in the first two.

5. Run the sensitivity analysis by selecting the three sets and clicking “Generate Report for Checked.”

6. Follow the link to the report page to view the results, either in PDF or in Excel. You should have four separate results, the baseline and one for each of the three sensitivity sets.