

FDA-iRISK® 4.2
Food Safety Modeling Tool

User Guide

March 2021

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Preface

About this Guide

This guide provides step-by-step instructions about how to navigate the FDA-iRISK[®] user interface, enter data and create risk scenarios, and share data and risk scenarios with other users.

The *FDA-iRISK[®] Quick Start* provides a high-level overview of the FDA-iRISK functionality using worked examples. If you are new to FDA-iRISK, it is recommended that you work through the *FDA-iRISK[®] Quick Start* before reading this document.

For more information about how FDA-iRISK computes risk estimates, refer to the *FDA-iRISK[®] Technical Document* that describes the underlying mathematical architecture and equations used for risk calculations. Both the *FDA-iRISK[®] Quick Start* and *FDA-iRISK[®] Technical Document* are available on the FDA-iRISK Help page.

FDA-iRISK Support

If, after reading this manual, you have a question about FDA-iRISK, first consult the resources on the Help page in the FDA-iRISK interface. If you still can't find the information that you need, click the Contact link at the bottom of the FDA-iRISK window, and complete and submit the form.

CHAPTER 1

Introduction

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 following:

- The food and its associated consumption data and processing/preparation methods.
- The hazard and its dose-response curve.
- The anticipated health effects of the hazard when ingested by humans.

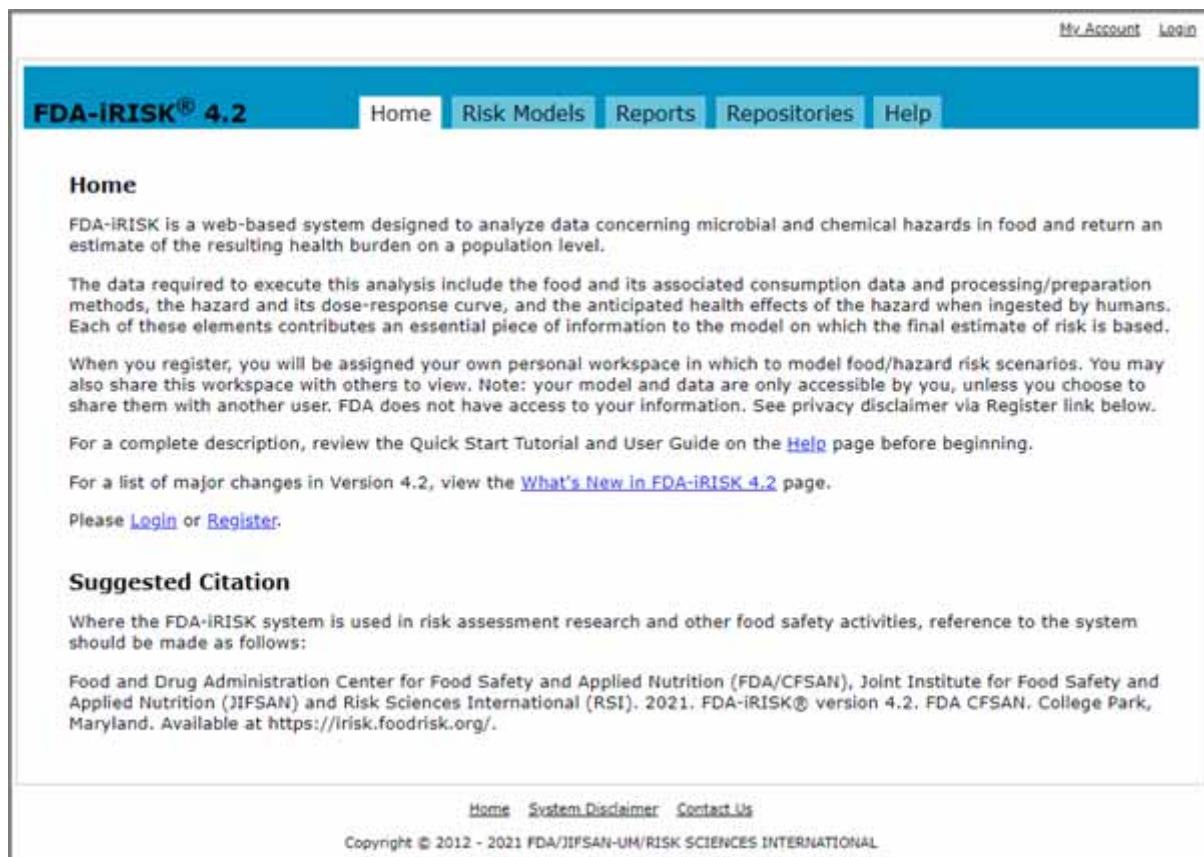
Each of these elements contributes an essential piece of information to the model on which the final estimate of risk is based.

FDA-iRISK supports the following risk (exposure) scenarios:

- Acute exposure to microbial hazards in a single food.
- Acute exposure to chemical hazards in a single food.
- Chronic exposure to chemical hazards in a single food.
- Chronic exposure to chemical hazards in multiple foods (multifood).

FDA-iRISK Home Page

Access the FDA-iRISK Home page at <https://irisk.foodrisk.org>.

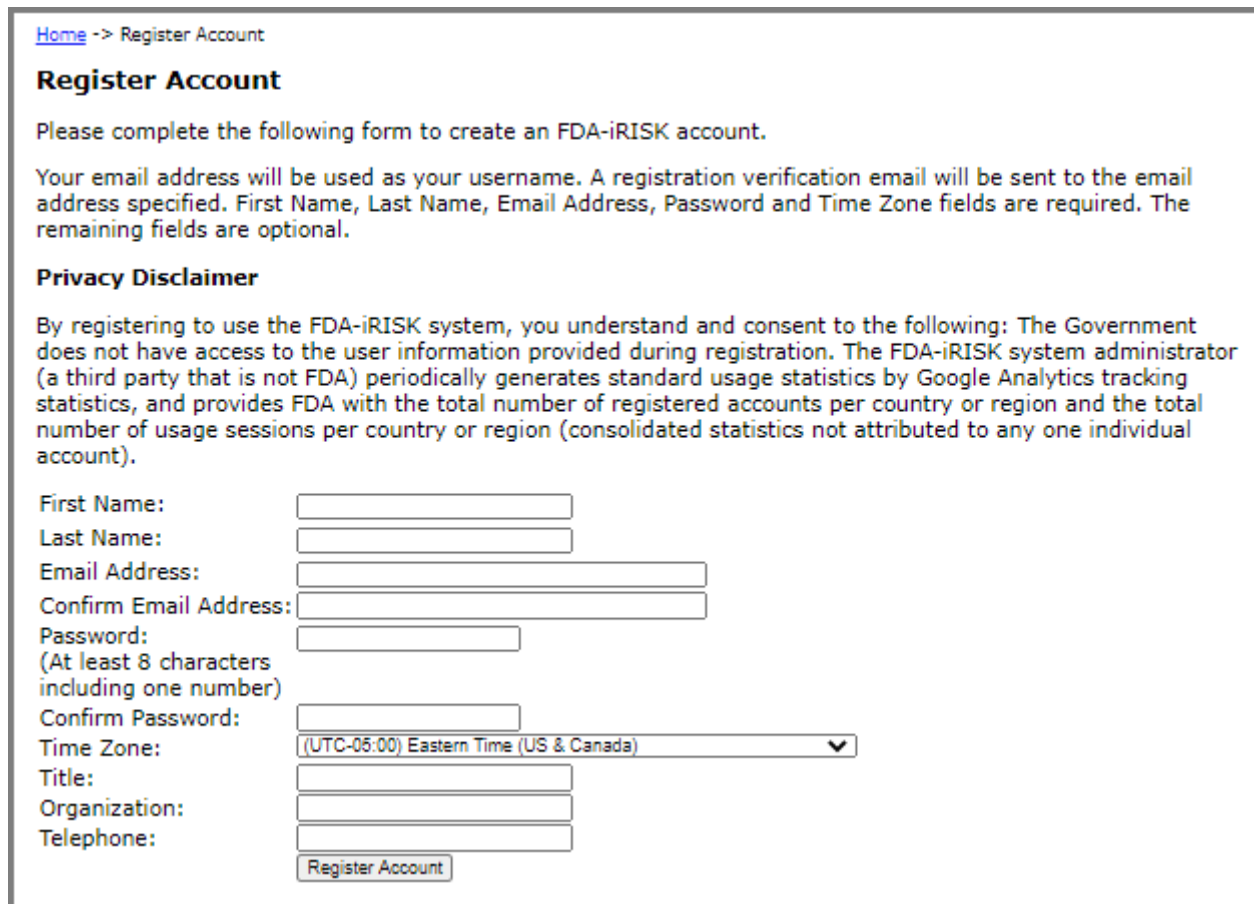


The main FDA-iRISK page consists of the following tabs:

- **Home** The “front” page that describes FDA-iRISK and provides Login and Register links.
- **Risk Models** Where you define the elements needed to create a risk scenario.
- **Reports** Where you customize and generate model summary and scenario ranking reports.
- **Repositories** Where you manage your repositories including creating a new repository, extending invitations to share elements with others, and monitoring current sharing privileges.
- **Help** Where you can learn more about where to access help and additional resources.

Registering for FDA-iRISK

- 1 To register for an FDA-iRISK account, click the **Register** link on the Home tab. The Register Account page opens.



The screenshot shows the 'Register Account' page. At the top, there is a link 'Home -> Register Account'. The title is 'Register Account'. Below the title, it says 'Please complete the following form to create an FDA-iRISK account.' and 'Your email address will be used as your username. A registration verification email will be sent to the email address specified. First Name, Last Name, Email Address, Password and Time Zone fields are required. The remaining fields are optional.' There is a 'Privacy Disclaimer' section. The form fields are: First Name, Last Name, Email Address, Confirm Email Address, Password (with a note: '(At least 8 characters including one number)'), Confirm Password, Time Zone (a dropdown menu showing '(UTC-05:00) Eastern Time (US & Canada)'), Title, Organization, and Telephone. A 'Register Account' button is at the bottom.

- 2 Enter your contact information, and then click **Register Account**.
An activation email will be sent to the email address provided.
- 3 Follow the instructions in the email to activate your account.

Logging into FDA-iRISK

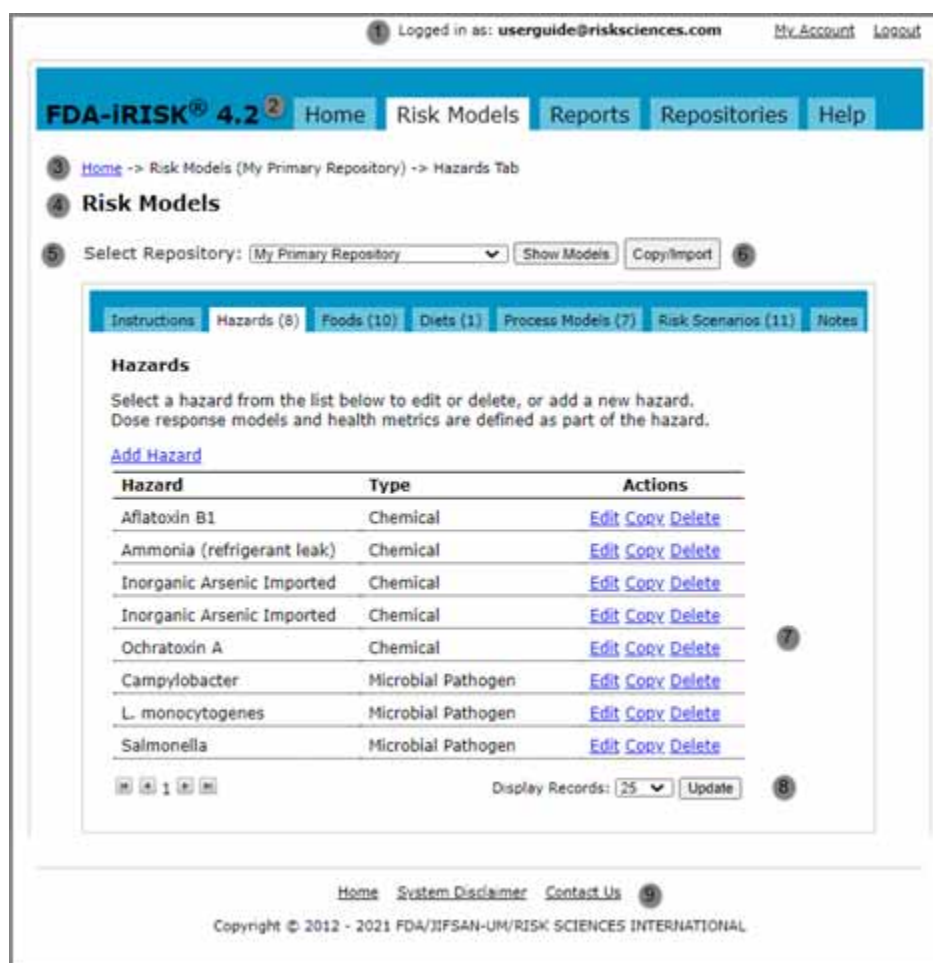
- 1 To log in, do one of the following:
 - Click the **Login** link at the top right of the main FDA-iRISK page.
 - Click the **Login** link on the Home tab.
- 2 Click the **Disclaimer** link and review the information. Select the check box.
- 3 Click **Login**. The Risk Models page opens.

Navigating FDA-iRISK

FDA-iRISK is comprised of a tabbed interface that provides access to its functionality. Click a link or tab to open the relevant page. Only one page may be open at a time.

Important: When navigating between tabs in FDA-iRISK, all data must be saved on the current page before opening a new page, even a page “within” the current element (e.g., an uncertainty page). Otherwise, any changes will be lost.

The numbers in the following figure highlight the different areas of the FDA-iRISK page. Each numbered area is described in the table below.



Area	Description
1	Logged In As Displays the email address of the user who is currently logged in. My Account Use the My Account link to edit your account settings, including changing your password. Logout Exits FDA-iRISK.
2	Main Tab Bar Consists of the tabs to navigate to the Home, Risk Models, Reports, Repositories, and Help pages.

Area	Description
3	Breadcrumbs The breadcrumb string indicates the location in the site hierarchy of the page presently visible. You can navigate back up the hierarchy by clicking the appropriate breadcrumb link.
4	Page Title Identifies the current page.
5	Select Repository If you have created multiple repositories or have access to repositories of models shared by other users, you can select the desired repository from this drop-down list to view data stored in that repository. All new accounts automatically have access to a set of Sample Models under the name Sample Models that provide examples of the different elements.
6	Section Tab Bar Allows you to navigate to different pages within the page selected on the Main Tab Bar. The active tab is white rather than blue. The numbers beside the tab name indicate the number of definitions that have been created for that element.
7	Work Area Displays the list of definitions, if any, that have been created for that element. You can add, edit, or delete definitions for the selected element from the work area.
8	Paging Controls Used to navigate between the pages that contain lists. In addition, you can select the number of records to display on a list page from the drop-down list on the right side. The new number is saved in your profile. The selected value applies to all list pages
9	Footer Links Links to the Home, Disclaimer, and Contact Us pages.

Notifications

The following types of notifications display at the top of each page:

- System-wide (e.g. planned upgrade or a new webinar).
- Report has completed. The message includes the report name and completion date and time.
- Share repository invitations. The message displays the repository name and invitation date.



Click the  button to the right to acknowledge receipt and close the notification.

Editing Account Information

- 1 Click the **My Account** link at the top right of the FDA-iRISK main page.
- 2 On the Manage Account page, edit the account information as required.
- 3 Click **Save Account Changes**.

Note: If you change the email address associated with your account, once you save the changes, you will be required to log in using the new email address.

Changing Your Password

- 1 Click the **My Account** link at the top right of the FDA-iRISK main page.
- 2 In the **Existing Password** input field, enter your current password.
- 3 Enter and confirm the new password.
- 4 Click **Change Password**.

Defining Numeric Parameters in FDA-iRISK

A risk scenario (or “risk model”) developed in FDA-iRISK, includes seven elements:

- the food
- the hazard
- the population of consumers
- a process model (i.e. food production, processing and handling practices)
- consumption pattern(s) in the population
- dose-response relationship(s)
- burden of disease measures associated with different adverse health effects from the hazard (i.e. a health metric such as losses in Disability-Adjusted Life Years, or DALYs).

Once you identify the food, the hazard, and the population of interest, the other four model elements in FDA-iRISK require numeric parameters and data. Parameters for some elements may require fixed (single) values, while others offer the option of fixed values or variability distributions. For most individual parameters, the user can also specify uncertainty using a distribution.

Note: When entering a numerical value, you must use a period (.) to represent the decimal (e.g. 0.1324 and 51.45). Entering a comma (,) will result in an error. This requirement applies to any place where numerical values are defined (e.g., when defining a dose response relationship or a contamination distribution).

Fixed Values

A parameter that takes a fixed numeric value is represented in the FDA-iRISK interface by a single input field on the appropriate page. For example, the annual consumers parameter of a chronic consumption model is defined as a fixed value.

You may enter the value in standard notation:

Model Name:	<input type="text" value="Tortilla Chip Consumption"/>
Exposure Type:	Chronic
Annual Consumers:	<input type="text" value="25,000,000"/>
Uncertainty:	Add
<input type="button" value="Save"/> <input type="button" value="Save and Close"/> <input type="button" value="Close"/>	

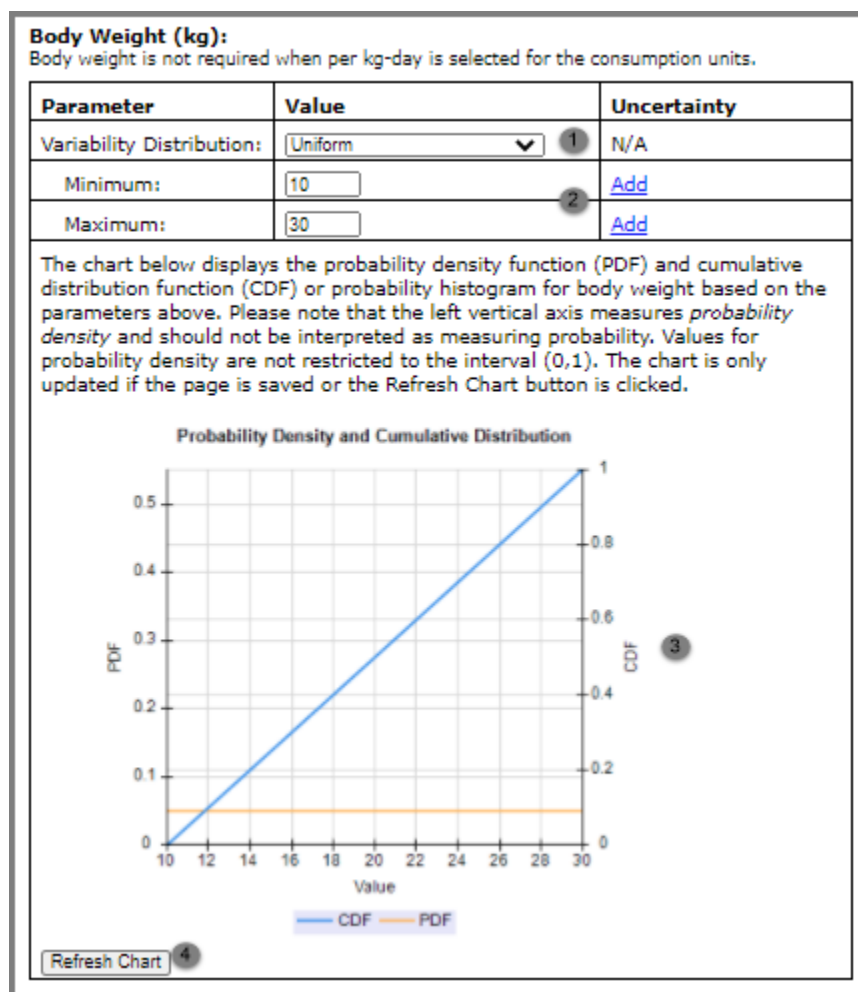
You may also enter the value in scientific notation:

Model Name:	<input type="text" value="Tortilla Chip Consumption"/>
Exposure Type:	Chronic
Annual Consumers:	<input type="text" value="25E6"/>
Uncertainty:	Add
<input type="button" value="Save"/> <input type="button" value="Save and Close"/> <input type="button" value="Close"/>	

Variability Distributions

A parameter that takes a variability distribution is represented in the FDA-iRISK interface by a combination of a drop-down list and one or more input fields.

For example, the body weight (kg) of 1 to 5 year olds might be represented as Uniform(10,30) distribution.

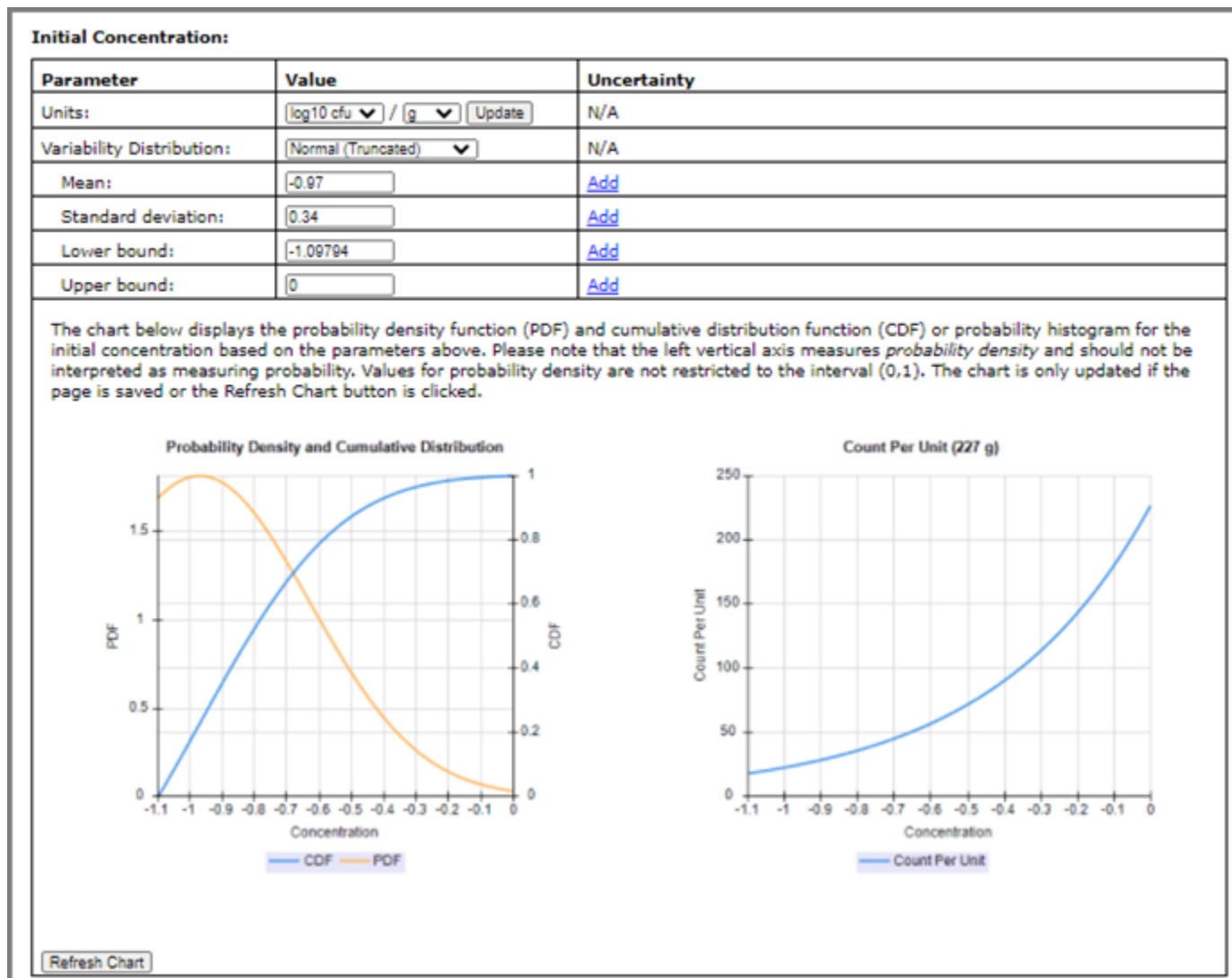


To achieve this, you would first select Uniform from the list of available distribution options 1. The page reloads and displays the Minimum and Maximum parameters 2. (The parameters that display depend on the distribution option that you select.)

If the values for a selected distribution are valid, a chart displaying the cumulative distribution function (CDF) and probability distribution function (PDF) for the distribution is provided below the distribution 3. (CDF only displays for cumulative empirical distributions.) If the distribution is not valid, or the parameter value set to Fixed, then no chart is displayed.

You can click the Refresh Chart button 4 to update the chart without saving the changes. The chart also reloads when the page is saved.

For process models involving microbial hazards, in addition to the CDF and PDF charts, a chart showing the actual count per food unit displays. This is useful for validating the entered parameters.



In addition, you have the option to impose the Spearman rank correlation between the following types of distributions:

- Time and temperature distributions for predictive microbial process stages
- Consumption and body weight for single food consumption models (when body weight is required)
- Pool size and transfer rate distributions for the process type: cross-contamination with concentration
- Pool amount and transfer rate distributions for process type: cross-contamination by amount

Cumulative Empirical Distributions

Consider the following:

- Cumulative probabilities should be expressed as a number between 0 and 1. The first row must have a cumulative probability of 0 (minimum of the distribution). The last row must have a cumulative probability of 1 (maximum of the distribution).

- Cumulative probabilities must be increasing and unique. Values must also be increasing but duplicate values are allowed.
- For each cumulative probability, the probability is given an outcome that is less than or equal to the corresponding value.
- Parameters for the cumulative empirical distributions (listed as “Empirical (cubic)” and “Empirical (linear)” in the drop-down list) are entered differently than the other distribution options.

You can enter a distribution using cumulative probability/value pairs as a table (default) or in an input field. When entered as a table, you add, delete, or add rows as required. When entered in an input field, each pair is entered on a separate line and the format is “cumulative probability, value” (e.g. 0.1, -3).

Example entering data as a table:

Value

g ▼

Empirical (cubic) ▼ [Import](#)

Enter as Table ▼

Probability	Value	Actions
0.0	10	Insert Delete
0.3	15	Insert Delete
0.5	20	Insert Delete
0.75	25	Insert Delete
1	30	Insert Delete

Number of Rows: 10 [Add](#)

Example entering the same data in an input field:

The screenshot shows a web form titled "Value". It contains a dropdown menu with "g" selected, another dropdown menu with "Empirical (cubic)" selected, and a blue "Import" link. Below these is a button labeled "Enter as List" with a dropdown arrow. Underneath is a text area containing the following data:

0.0	10
0.3	15
0.5	20
0.75	25
1	30

Alternatively, you can click the Import link to import empirical distributions from text, CSV, or Microsoft Excel files.

The screenshot shows a web page with a breadcrumb trail: [Home](#) -> [Risk Models \(My New Repository\)](#) -> [Foods](#) -> [Food \(Cantaloupe\)](#) -> [Consumption Model \(Cantelope Consumption 65+\)](#) -> [Edit Population Group and Consumption \(Cantelope Consumption Adults 65+\) -> Name and Parameters Tab](#)

Edit Population Group and Consumption

Import Empirical Distribution

Specify the file type and parameters, then select a file to import.

Note: all fields are required

File Type:

Field Delimiter:

Decimal Separator:

Number of Header Rows:

Select file: No file chosen

Once you specify the file type and parameters, and select the file to import, you can preview the data and select the probability column and the value column. Your source file can contain more than two columns. Simply indicate

which column should be used for probability and which for value using the drop-down lists. Click Import Data to complete the import. Note, the file must use probability values (0-1) and not percentage values (0-100).

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> [Food \(Cantaloupe Imported\)](#) -> [Consumption Model \(Cantaloupe Consumption Imported\)](#) -> Edit Population Group and Consumption (Adults 65+) -> Name and Parameters Tab

Edit Population Group and Consumption

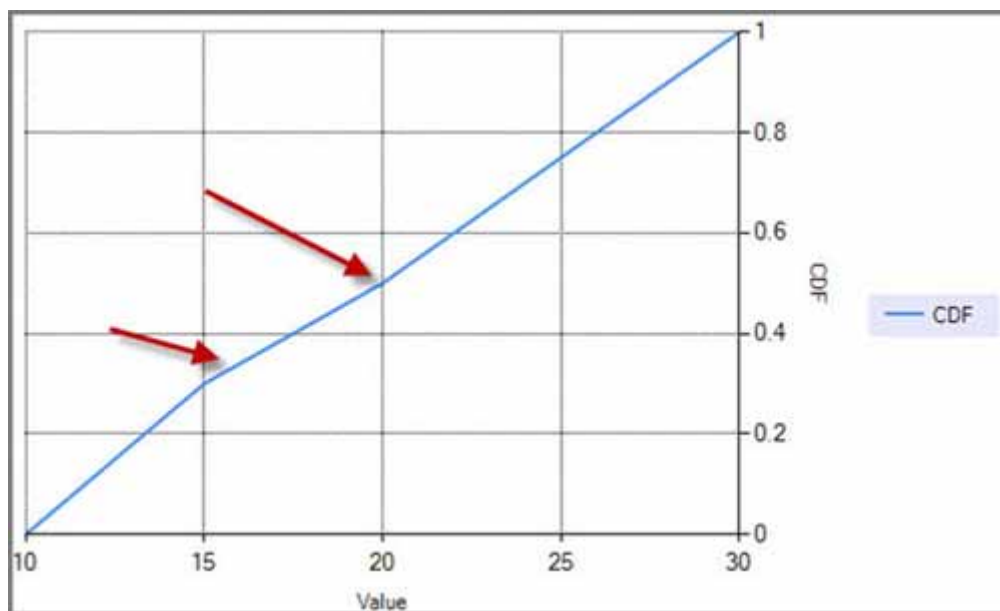
Import Empirical Distribution

Column 1	Column 2
-4.4	0.99
-4.09	0.98
-3.91	0.97
-3.79	0.96
-3.69	0.95
-3.61	0.94
-3.54	0.93
-3.48	0.92
-3.42	0.91
-3.38	0.9
-3.33	0.89
-3.29	0.88

Specify the probability column:

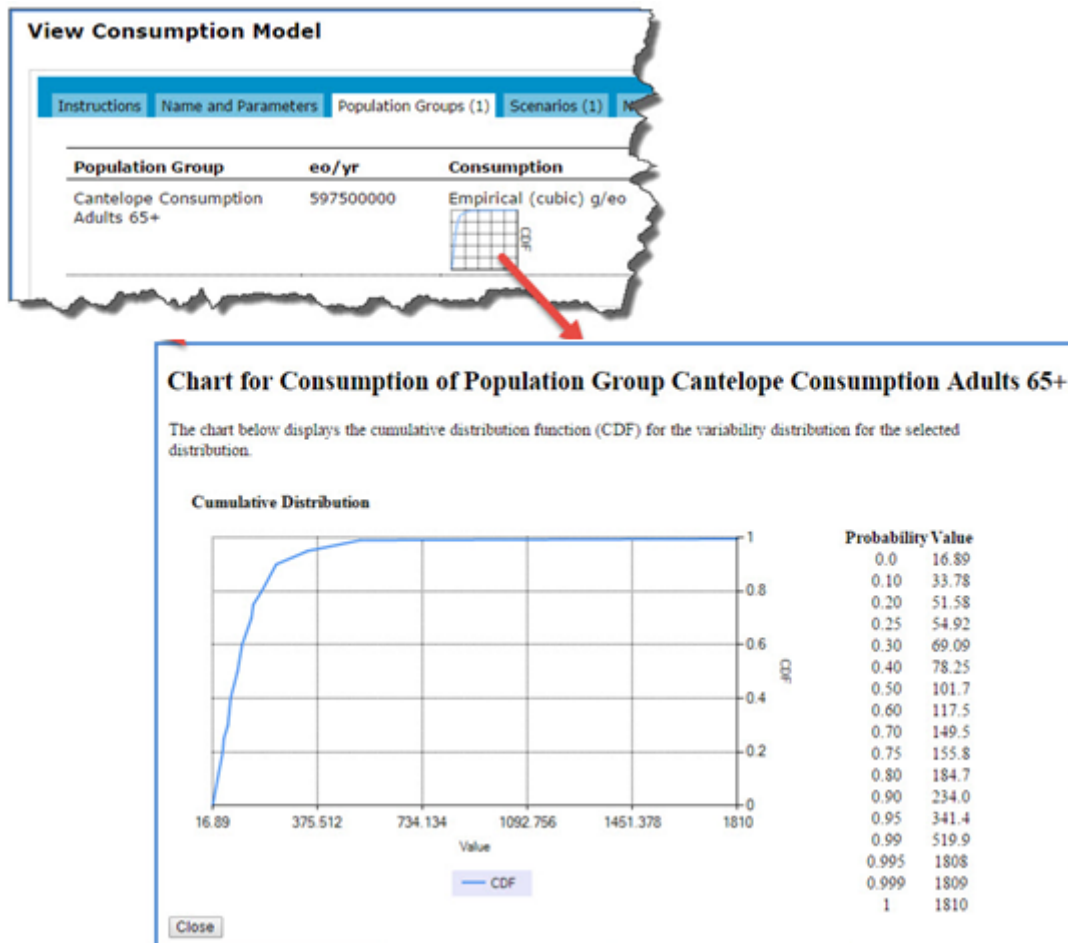
Specify the value column:

Note that the chart of the defined distribution uses linear interpolation between data points for both Empirical (cubic) and Empirical (linear):



However, during simulation a smooth, monotonic cubic interpolation is used for Empirical (cubic). Linear interpolation is used for Empirical (linear).

A representation of the distribution displays in lists and reports. Click the representation to enlarge the chart and view the details.




Chance Distributions

You can enter a set of discrete probability/value pairs as a table (default) or in an input field. When entered as a table, you add, delete, or add rows as required. When entered in an input field, each pair is entered on a separate line and the format is "probability,value" (e.g. 0.1, -3).

The discrete probabilities should be expressed as a number greater than 0 and less than 1, and must sum to 1.

Log and Non-Log Distributions

You can select either the log nor non-log scale for microbial concentrations and counts for process models and process stages.


Parameter	Value
Units:	log10 cfu / g  <input type="button" value="Update"/>
Variability Distribution:	Normal
Mean:	0
Standard deviation:	0

Uncertainty

In addition to specifying variability for FDA-iRISK model elements, you can also specify quantitative descriptions of uncertainty. This is achieved by specifying an uncertainty distribution for one or more model parameters.

Note: Ensure all uncertainty values are valid for the underlying scenario parameters. Invalid uncertainty parameters or combinations of parameters may result in simulation errors or invalid results.

If a model parameter supports uncertainty, there will be an “Add” link beside the parameter in the Uncertainty column. For example, you might define uncertainty for the initial prevalence of a process model:

Initial Contamination, Unit Size and Prevalence:		
Parameter	Value	Uncertainty
Hazard:	Ammonia	N/A
Food:	Frozen Pizza	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/>	N/A
Initial Prevalence:	1E-6	Add 
Select Mass Units:	g	N/A

All model parameters support single parameter uncertainty. Some model parameters also support linked uncertainty parameters. See the following sections for more information on these uncertainty types.

Single Parameter Uncertainty

For model parameters that support only single parameter uncertainty, when you click the Add link the uncertainty is added for that parameter and you are redirected to a page to define its distribution

[Home](#) -> [Risk Model \(My Primary Repository\)](#) -> [Process Model \(Ammonia in Frozen Pizza\)](#) -> Edit Uncertainty -> Parameters Tab

Edit Uncertainty

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

Instructions

Parameters

Set the distribution type and parameters for the uncertainty distribution.

Note: Ensure all uncertainty values are valid for the underlying scenario parameters. Invalid uncertainty parameters or combinations of parameters may result in simulation errors or invalid results.

Note: All fields are required

Parameter	Value
Model Element:	Process Model
Parameter Type:	Initial Prevalence
Parameter:	N/A
Uncertainty Distribution:	<input type="text" value="Uniform"/>
Minimum:	<input type="text" value="0"/>
Maximum:	<input type="text" value="0"/>

The chart below displays the probability density function (PDF) and cumulative distribution function (CDF) or probability histogram for uncertainty distribution based on the parameters above. Please note that the left vertical axis measures *probability density* and should not be interpreted as measuring probability. Values for probability density are not restricted to the interval (0,1). The chart is only updated if the page is saved or the Refresh Chart button is clicked.

Unable to render the chart.

Refresh Chart

Save

Save and Close

Close

Last Modified: 17-Aug-2020 15:14:08

Quick Links: [Back to previous page](#)

Click Save and Close to return to the previous page. This page will now show a summary of the uncertainty distribution in the Uncertainty column, with the options to Edit or Delete.


Model Name:

Define Initial Conditions Using:

Single Set of Parameters ☒

Upstream Process Model ☐

Initial Contamination, Unit Size and Prevalence:

Parameter	Value	Uncertainty
Hazard:	Ammonia (refrigerant leak)	N/A
Food:	Frozen Pizza	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/>	N/A
Initial Prevalence:	<input type="text" value="1E-6"/>	Uniform (Minimum: 0.9E-6, Maximum: 1.1E-6)  Edit Delete
Select Mass Units:	<input type="text" value="g"/> <input type="button" value="v"/>	N/A

Uncertainty for Microbial Process Model Initial Conditions

For microbial process models, you can import a set of linked uncertainty parameterizations for initial prevalence-concentration-unit size definitions from another tool or model, as initial conditions for a microbial process model. (Only available for the “Initial Prevalence, Concentration, and Size (e.g. mass)”.

When you click the “Add” link beside the parameter in the Uncertainty column, the Add Uncertainty Parameter page opens and you are presented with the option of adding a single or linked uncertainty type parameters. Select the Linked Parameters uncertainty type parameter option from the drop-down list and then click Add Uncertainty. You are prompted to choose the linked parameter set file to import. Select the file, click Open, and then click Confirm. The uncertainty parameters are added and you are redirected to a page to review the distributions. If any

validation issues are detected, they will be displayed in the table. Resolve the issues in the file and then re-import the file.

Home -> Risk Model (My Primary Repository) -> Process Model (Salmonella in Peanut Butter) -> Edit Uncertainty -> Parameters Tab

Edit Uncertainty

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

Instructions **Parameters**

Process Model Uncertainty

Validation Result	Probability	Prevalence	Initial Concentration Uncertainty	Initial Size Uncertainty
Valid	0.4	Fixed(0.01)	Empirical[(0,1),(0.3,2),(0.7,2.5),(1,3)]	Empirical[(0,100),(0.3,150),(1,200)]
Valid	0.1	Fixed(0.02)	Empirical[(0,1),(0.2,2),(0.5,3),(1,5)]	Empirical[(0,200),(1,200)]
Valid	0.5	Uniform(0.01,0.3)	Normal(0.9,0.1)	Triangular(100,175,200)

[Delete All](#) [Reimport](#) [Close](#)

Quick Links: [Back to previous page](#)

Click Close to return to the previous page. This page will now show that linked uncertainty is assigned to the initial prevalence, concentration and size in the Uncertainty column, with the options to Edit or Delete.

Initial Contamination, Unit Size and Prevalence:

For microbial hazards, review the relationship between unit size, prevalence, and concentration on the Instructions tab.

Parameter	Value	Uncertainty
Hazard:	Salmonella	N/A
Food:	Peanut Butter	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/>	N/A
Initial Prevalence:	<input type="text" value="5.5E-6"/>	Linked uncertainty, edit to view details. Edit Delete
Select Mass Units:	<input type="text" value="kg"/>	N/A

The data format for the tab-delimited text file is as follows:

Probability	Prevalence	InitialConcentrationUncertainty	InitialSizeUncertainty
0.4	Fixed(0.1)	Empirical[(0,1),(0.3,3),(0.7,3.5),(1,4)]	Empirical[(0,100),(0.3,150),(1,200)]
0.1	Fixed(0.2)	Empirical[(0,1),(0.2,2),(0.5,3),(1,5)]	Empirical[(0,200),(1,200)]
0.5	Fixed(0.3)	Empirical[(0,1),(0.1,2),(0.5,2.5),(1,3)]	Empirical[(0,100),(0.7,175),(1,200)]

The following distribution types are supported:

Distribution	Format	Example
Empirical	Empirical[(probability, value), (probability, value) , ..., (probability, value)]	Empirical[(0,1),(0.2,2),(0.5,3),(1,4)]
Chance	Chance[(probability, value), (probability, value) , ..., (probability, value)]	Chance[(0.3,1),(0.2,2),(0.5,3)]
BetaGeneral	BetaGeneral(alpha, beta, Lower bound, Upper bound)	BetaGeneral(5,1,1,8)
BetaPert	BetaPert(Minimum, Mode, Maximum)	BetaPert(2,5,9)
Fixed	Fixed (Value)	Fixed (0.5)
Normal	Normal(Mean, Standard Deviation)	Normal(5,2)
NormalTruncated	NormalTruncated(Mean, Standard Deviation, Lower Bound, Upper Bound)	NormalTruncated(5,2,1,8)
Triangular	Triangular(Minimum, Mode, Maximum)	Triangular(2,5,9)
TriangularPercentiles	TriangularPercentiles(5 th Percentile, Mode, 95 th Percentile)	TriangularPercentiles(3,5,8)
TriangularTruncated	TriangularTruncated(Minimum, Mode, Maximum, Lower Bound, Upper Bound)	TriangularTruncated(2,5,9,3,7)
Uniform	Uniform(Minimum, Maximum)	Uniform(1,9)
UniformPercentiles	UniformPercentiles(5 th Percentile, 95 th Percentile)	UniformPercentiles(2,8)

Uncertainty for Dose Response Models

For dose response models, you can define uncertainty as described above, or by specifying value pairs (or sets) to be used for sets of two or more parameters for dose response models (not available for the empirical dose response model).

For example, you can specify value pairs for the alpha and beta parameters for a Beta-Poisson dose response model, or value sets for the risk at reference point, reference point, and threshold of Threshold Linear dose response model. You can assign equal probability to the distinct value sets (e.g., a probability of 0.25 to each of 4 sets), or assign a specific probability value to each set (summing to 1).

When you click “Add” link beside the parameter in the Uncertainty column for a dose response model, you are presented with the option to select the uncertainty type (Single Parameter or Linked Parameter). If you select the Single Parameter option, the Edit Uncertainty page opens where you can define the distribution. However, if you select the Linked Parameters option, you will also select whether to assign equal probability to each set of

parameter values, or to specify individual probabilities for each set. The Edit Uncertainty page opens where you can enter sets of linked values.

Edit Uncertainty

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

Instructions

Parameters

Enter values for the linked sets of parameters:
Note: All fields are required

Parameter	Value									
Model Element:	Dose Response Model									
Parameter Type:	Model Parameters									
Linked Values:	<div>Enter as Table ▼</div> <div><table><thead><tr><th>alpha</th><th>beta</th><th>Actions</th></tr></thead><tbody><tr><td><input type="text" value="0"/></td><td><input type="text" value="0"/></td><td>Insert Delete</td></tr><tr><td colspan="2">Number of Rows: <input type="text" value="10"/></td><td><input type="button" value="Add"/></td></tr></tbody></table></div>	alpha	beta	Actions	<input type="text" value="0"/>	<input type="text" value="0"/>	Insert Delete	Number of Rows: <input type="text" value="10"/>		<input type="button" value="Add"/>
alpha	beta	Actions								
<input type="text" value="0"/>	<input type="text" value="0"/>	Insert Delete								
Number of Rows: <input type="text" value="10"/>		<input type="button" value="Add"/>								

Enter sets of linked values.
If user-defined probability was selected, enter a probability (0-1) in the last column. Otherwise, probabilities will be distributed equally.
Probability must sum to 1.

Click Save and Close to return to the previous page.

How uncertainty is applied to the model is discussed in the *Technical Document*.

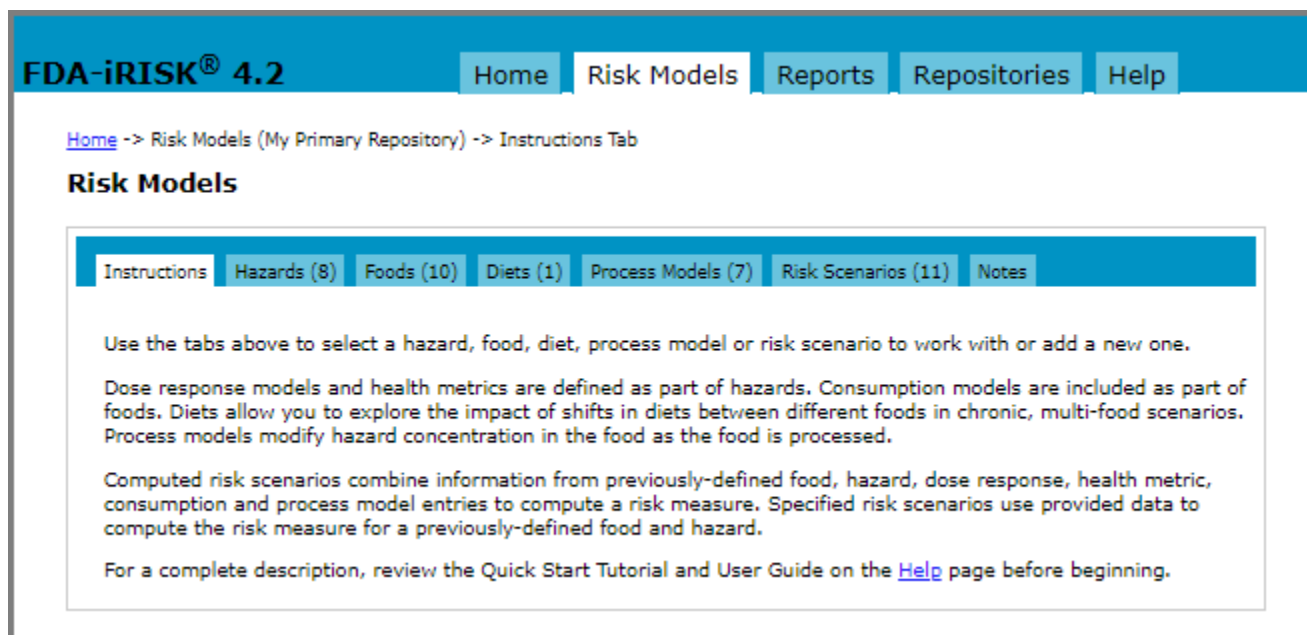
CHAPTER 2

Hazards, Dose Response Models, Health Metrics, and Predictive Models

Hazards

Adding a Hazard

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Add Hazard** link. The Add Hazard page opens.



- 4 In the **Name** input field, enter a name for the hazard.
- 5 In the **Type** drop-down list, select the hazard type. Your selection determines the appropriate assumptions for the risk calculation, and cannot be changed once added.

- 6 Click **Add**. The Edit Hazard page opens.

Home -> Risk Models (My Primary Repository) -> Hazards -> Edit Hazard (L. monocytogenes) -> Name and Type Tab

Edit Hazard

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

Instructions Name and Type Dose Response (3) Metrics (3) Predictive (0) Process Models (1) Scenarios (2) Notes (0)

Note: All fields are required

Type: Microbial Pathogen

Name: L. monocytogenes

Default Unit: cfu Update Default Unit

Save Save and Close Close

Last Modified: 10-Dec-2013 11:18:45

Quick Links: Hazards

- 7 In the **Default Unit** drop-down list, select the default unit for the hazard.
- 8 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Editing a Hazard

You can edit the hazard name and default unit.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard that you want to edit.

The screenshot shows the 'Hazards' tab selected in the top navigation bar. Below the tab, there is a table of hazards. The 'Edit' link for 'Aflatoxin B1' is highlighted with a red arrow.

Hazard	Type	Actions
Aflatoxin B1	Chemical	Edit Copy Delete
Ammonia (refrigerant leak)	Chemical	Edit Copy Delete
Inorganic Arsenic Imported	Chemical	Edit Copy Delete
Inorganic Arsenic Imported	Chemical	Edit Copy Delete
Ochratoxin A	Chemical	Edit Copy Delete
Campylobacter	Microbial Pathogen	Edit Copy Delete
L. monocytogenes	Microbial Pathogen	Edit Copy Delete
Salmonella	Microbial Pathogen	Edit Copy Delete

At the bottom of the table, there is a 'Display Records: 25' dropdown and an 'Update' button.

- 4 On the **Edit Hazard** page, make one or more of the following changes:
- The hazard name.
 - The default units for the hazard.

The screenshot shows the 'Edit Hazard' page for 'Aflatoxin B1'. The 'Name and Type' tab is selected. The page displays the following fields:

- Type:** Chemical
- Name:** Aflatoxin B1
- Default Unit:** mg (with a dropdown arrow) and an 'Update Default Unit' button.

At the bottom, there are 'Save', 'Save and Close', and 'Close' buttons. A note at the top states: 'The Instructions tab should be reviewed by first time users before proceeding.'

- 5 Do one of the following:
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.

- To close the page without saving the changes, click **Close**.

Deleting a Hazard

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Delete** link to the right of the hazard that you want to delete.
- 4 On the Delete Hazard page, do one of the following:
 - If there are no elements defined for the hazard (e.g. dose response models, process models, or risk scenarios), click **Delete**.
 - If there are elements defined for the hazard (e.g. dose response models, process models and risk scenarios), they are listed on the page. You must delete these elements before you can delete the hazard. (The Delete button will not display until the elements have been deleted.) For more information, see *"Deleting a Process Model" on page 91* and *"Deleting a Risk Scenario" on page 131*. Once the elements are deleted, navigate back to this page and click **Delete**.

Copying a Hazard

When you are working with your own models, you have the option to copy a hazard. When you copy a hazard, all related elements are linked to the new hazard. However, the process model remains linked to the existing food for which it was defined.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Copy** link to the right of the hazard that you want to copy.
- 4 On the Copy Hazard page, switch between the tabs and review all element definitions associated with the hazard.
- 5 Click the **Name and Type** tab to enter a new name. By default, the copied hazard will have the name *<hazard_name> Copy*.

- Click the **Instructions** tab.

Home -> Risk Models (My Primary Repository) -> Hazards -> Copy Hazard (Aflatoxin B1) -> Instructions Tab

Copy Hazard

Instructions
Name and Type
Dose Response (1)
Metrics (6)
Process Models (1)
Notes (0)

Use this feature to make a copy of the selected hazard.

Use the checkboxes to include or exclude specific elements from being copied with the hazard.

Use the tabs to change the hazard name used for the copy and to review the data currently associated with the hazard.

If process models are included, they will remain linked to the same food.

Include with copy:

Health Metrics: ☒

Dose Response Models: ☒

Process Models: ☒

Notes (for all copied items): ☒

After creating the copy:

Open the edit page for the copy ☒

Return to the list of hazards ☐

Copy Cancel

- Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- Click **Copy**.

Importing a Hazard

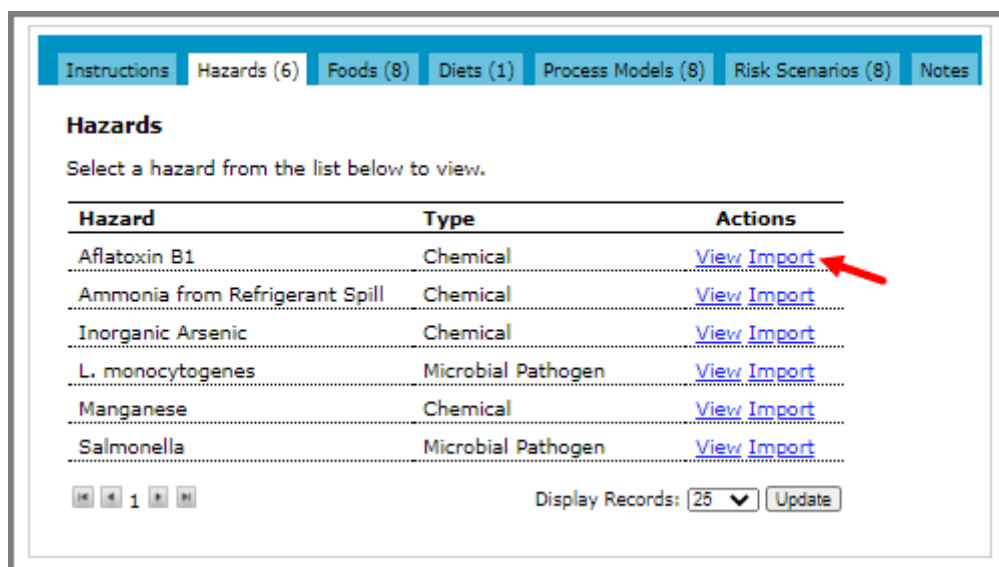
When you are viewing models shared from others, you have the option to import a hazard into your own models.

When you import a hazard, all associated elements are also imported, including dose response models, health metrics, and notes. However, the process model is not imported. For information about how to import a complete process model, see *"Importing a Process Model"* on page 93.

The imported hazard will have the name: *<hazard_name> Imported*.

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository that is being shared with you.

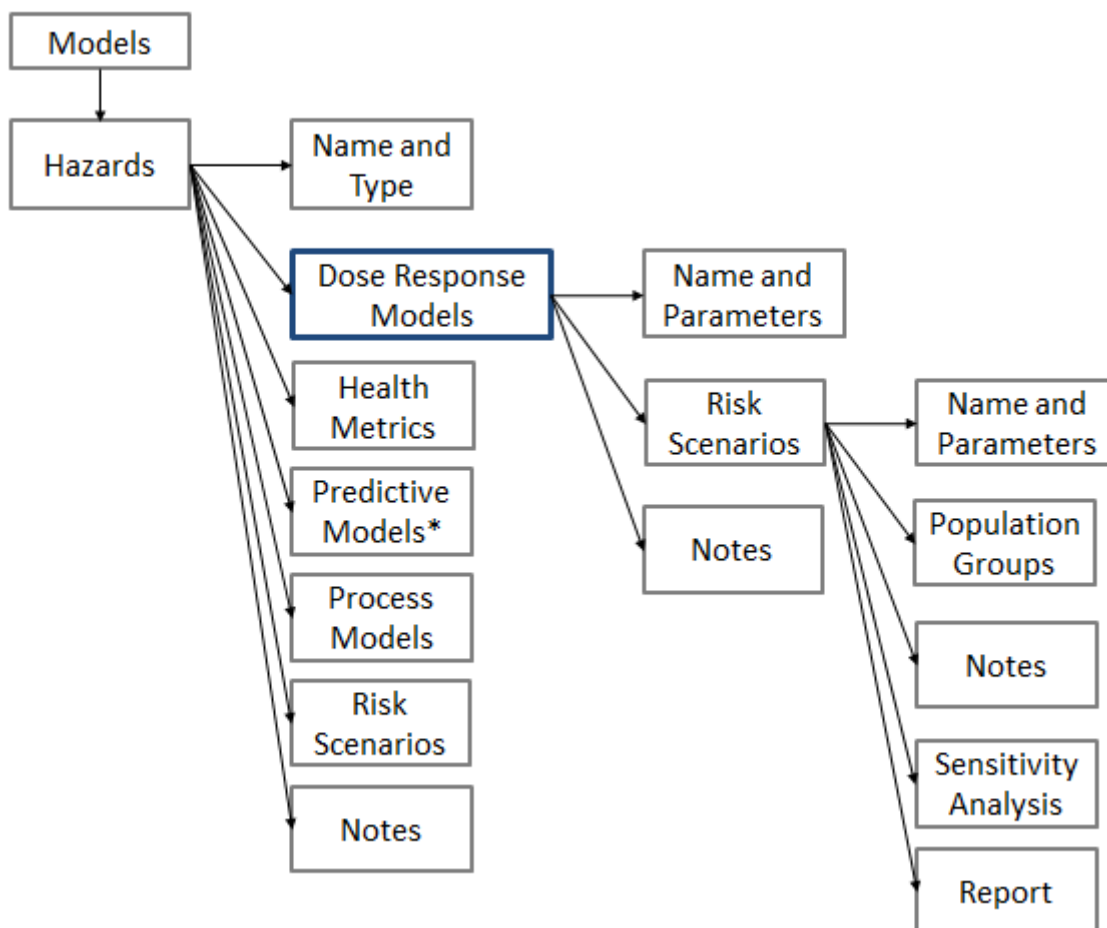
- 3 Click the **Hazards** tab, and then click the **Import** link to the right of the hazard that you want to import.



- 4 On the Import Hazard page, switch between the tabs and review all element definitions associated with the hazard.
- 5 Click the **Instructions** tab.
- 6 In the **Select Repository** drop-down list, select a model repository in which to import the hazard.
- 7 Click **Import**.
- 8 Do one of the following:
- To edit the imported hazard, click the **View Imported Hazard** link.
 - To return to your list of hazards, click **Close**.

Dose Response Models

The following illustration shows the edit pathways for dose response models in FDA-iRISK. Each arrow represents a potential one-to-many relationship:



**Predictive models are only available for microbial hazards.*

For a details about the dose response models for microbial hazards and chemical hazards, see the *Technical Guide*.

Adding a Dose Response Model

Before you begin: The hazard to which you want to add the dose response model must exist. For more information, see *"Adding a Hazard"* on page 21.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a dose response model.
- 4 On the Edit Hazard page, click the **Dose Response** tab.

5 Click the **Add Dose Response** link. The Add Dose Response Model page opens.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Aflatoxin B₁) -> Add Dose Response Model

Add Dose Response Model

Step 1: Enter a name for the dose response model, and select the exposure type.

Note: all fields are required

Name:

Exposure Type:

Available models:

for Acute Exposure	for Chronic Exposure
<ul style="list-style-type: none"> Cumulative Lognormal Dose Unit: mass/kg (e.g. mg/kg body weight) Cumulative Lognormal Dose Unit: mass (e.g. mg) Empirical Dose Unit: mass/kg (e.g. mg/kg body weight) Empirical Dose Unit: mass (e.g. mg) Linear by Slope Factor Dose Unit: mass/kg (e.g. mg/kg body weight) Linear by Slope Factor Dose Unit: mass (e.g. mg) Non-Threshold Linear Dose Unit: mass/kg (e.g. mg/kg body weight) Non-Threshold Linear Dose Unit: mass (e.g. mg) Step Threshold Dose Unit: mass/kg (e.g. mg/kg body weight) Step Threshold Dose Unit: mass (e.g. mg) Threshold Linear Dose Unit: mass/kg (e.g. mg/kg body weight) Threshold Linear Dose Unit: mass (e.g. mg) Weibull Dose Unit: mass (e.g. mg) Weibull Dose Unit: mass/kg (e.g. mg/kg body weight) 	<ul style="list-style-type: none"> Cumulative Lognormal Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Cumulative Lognormal (APROBA) Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Decreasing Log10-Logistic Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Decreasing Logistic Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Decreasing Log-Logistic Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Decreasing Probit Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Empirical Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Gamma Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Linear by Slope Factor Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Logistic Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Log-Logistic Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Log-Logistic with Background Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Multistage Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Non-Threshold Linear Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Probit Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Restricted Log Probit Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Restricted Weibull Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Step Threshold Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Threshold Linear Dose Unit: mass/kg-day (e.g. mg/kg body weight-day) Weibull Dose Unit: mass/kg-day (e.g. mg/kg body weight-day)

6 Do one of the following on the Add Dose Response Model page:

Task	Steps
To add a dose response model for a Microbial pathogen hazard.	<ol style="list-style-type: none"> 1. Type a name for the dose response model in the Name input field. 2. Verify that the exposure type is Acute. (The exposure type is defined during the hazard definition and is automatically set to Acute for a microbial pathogen.) 3. Click Next.

Task	Steps
To add a dose response model for a Chemical hazard.	<ol style="list-style-type: none"> 1. Type a name for the dose response model in the Name input field. 2. In the Exposure Type drop-down list, select one of Acute or Chronic. 3. Click Next.

7 In dose response models for acute exposures to a chemical hazard, units can be mass/kg body weight or simply mass, whereas for chronic exposures the units must be mass/kg body weight per day. Confirm that the units appropriately describe the dose, and then click **Next**.

8 Select a response type from the drop-down menu list, and then click **Add**.

The parameters that display on the next page (Edit Dose Response Model) are based on the response type that you select.

Note: The parameters for the APROBA Cumulative Lognormal dose response model type are derived using the Excel model provided from the WHO site. The Edit Dose Response Model page includes instructions about how to import the model.

9 On the Edit Dose Response Model page, enter the parameter value(s).

For the Empirical response type, you can import empirical dose response models from a file (text, CSV, or Excel format). Click the **Import** link to the right of Empirical in the Response Type table row. Select the file type and select the file (Choose File). Click **Preview Data** to preview the file. Using the information from the preview, complete the remaining fields on the Import Empirical Distribution page, and then click **Import Data**. See the Edit page for additional instructions about file format.

10 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

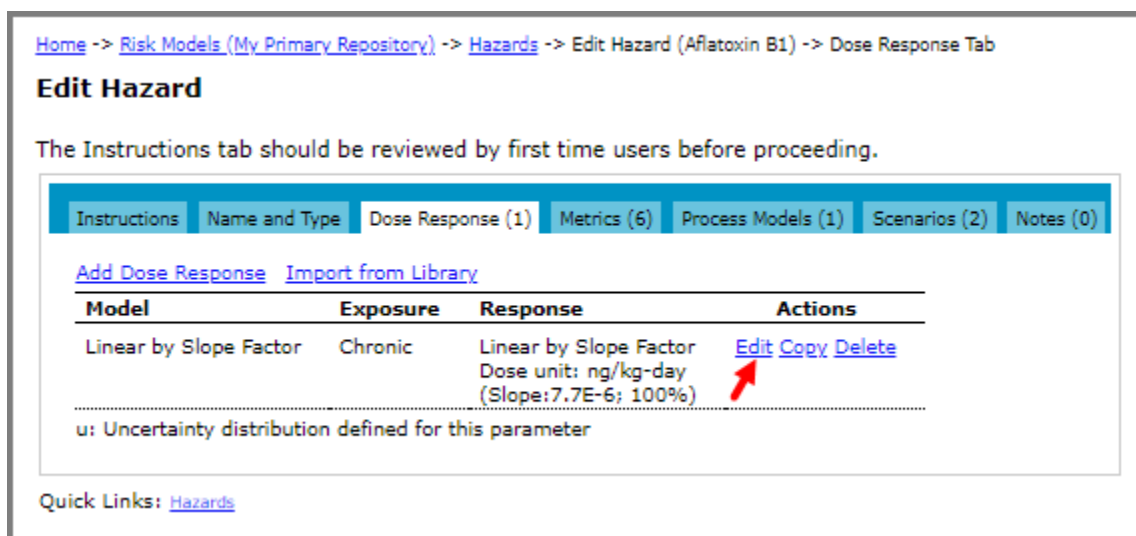
Editing a Dose Response Model

1 Click the **Risk Models** tab on the main tab bar.

2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard for which you want to edit a dose response model.

- 4 On the Edit Hazard page, click the **Dose Response** tab.



- 5 Click the **Edit** link to the right of the dose response model that you want to edit.
- 6 On the Edit Dose Response Model page, make one or more of the following changes:
- The dose response model name.
 - The parameters for the dose response model.
 - For the Empirical response type, you can import empirical dose response models from a file (text, CSV, or Excel format). See the Edit page for additional instructions about file format.
- 7 Do one of the following:
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Dose Response Model

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard from which you want to delete a dose response model.
- On the Edit Hazard page, click the **Dose Response** tab.
- Click the **Delete** link to the right of the dose response model that you want to delete.
- On the Delete Dose Response Model page, do one of the following:
 - If there are no risk scenarios defined using the model, click **Delete**.
 - If there are risk scenarios defined using the model, they are listed on the page. You must delete the risk scenarios before you can delete the dose response model. (The Delete button will not display until the risk

scenarios have been deleted.) For more information, see *"Deleting a Risk Scenario" on page 131*. Once the elements are deleted, navigate back to this page and click **Delete**.

Copying a Dose Response Model

When you are working with your own models, you have the option to copy a dose response model. When you copy a dose response model, all related elements are linked to the new dose response model.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard from which you want to copy a dose response model.
- 4 On the Edit Hazard page, click the **Dose Response** tab.
- 5 Click the **Copy** link to the right of the dose response model that you want to copy.
- 6 On the Copy Dose Response Model page, switch between the tabs and review all element definitions associated with the dose response model.
- 7 Click the **Name and Parameters** tab to enter a new name. By default, the copied dose response model will have the name `<dose_response_model_name> Copy`.
- 8 Click the **Instructions** tab.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Aflatoxin B1) -> Copy Dose Response Model (Linear by Slope Factor) -> Instructions Tab

Copy Dose Response Model

Instructions Name and Parameters Notes (0)

Use this feature to make a copy of the selected dose response model for the same hazard.

Use the checkboxes to include or exclude specific elements from being copied with the model.

Use the tabs to change the model name used for the copy and to review the data currently associated with the model.

Include with copy:

Notes: ☒

After creating the copy:

Open the edit page for the copy ☒

Return to the list of dose responses ☐

Copy Cancel

- 9 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 10 Click **Copy**.

Importing a Dose Response Model

You have the option to import a dose response model from the Dose Response Library or from a Risk Model that is shared with you.

Importing a Model from the Dose Response Library

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a dose response model.
- 4 On the Edit Hazard page, click the **Dose Response** tab.
- 5 Click the **Import from Library** link. The Dose Response Library page opens and displays the list models that match the current hazard type (microbial or chemical).

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Aflatoxin B1) -> Dose Response Library -> Dose Response Library Tab

Dose Response Library

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

[Instructions](#)
[Dose Response Library](#)

Hazard	Model	Exposure	Response	Actions
Aflatoxin B1	Linear by Slope Factor	Chronic	Linear by Slope Factor Dose unit: ng/kg-day (Slope:7.7E-6; 100%)	View Import
Ammonia from Refrigerant Spill	Ammonia Non-Threshold Linear	Acute	Non-Threshold Linear Dose unit: mg (Risk at Reference Point:0.21 , Reference Point:118; 100%)	View Import
Inorganic Arsenic	Bladder Cancer, Probit, Median	Chronic	Probit Dose unit: mg/kg-day (alpha:-2.3502892 , beta:14.952676; 100%)	View Import
Inorganic Arsenic	Lung Cancer, Probit, Median	Chronic	Probit Dose unit: mg/kg-day (alpha:-1.6151 , beta:10.328615; 100%)	View Import

u: Uncertainty distribution defined for this parameter

[Cancel](#)

Quick Links: [Aflatoxin B1 \(H\)](#)

- 6 Do one of the following:
 - To view the details of a dose response model, click the **View** link to the right of the dose response model. (If required, click the **Import** button to import the dose response model; otherwise, click **Close** to return to the Dose Response Library page.)
 - To import a dose response model, click the **Import** link to the right of the dose response model. Confirm the details on the Import Dose Response Model page, and then click **Import**.

Importing a Dose Response Model from a Shared Risk Model

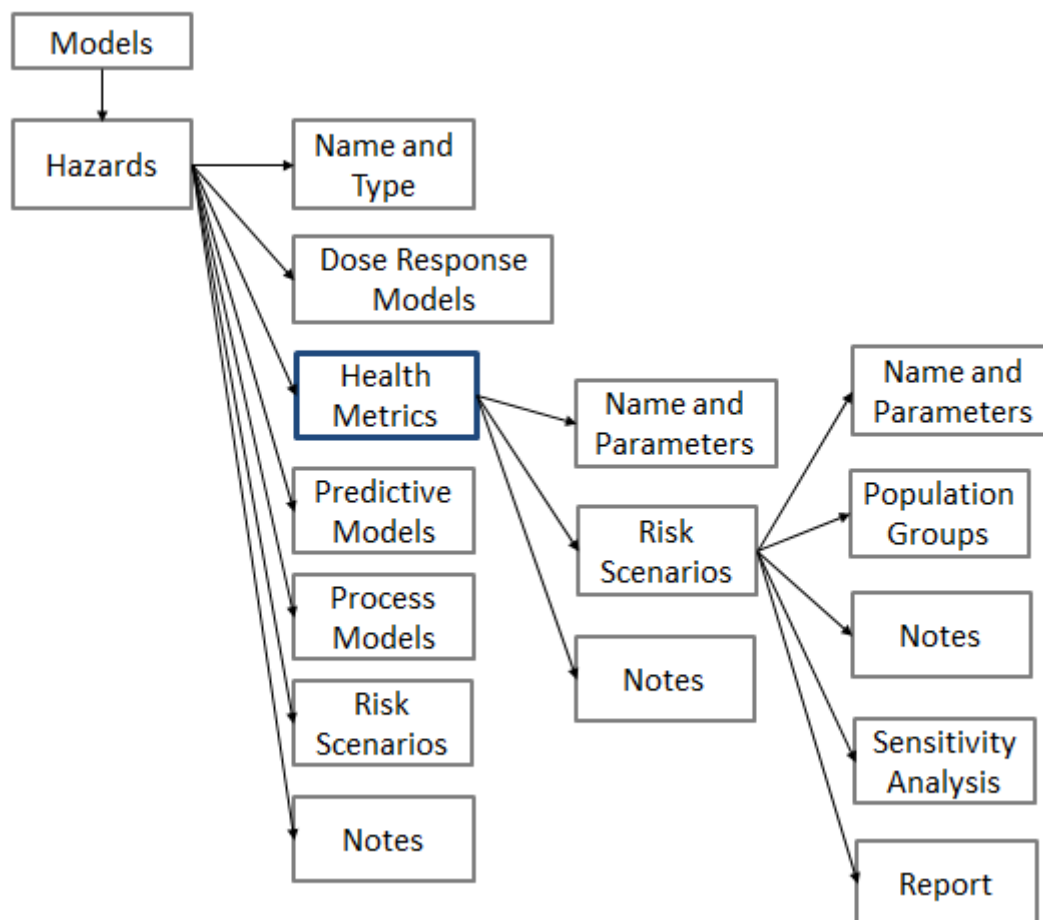
When you are viewing models shared from others, you have the option to import a dose response model into your own models. When you import a dose response model, all its notes are also imported.

The imported dose response models will have the name: `<dose_response_model_name> Imported`.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository being shared with you.
- 3 Click the **Hazards** tab, and then click the **View** link to the right of the hazard from which you want to import a dose response model.
- 4 On the Hazard page, click the **Dose Response** tab.
- 5 Click the **Import** link to the right of the dose response model that you want to import.
- 6 On the Import Dose Response Model page, switch between the tabs and review all element definitions associated with the dose response model.
- 7 Click the **Instructions** tab.
- 8 In the **Select Repository** drop-down list, select a repository in which to import the dose response model.
- 9 Choose the hazard to link the dose response model to. Do one of the following:
 - To link the imported dose response model to a hazard in your model, select the **Link to my hazard** option and select the hazard from the drop-down list. Note that the type and unit of the selected hazard must be the same as the hazard originally associated with the dose response model that you are importing.
 - To import the hazard with the dose response, select the **Import hazard with dose response** option. Note that only this dose response model will be imported. Other dose response models and all health metrics for the hazard will not be imported. To import all dose response models for a hazard, import the hazard instead. For more information, see *"Importing a Hazard" on page 25*.
- 10 Click **Import**. The page reloads and a View Imported Dose Response link displays.
- 11 Do one of the following:
 - To edit the dose response model, click the **View Imported Dose Response** link.
 - To return to the list of shared dose response models, click **Close**.

Health Metrics

The following illustration shows the edit pathways for health metrics in FDA-iRISK. Each arrow represents a potential one-to-many relationship:



Adding a Health Metric

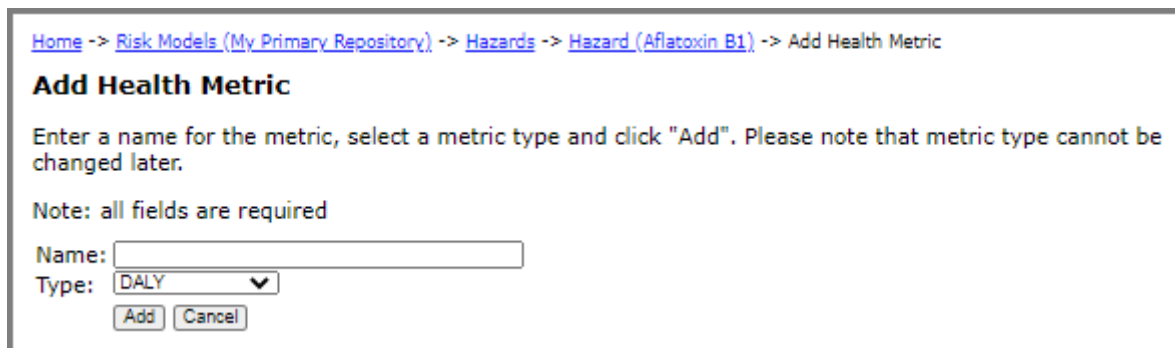
A health metric can be defined by entering a single, specified value, or by computing the value from a selection of health endpoints.

Adding a Health Metric; Specified Value

Before you begin: The hazard to which you want to add the health metric must exist. For more information, see *"Adding a Hazard"* on page 21.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a health metric.
- 4 On the Edit Hazard page, click the **Metrics** tab. The list of health metrics for the hazard displays.

- 5 Click the **Add Health Metric** link.
- 6 On the Add Health Metric page, type a name for the health metric in the **Name** input field.



The screenshot shows a web browser window with the following content:

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Aflatoxin B1) -> Add Health Metric

Add Health Metric

Enter a name for the metric, select a metric type and click "Add". Please note that metric type cannot be changed later.

Note: all fields are required

Name:

Type: DALY ▼

- 7 Do one of the following:
 - To add a DALY (Disability-Adjusted Life Year), select **DALY** from the **Type** drop-down list.
 - To add a cost per illness, select **Cost per Illness** from the **Type** drop-down list.
 - To add a QALY loss, select **QALY Loss** from the **Type** drop-down list.
- 8 Click **Add**.
- 9 On the Edit Health Metric page, enter the appropriate value in the **Value** input field.
- 10 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Adding a Health Metric; Computed Value, DALY

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a health metric.
- 4 On the Edit Hazard page, click the **Metrics** tab. The list of health metrics for the hazard displays.
- 5 Click the **Add Health Metric** link.
- 6 On the Add Health Metric page, type a name for the health metric in the **Name** input field.
- 7 In the **Type** drop-down list, select **DALY**.
- 8 Click **Add**.

- 9 On the Edit Health Metric page, click the **Compute from Health Endpoints** link. The Compute DALY page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> [Hazard \(Aflatoxin B1\)](#) -> [Compute QALY \(Liver Cancer\)](#)

Compute QALY Loss

Use the Add button to add new health endpoints. Each endpoint must have a duration value in either years (Y) or days (D), a utility loss value ranging from 0 to 1, and a fraction of cases value (typically between 0 and 1).

The individual health endpoints are combined to compute the total QALY Loss measure.

Note: all fields are required

Health Endpoint	Duration	Unit	Utility Loss	QALY Loss	Fraction of Cases	Weighted QALY Loss	Actions
<input type="text"/>	<input type="text"/>	Y ▼	<input type="text"/>		<input type="text"/>		<input type="button" value="Add"/>
Totals:					0.000000 (< 1)	0.00	

Quick Links: [Aflatoxin B1 \(H\)](#) | [Liver Cancer \(HM\)](#)

- 10 Under **Health Endpoint**, type the name of one of the relevant health endpoints resulting from exposure to the hazard in question in the empty input field.
- 11 Enter the following required data to calculate the burden:
- Under **Duration**, enter the duration value and then select one of (D)ays or (Y)ears from the **Unit** drop-down list.
 - Under **Severity**, enter a severity value (a.k.a., disability weight) ranging from 0 to 1.
 - Under **Fraction of Cases**, enter the fraction of all cases of illness resulting from exposure to the hazard that is expected to experience the named health endpoint (typically between 0 and 1).
- 12 Click **Add**. FDA-iRISK calculates the weighted DALY attributable to the health endpoint. In addition, a new input field is added so that you can continue adding other health endpoints that are expected to occur because of exposure to the hazard.

- 13 To add more health endpoints, repeat [Step 10](#) to [Step 12](#) as required. When all health endpoints have been entered, the sum of the weighted DALY values for the individual endpoints represents the average DALY value per case of illness.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> [Hazard \(Aflatoxin B1\)](#) -> [Compute DALY \(Liver Cancer \(computed\)\)](#)

Compute DALY

Use the Add button to add new health endpoints. Each endpoint must have a duration value in either years (Y) or days (D), a severity value ranging from 0 to 1, and a fraction of cases value (typically between 0 and 1).

The individual health endpoints are combined to compute the total DALY measure.

Note: all fields are required

Health Endpoint	Duration	Unit	Severity	DALY	Fraction of Cases	Weighted DALY	Actions
Morbidity fatal Liver Cancer	148	D	0.68	0.22400	0.95	0.21280	Delete
Morbidity:Non-fatal Liver Cancer	15.1	Y	0.2	3.0200	0.05	0.15100	Delete
Mortality:Fatal Liver Cancer	20	Y	1	20.000	0.95	19.000	Delete
		Y					Add
Totals:					1.950000 (> 1)	19.4	

Save Save and Close Close

Quick Links: [Aflatoxin B1 \(H\)](#) | [Liver Cancer \(computed\) \(HM\)](#)

- 14 Do one of the following:
- To save the changes and remain on the Compute DALY page, click **Save**.
 - To save the changes and close the page, click **Save and Close**. The Edit Health Metric page remains open and if required, you can access the other tabs on the page.
 - To close the page without saving the changes, click **Close**. The Edit Health Metric page remains open and if required, you can access the other tabs on the page.

Adding a Health Metric; Computed Value, Cost per Illness

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a health metric.
- On the Edit Hazard page, click the **Metrics** tab. The list of health metrics for the hazard displays.
- Click the **Add Health Metric** link.
- On the Add Health Metric page, type a name for the health metric in the **Name** input field.
- In the **Type** drop-down list, select **Cost per Illness**.
- Click **Add**.

- 9 On the Edit Health Metric page, click **Compute from Health Endpoints**. The Compute Cost Per Illness page opens.

[Home](#) -> [My Primary Repository](#) -> [Hazards](#) -> [Hazard \(Aflatoxin B1\)](#) -> [Compute Cost Per Illness \(Liver Cancer \(COI\)\)](#)

Compute Cost Per Illness

Use the Add button to add new health endpoints. Each endpoint must have a cost value in dollars and a fraction of cases value (typically between 0 and 1).

The individual health endpoints are combined to compute the total cost per illness measure.

Note: all fields are required

Health Endpoint	Cost	Fraction of Cases	Weighted Cost	Actions
<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="button" value="Add"/>
Totals:		0.000000 (< 1)	0.00	

Quick Links: [Aflatoxin B1 \(H\)](#) | [Liver Cancer \(COI\) \(HM\)](#)

- 10 Under **Health Endpoint**, type the name of one of the relevant health endpoints resulting from exposure to the Hazard in question in the empty input field.
- 11 Enter the following required data to calculate the burden:
- Under **Cost**, enter the cost of each health endpoint expected to occur because of exposure to the hazard.
 - Under **Fraction of Cases**, enter the fraction of all cases of illness resulting from exposure to the hazard that is expected to experience the named health endpoint (typically between 0 and 1).
- 12 Click **Add**. FDA-iRISK calculates the weighted Cost per Illness attributable to the health endpoint. In addition, a new input field is added so that you can continue adding other health endpoints that are expected to occur because of exposure to the hazard.

- 13 To add more health endpoints, repeat [Step 10](#) to [Step 12](#) as required. When all health endpoints have been entered, the sum of the weighted cost values for the individual endpoints represents the average cost per case of illness.

Home -> [My Primary Repository](#) -> [Hazards](#) -> [Hazard \(Aflatoxin B1\)](#) -> Compute Cost Per Illness ([Liver Cancer \(COI, computed\)](#))

Compute Cost Per Illness

Use the Add button to add new health endpoints. Each endpoint must have a cost value in dollars and a fraction of cases value (typically between 0 and 1).

The individual health endpoints are combined to compute the total cost per illness measure.

Note: all fields are required

Health Endpoint	Cost	Fraction of Cases	Weighted Cost	Actions
Fatal Liver Cancer	71400	0.90	64260	Delete
Nonfatal Liver Cancer	99750	0.1	9975.0	Delete
<input type="text"/>	<input type="text"/>	<input type="text"/>		Add
Totals:		1.000000	74200	

[Save](#) [Save and Close](#) [Close](#)

Quick Links: [Aflatoxin B1 \(H\)](#) | [Liver Cancer \(COI, computed\) \(HM\)](#)

- 14 Do one of the following:
- To save the changes and remain on the page, click **Save**.
 - To save the changes and close the page, click **Save and Close**. The Edit Health Metric page remains open and if required, you can access the other tabs on the page.
 - To close the page without saving the changes, click **Close**. The Edit Health Metric page remains open and if required, you can access the other tabs on the page.

Adding a Health Metric; Computed Value, QALY Loss

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a health metric.
- On the Edit Hazard page, click the **Metrics** tab. The list of health metrics for the hazard displays.
- Click the **Add Health Metric** link.
- On the Add Health Metric page, type a name for the health metric in the **Name** input field.
- In the **Type** drop-down list, select **QALY Loss**.
- Click **Add**.

- 9 On the Edit Health Metric page, click the **Compute from Health Endpoints** link. The Compute QALY Loss page opens.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Aflatoxin B1) -> Compute QALY (Liver Cancer (QALY Loss))

Compute QALY Loss

Use the Add button to add new health endpoints. Each endpoint must have a duration value in either years (Y) or days (D), a utility loss value ranging from 0 to 1, and a fraction of cases value (typically between 0 and 1).

The individual health endpoints are combined to compute the total QALY Loss measure.

Note: all fields are required

Health Endpoint	Duration	Unit	Utility Loss	QALY Loss	Fraction of Cases	Weighted QALY Loss	Actions
<input type="text"/>	<input type="text"/>	Y ▼	<input type="text"/>		<input type="text"/>		<input type="button" value="Add"/>
Totals:					0.000000 (< 1)	0.00	

Quick Links: [Aflatoxin B1 \(H\)](#) | [Liver Cancer \(QALY Loss\) \(HM\)](#)

- 10 Under **Health Endpoint**, type the name of one of the relevant health endpoint resulting from exposure to the hazard in question in the empty input field.
- 11 Enter the following required data to calculate the QALY loss:
- Under **Duration**, enter the duration value and then select one of (D)ays or (Y)ears from the **Unit** drop-down list.
 - Under **Utility Loss**, enter a utility loss value ranging from 0 to 1.
 - Under **Fraction of Cases**, enter the fraction of all cases of illness resulting from exposure to the hazard that are expected to experience the named health endpoint (typically between 0 and 1).
- 12 Click **Add**. FDA-iRISK calculates the weighted QALY Loss attributable to the health endpoint. In addition, a new input field is added so that you can continue adding other health endpoints that are expected to occur because of exposure to the hazard.
- 13 To add more health endpoints, repeat [Step 10](#) to [Step 12](#) as required. When all health endpoints have been entered, the sum of the weighted QALY Loss values for the individual endpoints represents the average QALY Loss per case of illness.
- 14 Do one of the following:
- To save the changes and remain on the page, click **Save**.
 - To save the changes and close the page, click **Save and Close**. The Edit Health Metric page remains open and if required, you can access the other tabs on the page.
 - To close the page without saving the changes, click **Close**. The Edit Health Metric page remains open and if required, you can access the other tabs on the page.

Editing a Health Metric

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository and click **Show Models**.

- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard for which you want to edit a health metric.
- 4 On the Edit Hazard page, click the **Metrics** tab.
- 5 Click the **Edit** link to the right of the health metric that you want to edit.

Home -> Risk Models (My Primary Repository) -> Hazards -> Edit Hazard (Aflatoxin B1) -> Metrics Tab

Edit Hazard

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

[Instructions](#)
[Name and Type](#)
[Dose Response \(1\)](#)
[Metrics \(6\)](#)
[Process Models \(1\)](#)
[Scenarios \(2\)](#)
[Notes \(0\)](#)

[Add Health Metric](#)

Name	Type	Value	Actions
Liver Cancer	DALY	0.364	Edit Copy Delete
Liver Cancer (COI)	Cost per Illness	70000	Edit Copy Delete
Liver Cancer (COI, computed)	Cost per Illness	69400 ^u	Edit Copy Delete
Liver Cancer (computed)	DALY	19.4	Edit Copy Delete
Liver Cancer (QALY Loss)	QALY Loss	0	Edit Copy Delete
Liver Cancer Imported	DALY	19.4	Edit Copy Delete

^u: Uncertainty distribution defined for this parameter

Quick Links: [Hazards](#)

- 6 On the Edit Health Metric page, make one or more of the following changes:
 - The health metric name.
 - To override a computed value or replace a specified value, enter a value in the **Value** field.
 - To edit the values on which the computed value is based, click the **Compute from Health Endpoints** link. Edit the values. (**Tip:** Click **Save** to recalculate the totals.) Click **Save and Close** to return to the Edit Health Metric page. The new computed value is saved.
- 7 Do one of the following:
 - To save the changes to the Edit Health Metric page and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Health Metric

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard from which you want to delete a health metric.
- 4 On the Edit Hazard page, click the **Metrics** tab.

- 5 Click the **Delete** link to the right of the health metric that you want to delete.
- 6 On the Delete Health Metric page, do one of the following:
 - If there are no risk scenarios defined using the health metric, click **Delete**.
 - If there are risk scenarios defined using the health metric, they must be deleted first. (The Delete button will not display until the risk scenarios have been deleted.) For more information, see *"Deleting a Risk Scenario" on page 131*. Once the elements are deleted, navigate back to this page and click **Delete**.

Home -> Risk Models (My Primary Repository) -> Hazards -> Aflatoxin B1 -> Delete Health Metric (Liver Cancer (computed))

Delete Health Metric

Please correct the following:

Unable to delete health metric unless the related risk scenarios are deleted first.

Deleting the health metric *Liver Cancer (computed)* will also delete the following:

Risk Scenarios	Notes
Aflatoxin B1 in Tortilla Chips	Rationale for computed liver cancer DALY

Copying a Health Metric

When you are working with your own models, you have the option to copy a health metric for the same hazard. When you copy a health metric, all related elements are also linked to the new health metric.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard from which you want to copy a health metric.
- 4 On the Edit Hazard page, click the **Metrics** tab.
- 5 Click the **Copy** link to the right of the health metric that you want to copy.
- 6 On the Copy Health Metric page, switch between the tabs and review all element definitions associated with the health metric.
- 7 Click the **Name and Parameters** tab to enter a new name. By default, the copied health metric will have the name `<health_metric_name> Copy`.

- 8 Click the **Instructions** tab.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Aflatoxin B1) -> Copy Health Metric (Liver Cancer (computed)) -> Instructions Tab

Copy Health Metric

Instructions Name and Parameters Notes (1)

Use this feature to make a copy of the selected health metric for the same hazard.

Use the checkboxes to include or exclude specific elements from being copied with the health metric.

Use the tabs to change the health metric name used for the copy and to review the data currently associated with the health metric.

Copy Options:

Notes: ☒

After creating the copy:

Open the edit page for the copy ☒

Return to the list of health metrics ☐

Copy Cancel

- 9 Select the check boxes for the elements that you want to include with the copy (the option is Notes) and the action that you want taken after the copy completes.
- 10 Click **Copy**.

Importing a Health Metric

When you are viewing models shared from others, you have the option to import a health metric into your own models.

When you import a health metric, all its health endpoints and notes are also imported.

The imported health metric will have the name: *<health_metric_name> Imported*.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository being shared with you.
- 3 Click the **Hazards** tab, and then click the **View** link to the right of the hazard from which you want to import a health metric.
- 4 On the Hazard page, click the **Metrics** tab.
- 5 Click the **Import** link to the right of the health metric that you want to import.
- 6 On the Import Health Metric page, switch between the tabs and review all element definitions associated with the health metric.
- 7 Click the **Instructions** tab.

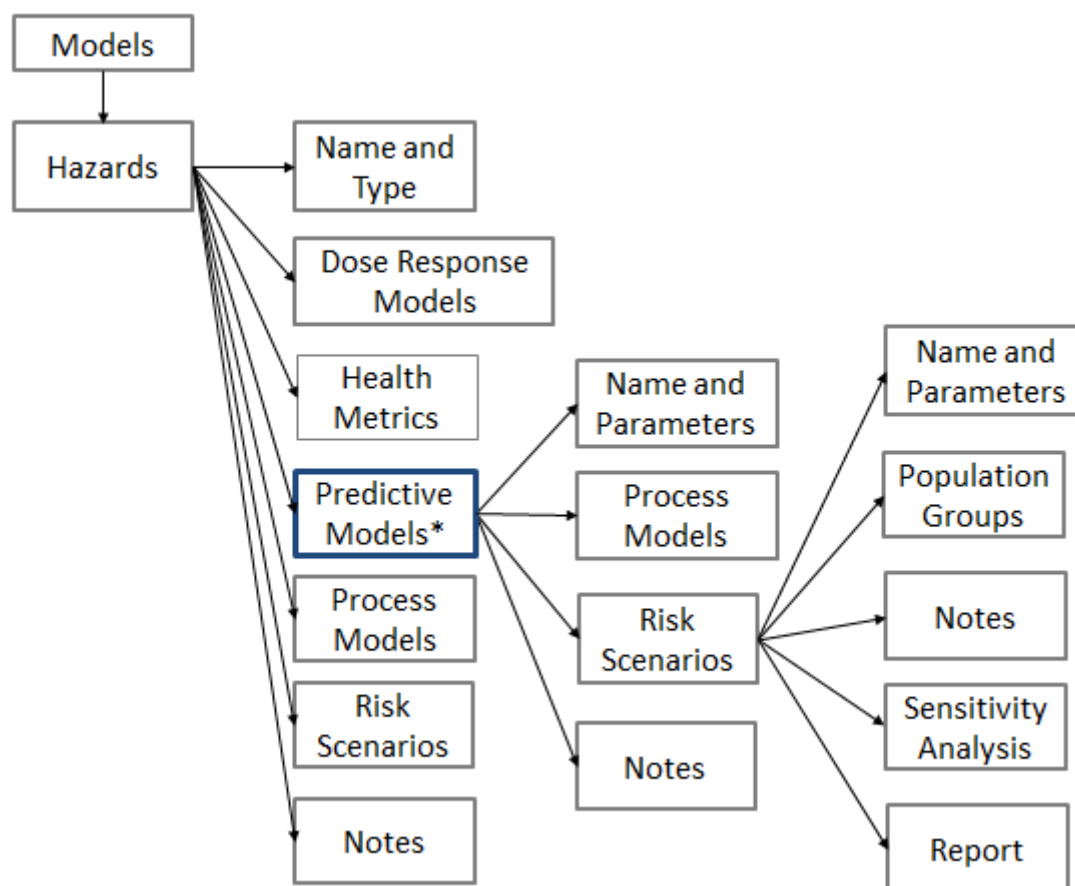
- 8 In the **Select Repository** drop-down list, select the repository in which to import the health metric.
- 9 Choose the hazard to link the health metric to. Do one of the following:
 - To link the imported health metric to a hazard in your model, select the **Link to my hazard** option and select the hazard from the drop-down list. Note that the hazard type of the selected hazard must be the same as the hazard that is linked to the health metric that you are importing.
 - To import the hazard with the health metric, select the **Import hazard with health metric** option. The related health endpoints and notes are imported as well. Other health metrics and all dose response models for the hazard will not be imported. To import all health metrics for a hazard, import the hazard instead. For more information, see *"Importing a Hazard"* on page 25.
- 10 Click **Import**. The page reloads and a View Imported Dose Response link displays.
- 11 Do one of the following:
 - To edit the imported health metric, click the **View Imported Dose Response** link.
 - To return to the list of shared health metrics, click **Close**.

Predictive Models

The predictive models option is available for microbial hazards and provides a way to specify the inactivation, growth, and lag models that can be used to describe the response of the hazard to environmental conditions. You select a predictive model for the current hazard, from among those you have defined for that hazard, when adding process stages of the Decrease by Inactivation Model process type or of the Increase by Growth Model process type to the process model.

You can add one or more of these models for each hazard. Predictive models can be re-used in multiple process models.

The following illustration shows the edit pathways for predictive models in FDA-iRISK. Each arrow represents a potential one-to-many relationship:



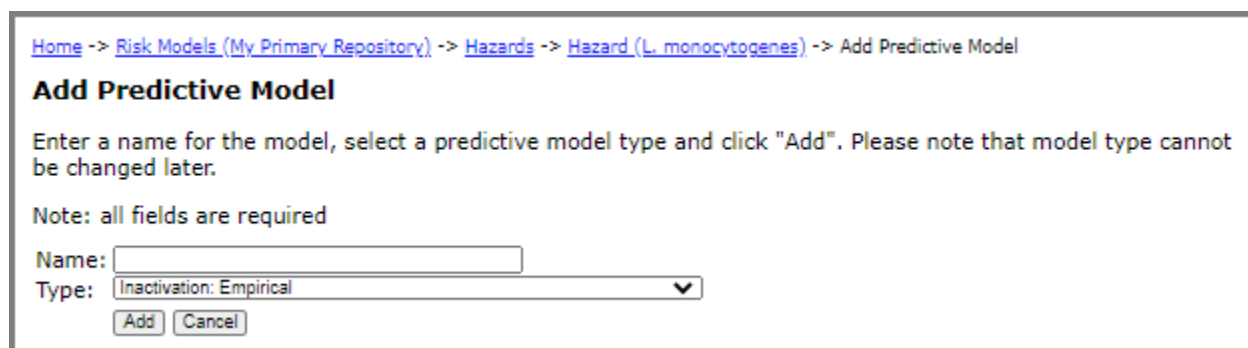
**Predictive models are only available for microbial hazards.*

Adding a Predictive Model for Microbial Hazards

Before you begin: The hazard to which you want to add the predictive model must exist. For more information, see "Adding a Hazard" on page 21.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a predictive model.
- 4 On the Edit Hazard page, click the **Predictive** tab. The list of predictive models for the hazard displays. The Predictive tab is only visible for microbial hazards.
- 5 Click the **Add Predictive Model** link.

- 6 On the Add Predictive Model page, type a name for the predictive model in the **Name** input field.



Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (L. monocytogenes) -> Add Predictive Model

Add Predictive Model

Enter a name for the model, select a predictive model type and click "Add". Please note that model type cannot be changed later.

Note: all fields are required

Name:

Type:

- 7 In the **Type** drop-down list, select the predictive model type.
- 8 Click **Add**. The Edit Predictive Model page opens. The input fields that display on this page are determined by the predictive model type that you selected on the previous page.

Note: The Inactivation: Empirical and Growth: Empirical predictive model types allow you to add or import time/concentration curves or models generated by external tools. You can either import the curve or model (in text, CSV, or Excel format) using the Import Time/Concentration Data link, or directly enter the data in the table provided. The first entry must be for time 0. Time values must be increasing. Concentration values must remain unchanged or be decreasing for inactivation models or increasing for growth models. The data format for the import file is as follows:

Time (h)	Log10 cfu/g
0.0	0.00
0.2	0.50
0.4	0.10
0.6	0.15
0.8	0.20
1.0	0.27
1.2	0.35
1.4	0.45
1.6	0.56
1.8	0.69
2.0	0.83
2.2	0.99
2.4	1.16
2.6	1.34
2.8	1.53
3.0	1.73

Note that this example data is for a growth model (increasing).

- 9 Enter the appropriate values.
- 10 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Editing a Predictive Model

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard to which you want to add a predictive model.
- 4 On the Edit Hazard page, click the **Predictive** tab.
- 5 Click the **Edit** link to the right of the predictive model that you want to edit.
- 6 On the Edit Predictive Model page, edit the fields as required.
- 7 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Predictive Model

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard from which you want to delete a predictive model.
- 4 On the Edit Hazard page, click the **Predictive** tab.
- 5 Click the **Delete** link to the right of the predictive model that you want to delete.
- 6 On the Delete Predictive Model page, do one of the following:
 - If there are no risk scenarios defined using the predictive model, click **Delete**.
 - If there are risk scenarios defined using the predictive, they must be deleted first. (The Delete button will not display until the risk scenarios have been deleted.) For more information, see *"Deleting a Risk Scenario" on page 131*. Once the elements are deleted, navigate back to this page and click **Delete**.

Copying a Predictive Model

When you are working with your own models, you have the option to copy a predictive model. When you copy a predictive model, all related elements are linked to the new model.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard from which you want to copy a predictive model.
- 4 On the Edit Hazard page, click the **Predictive** tab.
- 5 Click the **Copy** link to the right of the predictive model that you want to copy.
- 6 On the Copy Predictive Model page, switch between the tabs and review all element definitions associated with the predictive model.
- 7 Click the **Name and Parameters** tab to enter a new name. By default, the copied model will have the name *<predictive_model_name> Copy*.
- 8 Click the **Instructions** tab.
- 9 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 10 Click **Copy**.

Importing a Predictive Model

When you are viewing models shared from others, you have the option to import a predictive model into your own models.

The imported predictive model will have the name: *<model_name> Imported*.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository being shared with you.
- 3 Click the **Hazards** tab, and then click the **View** link to the right of the hazard from which you want to import a predictive mode.
- 4 On the Hazard page, click the **Predictive** tab.
- 5 Click the **Import** link to the right of the model that you want to import.
- 6 On the Import Predictive Model page, switch between the tabs and review all element definitions associated with the model.
- 7 Click the **Instructions** tab.
- 8 In the **Select Repository** drop-down list, select the repository in which to import the predictive model.
- 9 Choose the hazard to link the predictive model to. Do one of the following:

- To link the imported predictive model to a hazard in your model, select the **Link to my hazard** option and select the hazard from the drop-down list. Note that the hazard type of the selected hazard must be the same as the hazard that is linked to the predictive model that you are importing.
 - To import the hazard with the predictive model, select the **Import hazard with predictive model** option. If importing the hazard as well, only this predictive model will be imported. Other predictive models and all dose response models for the hazard will not be imported. Importing a predictive model will also import its notes. *Note:* to link this predictive model to a hazard from your models, the hazard type must be microbial.
- 10 Click **Import**. The page reloads and a View Imported Predictive Model link displays.
- 11 Do one of the following:
- To edit the imported health metric, click the **View Imported Dose Response** link.
 - To return to the list of shared health metrics, click **Close**.

CHAPTER 3

Foods, Consumption Models, and Population Groups

Foods

Adding a Food

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Add Food** link. The Add Food page opens.

FDA-iRISK® 4.2 Home Risk Models Reports Repositories Help

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> Add Food

Add Food

Enter a food name, select the default unit type for measuring food quantity and click "Add". Please note that unit type cannot be changed once the food is added. Once the food is created, you will be able to add consumption models.

Note: all fields are required

Name:

Measured using: Mass ▼

- 4 In the **Name** input field, enter a name for the food.
 - 5 In the **Measured using** drop-down list, select the default unit for measuring the food quantity.
- Note:** The measurement unit cannot be changed once it is added.

- 6 Click **Add**. The Edit Food page opens.

Home -> Risk Models (My Primary Repository) -> Foods -> Edit Food (Peanut Butter) -> Name and Type Tab

Edit Food

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

Instructions Name and Type Consumption Models (2) Process Models (1) Scenarios (2) Notes (0)

Note: All fields are required

Name:

Quantity Measured In:

Last Modified: 16-Dec-2013 11:37:07

Quick Links: [Foods](#)

- 7 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Editing a Food

Only the food name may be edited.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food that you want to edit.
- 4 On the Edit Food page, edit the food name.
- 5 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Food

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Delete** link to the right of the food that you want to delete.

- 4 On the Delete Food page, do one of the following:
 - If there are no elements defined for the food (e.g. process models or risk scenarios), click **Delete**.
 - If there are elements defined for the food (e.g. process models and risk scenarios), they are listed on the page. You must delete these elements before you can delete the food. (The Delete button will not display until the elements have been deleted.) For more information, see *"Deleting a Process Model" on page 91* and *"Deleting a Risk Scenario" on page 131*. Once the elements are deleted, navigate back to this page and click **Delete**.

Home -> Risk Models (My Primary Repository) -> Foods -> Delete Food (Peanut Butter)

Delete Food

Please correct the following:

Unable to delete food unless the related process models are deleted first.

Deleting the food *Peanut Butter* will also delete the following:

Consumption Models	Diets	Process Models	Risk Scenarios	Notes
Peanut butter Annual Consumption	None specified	Salmonella in Peanut Butter	Salmonella in peanut butter	None specified
Peanut Butter by General Population			Salmonella in peanut butter - Specified	

Copying a Food

When you are working with your own models, you have the option to copy a food. When copying a food, all related elements are linked to the new food. However, the process model remains linked to the existing hazard for which it is defined.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Copy** link to the right of the food that you want to copy.
- 4 On the Copy Food page, switch between the tabs and review all element definitions associated with the food.
- 5 Click the **Name and Type** tab to enter a new name. By default, the copied food will have the name `<food_name> Copy`.

- 6 Click the **Instructions** tab.

- 7 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 8 Click **Copy**.

Importing a Food

When you are viewing models shared from others, you have the option to import a food into your own models.

When you import a food, all associated elements are also imported, including consumption models and notes. However, the process model is not imported. For information about how to import a complete process model, see *"Importing a Process Model" on page 93*.

The imported food will have the name: *<food_name> Imported*.

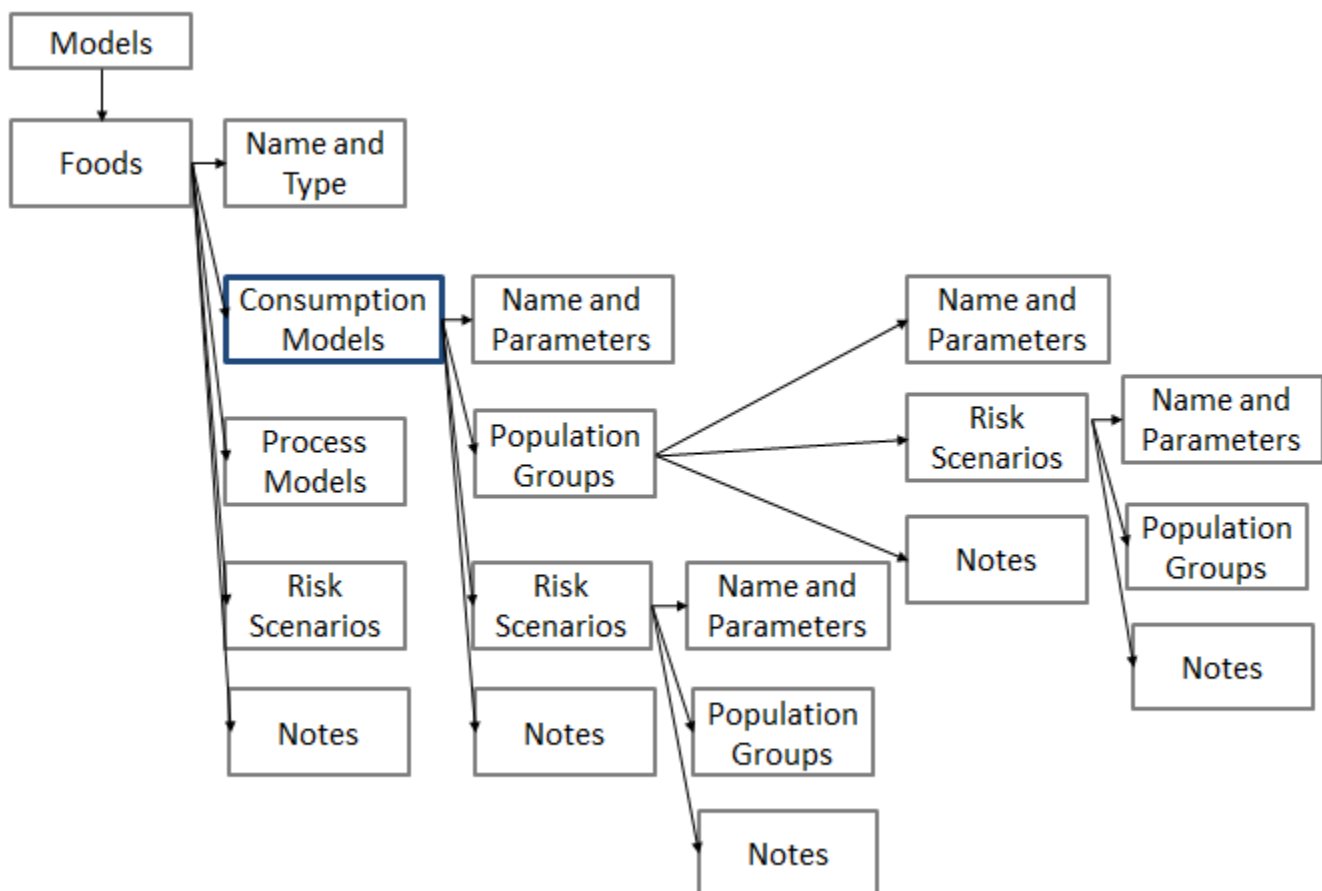
- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository that is being shared with you.
- 3 Click the **Foods** tab, and then click the **Import** link to the right of the food that you want to import.
- 4 On the Import Food page, switch between the tabs and review all element definitions associated with the food.
- 5 Click the **Instructions** tab.
- 6 In the **Select Repository** drop-down list, select a model repository in which to import the food.
- 7 Click **Import**.

- 8 Do one of the following:
- To edit the imported food, click the **View Imported Food** link.
 - To return to your list of foods, click **Close**.

Consumption Models

A consumption model consists of a set of one or more population groups (for acute exposures) or life stages (for chronic exposures), with each having an associated consumption pattern. The consumption model itself can be thought of as a container for such a collection of consumption patterns associated with the consumers of the food.

The following illustration shows the edit pathways for acute consumption models in FDA-iRISK. Each arrow represents a potential one-to-many relationship:



The Population Groups associated with an acute consumption model (a consumption model representing acute exposure to a food) represent a “snapshot in time” of the consumers of the food, and a scenario will include mutually-exclusive Population Groups (e.g., children to age 18, immunocompetent adults over 18, immunodeficient adults over 18). There is also the ability to compute the risk (e.g. DALYs) per person per year for variability-only scenarios by defining a distribution for the number of servings per person within a population group.

On the other hand, the Life Stages associated with a chronic consumption model represent a chronological sequence of consumption patterns for a single consumer through the lifetime (then multiplied by a number of

such consumers). Therefore a chronic exposure scenario typically includes a “lifetime's worth” of Life Stages, representing the same population of consumers at different ages.

Adding a Consumption Model

Adding a Consumption Model, Acute Exposure

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food to which you want to add a consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.
- 5 Click the **Add Consumption Model** link. The Add Consumption Model page opens.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Peanut Butter) -> Add Consumption Model

Add Consumption Model

Enter a consumption model name, select the exposure type and click "Add". Please note that exposure type cannot be changed after the model is created.

Note: all fields are required

Name:

Exposure Type: Acute ▼

- 6 In the **Name** input field, enter a name for the consumption model.
- 7 In the **Exposure Type** drop-down list, select **Acute**.
- 8 Click **Add**. The Edit Acute Consumption Model page opens.
Each consumption model requires at least one population group. At this point, you have the option to continue and add the population groups, or you can save the consumption model and return later to add the population groups.
- 9 Do one of the following:
 - To save the changes and remain on the page so that you can continue and add one or more population groups, click **Save**. The page remains open and you can access the Population Groups tab. For information about how to add population groups, see *"Adding a Population Group / Life Stage" on page 62*
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Adding a Consumption Model, Chronic Exposure

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food to which you want to add a consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.
- 5 Click the **Add Consumption Model** link. The Add Consumption Model page opens.
- 6 In the **Name** input field, enter a name for the consumption model.
- 7 In the **Exposure Type** drop-down list, select **Chronic**.
- 8 Click **Add**. The Edit Chronic Consumption Model page opens.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Tortilla Chips) -> Edit Chronic Consumption Model (Tortilla Chip Consumption) -> Name and Parameters Tab

Edit Chronic Consumption Model

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

Instructions | Name and Parameters | Life Stages (5) | Scenarios (2) | Notes (0)

Note: All fields are required

Model Name:

Exposure Type:

Annual Consumers:

Uncertainty: [Add](#)

Last Modified: 25-Sep-2014 09:27:18

Quick Links: [Tortilla Chips \(F\)](#)

- 9 In the **Annual Consumers** input field, enter a value for the number of consumers that will be exposed to the hazard for a lifetime.
- Each consumption model requires at least one life stage. At this point, you have the option to continue and add the life stages, or you can save the consumption model and return later to add the life stages.
- 10 Do one of the following:
 - To save the changes and remain on the page so that you can continue and add one or more life stages, click **Save**. The page remains open and you can access the Life Stages tab. For information about how to add life stages, see *"Adding a Population Group / Life Stage"* on page 62.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Adding a Consumption Model, Chronic Multifood Exposure

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food to which you want to add a consumption model.

- 4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.
- 5 Click the **Add Consumption Model** link. The Add Consumption Model page opens.
- 6 In the **Name** input field, enter a name for the consumption model.
- 7 In the **Exposure Type** drop-down list, select **Chronic - Multifood**.
- 8 Click **Add**. The Edit Chronic Multifood Consumption Model page opens.

There are no parameters other than name to edit on this page. All remaining data is defined with the life stages or risk scenario.

- 9 Do one of the following:
 - To save the changes and remain on the page so that you can continue and add one or more life stages, click **Save**. The page remains open and you can access the Life Stages tab. For information about how to add life stages, see *"Adding a Population Group / Life Stage" on page 62*.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Editing a Consumption Model

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food for which you want to edit a consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab.

- 5 Click the **Edit** link to the right of the consumption model that you want to edit.

Home -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> Edit Food (Tortilla Chips) -> Consumption Models Tab

Edit Food

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

Instructions Name and Type Consumption Models (2) Process Models (1) Scenarios (2) Notes (0)

[Add Consumption Model](#) [Import from Library](#)

Model	Exposure Type	Multifood	Population Groups / Life Stages	Actions
Tortilla Chip Consumption	Chronic		5	Edit Copy Delete
Tortilla Chip Consumption - Multifood	Chronic	*	1	Edit Copy Delete

Quick Links: [Foods](#)

- 6 On the Edit Consumption Model page, make one or more of the following changes:

- For all exposure types, you can change the consumption model name.
- For the chronic exposure type, you can change the value for the number of consumers.

For information about editing population groups, see *"Editing a Population Group / Life Stage"* on page 70.

- 7 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

Deleting a Consumption Model

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food from which you want to delete a consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab.
- 5 Click the **Delete** link to the right of the consumption model that you want to delete.
- 6 On the Delete Food page, do one of the following:
 - If there are no risk scenarios defined using the model, click **Delete**.
 - If there are risk scenarios defined using the model, they are listed on the page. You must delete the risk scenarios before you can delete the consumption model. (The Delete button will not display until the process models and risk scenarios have been deleted.) For more information, see *"Deleting a Risk Scenario"*

on page 131 and "Deleting a Process Model" on page 91. Once the risk scenarios are deleted, navigate back to this page and click **Delete**.

Home -> Risk Models (My Primary Repository) -> Foods -> Tortilla Chips -> Delete Consumption Model (Tortilla Chip Consumption)

Delete Consumption Model

Please correct the following:

Unable to delete consumption model unless the related risk scenarios are deleted first.

Deleting the consumption model *Tortilla Chip Consumption* will also delete the following:

Population Groups /Life Stages	Risk Scenarios	Notes
Adults aged 20 years and over	Aflatoxin B1 in Tortilla Chips	None specified
Children aged 1 to 5 years	Aflatoxin B1 in Tortilla Chips (Exposure Only)	
Children aged 11 to 15		
Children aged 6 to 10		
Youth aged 16 to 20 years		

Copying a Consumption Model

When you are working with your own models, you have the option to copy a consumption model. When you copy a consumption model, all related elements are linked to the new consumption model.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food from which you want to copy a consumption model.
- 4 Click the **Consumption Models** tab, and then click the **Copy** link to the right of the consumption model that you want to copy.
- 5 On the Copy Consumption Model page, switch between the tabs and review all element definitions associated with the consumption model.
- 6 Click the **Name and Parameters** tab to enter a new name. By default, the copied model will have the name `<consumption_model_name> Copy`.

- 7 Click the **Instructions** tab.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Tortilla Chips) -> Copy Consumption Model (Tortilla Chip Consumption) -> Instructions Tab

Copy Consumption Model

Instructions Name and Parameters Life Stages (5) Notes (0)

Use this feature to make a copy of the selected model.

Use the checkboxes to include or exclude specific elements from being copied with the model.

Use the tabs to change the model name used for the copy and to review the data currently associated with the model.

Include with copy:

Life Stages: ☒

Notes: ☒

After creating the copy:

Open the edit page for the copy ☒

Return to the list of consumption models ☐

Copy Cancel

- 8 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 9 Click **Copy**.

Importing a Consumption Model

You have the option to import a consumption model from the Consumption Model Library or from a Risk Model that is shared with you.

Importing a Model from the Consumption Library

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food to which you want to add a consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab.
- 5 Click the **Import from Library** link. The Consumption Model Library page opens and displays the list models that match the current food unit type - volume or mass.
- 6 Do one of the following:
 - To view the details of a consumption model, click the **View** link to the right of the model. (If required, click the **Import** button to import the consumption model; otherwise, click **Close** to return to the Consumption Model Library page.)

- To import a consumption model, click the **Import** link to the right of the consumption model. Confirm the details on the Import Consumption Model page, and then click **Import**.

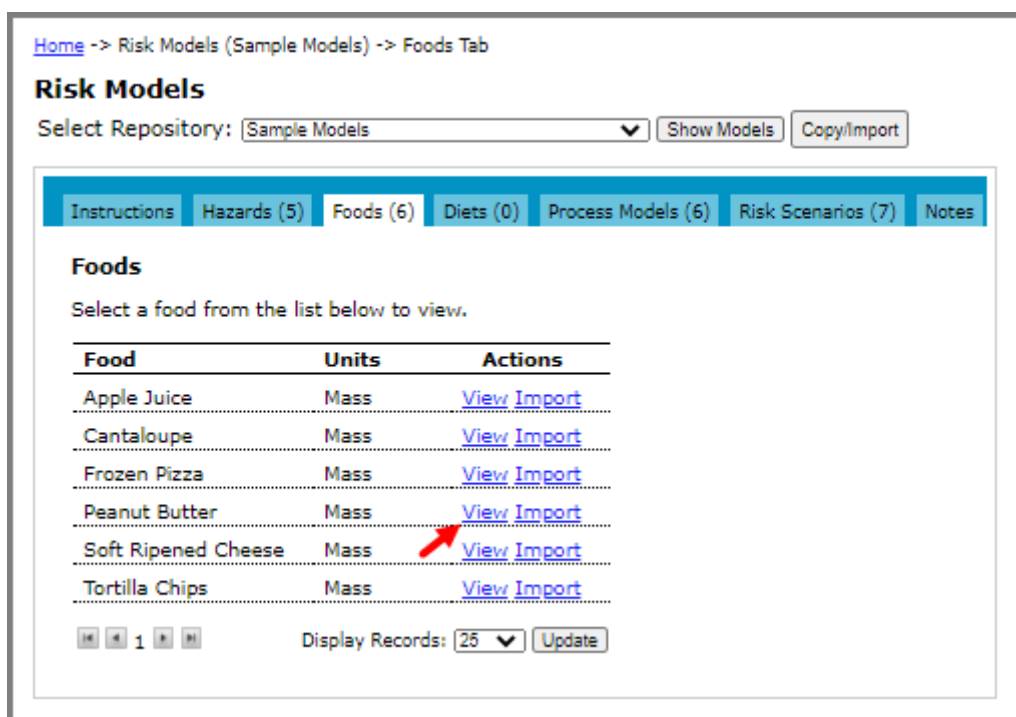
Importing a Consumption Model from a Shared Risk Model

When you are viewing models shared from others, you have the option to import a consumption model into your own models.

When you import a consumption model, its consumption population groups and notes are also imported.

The imported consumption model will have the name: *<consumption_model_name> Imported*.

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository that is being shared with you.
- Click the **Foods** tab, and then click the **View** link to the right of the food.



- On the Food page, click the **Consumption Models** tab.
- Click the **Import** link to the right of the consumption model that you want to import.
- On the Import Consumption Model page, switch between the tabs and review all element definitions associated with the consumption model.
- Click the **Instructions** tab.
- In the **Select Repository** drop-down list, select a repository in which to import the consumption model.
- Choose the food to link the consumption model to. Do one of the following:

- To link the imported consumption model to a food in your model, select the **Link to my food** option and select the food from the drop-down list. Note that the food unit type of the selected food must be the same as the food that is linked to the consumption model that you are importing.
- To import the food with the consumption model, select the **Import food with consumption model** option. The related consumption population groups and notes are imported as well.

10 Click **Import**.

11 Do one of the following:

- To edit the consumption model, click the **View Imported Consumption Model** link.
- To return to the list of shared consumption models, click **Close**.

Population Groups / Life Stages

Consumption models consist of one or more population groups (acute) or life stages (chronic), each having an associated consumption pattern. Population groups may be referred to as “Consumption Population Groups” to emphasize the fact that each population group is defined as having a particular consumption pattern associated with it. Alternately, they may have similar consumption patterns but be defined separately because they differ in susceptibility to a hazard, or in the severity of the health effects.

Adding a Population Group / Life Stage

Adding a Population Group, Acute Exposure - Microbial Hazard

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food for which you want to add a population group to the consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.
- 5 Click the **Edit** link to the right of the consumption model to which you want to add a population group.
- 6 Click the **Population Groups** tab, and then click the **Add Population Group** link. The Add Population Group page opens.

Home -> Risk Models (My Primary Repository) -> Foods -> Consumption Model (Peanut Butter by General Population) -> Add Population Group

Add Population Group

Enter a population group name and click "Add".

Note: all fields are required

Population Group Name:

- 7 In the **Population Group Name** input field, enter a population group name.

- 8 Click **Add**. The Edit Population Group and Consumption page opens.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Peanut Butter) -> Consumption Model (Peanut Butter by General Population) -> Edit Population Group and Consumption (General Population) -> Name and Parameters Tab

Edit Population Group and Consumption

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

Instructions | Name and Parameters | Scenarios (0) | Notes (0)

Note: All fields are required

Name:

Parameter	Value	Uncertainty
Eating occasions per year:	<input type="text" value="0"/>	Add

Amount per eating occasion:

Parameter	Value	Uncertainty
Unit:	<input type="text" value="g"/>	N/A
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="0"/>	Add

Chart is not displayed when the distribution is set to Fixed Value

Body Weight (kg):

Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="0"/>	Add

Chart is not displayed when the distribution is set to Fixed Value

Number of servings per person:

Note: Assumptions necessary, e.g., mean risk per serving for the population applicable to the individual. Refer to the [Technical Documentation](#) section 4.2.2 for additional information before using this feature.

Parameter	Value
Include in Results:	<input type="checkbox"/>
Serving Units:	<input type="text" value="Per day"/>
Variability Distribution:	<input type="text" value="Fixed Value"/>
Value:	<input type="text" value="0"/>

Chart is not displayed when the distribution is set to Fixed Value

Spearman (Rank) Correlation:

Parameter	Value
Correlation Option:	<input type="text" value="No Correlation"/>
Correlation Coefficient:	<input type="text" value="0"/>

Last Modified: 16-Mar-2016 20:24:00

Quick Links: [Peanut Butter \(F\)](#) | [Peanut Butter by General Population \(CM\)](#)

- 9 In the **Eating occasions per year** input field, enter the number of eating occasions per year across the population group.
- 10 Under **Amount per eating occasion**, select a variability distribution from the drop-down list, and then select the unit and enter a value.
- Note:** Distribution charts are not displayed when a fixed value is selected rather than a variability distribution.

- 11 To compute the risk (e.g., DALYs) per person per year, do the following in the **Number of servings per person** input field:
 - Specify a distribution of number of servings consumed per person either per year or per day. FDA-iRISK uses the mean risk (e.g., DALYs) per serving for the scenario to compute the distribution of risk (e.g., DALYs) per person per year and includes a chart from 1st to 99th percentiles in the report. This applies to variability-only scenarios.
 - To include the result in the report, select the **Include in Results** check box.

For microbial hazards whose dose response model is independent of body weight, the fields in the Body Weight area do not need to be completed.
- 12 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Adding a Population Group, Acute Exposure - Chemical Hazard

The steps for adding a population group that has acute exposure to a chemical hazard are the same as those described in the previous section.

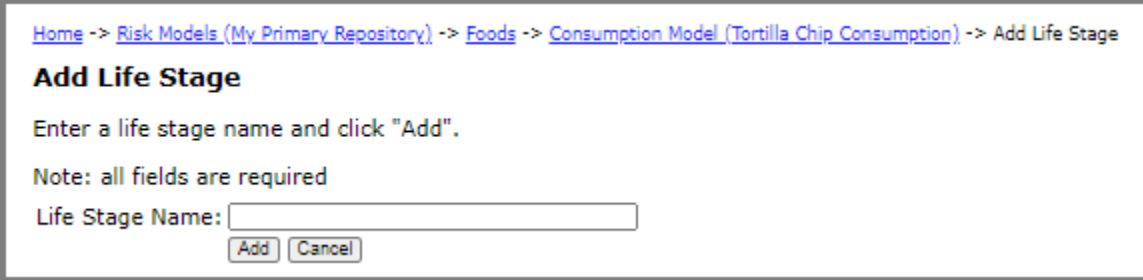
Note that if the population group being defined will be exposed to a chemical hazard having a dose response model expressed in units of mg chemical per kg body weight, then a body weight needs to be defined (in the Body Weight area of the Edit Population Group and Consumption page). For chemical hazards whose dose response model is independent of body weight, the body weight does not need to be defined.

When body weight is defined, you have the option to impose the Spearman rank correlation between amount per eating occasion and body weight for single food consumption models.

Adding a Life Stage, Chronic Exposure

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food for which you want to add life stages to the consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.
- 5 Click the **Edit** link to the right of the consumption model to which you want to add a life stage.

- 6 Click the **Life Stages** tab, and then click the **Add Life Stage** link. The Add Life Stage page opens.



[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> [Consumption Model \(Tortilla Chip Consumption\)](#) -> Add Life Stage

Add Life Stage

Enter a life stage name and click "Add".

Note: all fields are required

Life Stage Name:

- 7 In the **Life Stage Name** input field, enter a life stage name.

- 8 Click **Add**. The Edit Life Stage and Consumption page opens.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Tortilla Chips) -> Consumption Model (Tortilla Chips Consumption) -> Edit Life Stage and Consumption (Children aged 1 to 5 years) -> Name and Parameters Tab

Edit Life Stage and Consumption

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

Instructions | **Name and Parameters** | **Scenarios (2)** | **Notes (0)**

Note: All fields are required

Name:

Span in years:

Average Daily Consumption:

Parameter	Value	Uncertainty
Units:	<input type="text" value="g"/> <input type="text" value="per day"/>	N/A
Variability Distributions:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="5"/>	Add

Chart is not displayed when the distribution is set to Fixed Value

Body Weight (kg):
Body weight is not required when per kg-day is selected for the consumption units.

Parameter	Value	Uncertainty
Variability Distributions:	<input type="text" value="Uniform"/>	N/A
Minimum:	<input type="text" value="10"/>	Add
Maximum:	<input type="text" value="30"/>	Add

The chart below displays the probability density function (PDF) and cumulative distribution function (CDF) or probability histogram for body weight based on the parameters above. Please note that the left vertical axis measures probability density and should not be interpreted as measuring probability. Values for probability density are not restricted to the interval (0,1). The chart is only updated if the page is saved or the Refresh Chart button is clicked.

Probability Density and Cumulative Distribution

[Refresh Chart](#)

Spearman (Rank) Correlation:

Parameter	Value
Correlation Options:	<input type="text" value="No Correlation"/>
Correlation Coefficient:	<input type="text" value="0"/>

[Save](#) [Save and Close](#) [Close](#)

Last Modified: 10-Dec-2013 17:40:38

Quick Links: [Tortilla Chips \(F\)](#) | [Tortilla Chips Consumption \(CM\)](#)

- 9 In the **Span in years** input field, enter the lifespan in years over which this life stage covers.
- 10 Under **Average Daily Consumption**, select a variability distribution from the drop-down list, and then select the unit and enter a value.

- 11 Because the dose units of the dose response model for a chronic chemical hazard are automatically set as “mass/kg-day”, you need to enter the body weight of an individual in the age group, as either a fixed value or distribution under **Body Weight**.

Note: When using consumption data that are expressed in terms of “grams of food per kg body weight”, the body weight of the associated life stage should be entered as “1 kg” to recognize that this division by body weight has already been considered.

- 12 Do one of the following:
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.
- 13 Continue adding life stages until consumption has been defined over the full lifespan.

When you add a series of consumption life stages for different ages until you have defined a lifetime of exposure, FDA-iRISK can calculate a lifetime average daily dose (LADD).

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> [Food \(Tortilla Chips\)](#) -> Edit Chronic Consumption Model (Tortilla Chip Consumption) -> Life Stages Tab

Edit Chronic Consumption Model

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

[Instructions](#)
[Name and Parameters](#)
[Life Stages \(5\)](#)
[Scenarios \(2\)](#)
[Notes \(0\)](#)

[Add Life Stage](#)

Life Stage	Span (Years)	Consumption	Body Weight	Actions
Adults aged 20 years and over	57	Fixed Value (Value: 15) g/day	Normal (Mean: 80, Standard deviation: 16) Kg	Edit Copy Delete
Children aged 1 to 5 years	5	Fixed Value (Value: 6) g/day	Uniform (Minimum: 10, Maximum: 30) Kg	Edit Copy Delete
Children aged 11 to 15	5	Fixed Value (Value: 13) g/day	Uniform (Minimum: 30, Maximum: 70) Kg	Edit Copy Delete
Children aged 6 to 10	5	Fixed Value (Value: 9) g/day	Uniform (Minimum: 20, Maximum: 60) Kg	Edit Copy Delete
Youth aged 16 to 20 years	5	Fixed Value (Value: 18) g/day	Uniform (Minimum: 60, Maximum: 90) Kg	Edit Copy Delete
Total Span in Years: 77				

u: Uncertainty distribution defined for this parameter

Quick Links: [Tortilla Chips \(F\)](#)

Adding a Life Stage, Chronic Multifood Exposure

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food for which you want to add a life stage to the consumption model.
- 4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.
- 5 Click the **Edit** link to the right of the consumption model to which you want to add a life stage.
- 6 Click the **Life Stages** tab, and then click the **Add Life Stage** link. The Add Life Stage page opens.
- 7 In the **Life Stage Name** input field, enter a life stage name.

- 8 Click **Add**. The Edit Multifood Life Stage and Consumption page opens.

Edit Multifood Life Stage and Consumption

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

Instructions
Name and Parameters
Scenarios (1)
Notes (0)

Note: All fields are required

Name:

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

Sex: Start: Year Month End: Year Month

Average Daily Consumption:

Units: per kg-day

Distribution: [Import](#)

The cumulative empirical distribution (cubic or linear) is used to enter a distribution using cumulative probability/value pairs.

It may be entered as a table (default) or in a textbox.

When entered as a table, insert, delete or add rows as required. When entered in a textbox, each pair must be on a separate line and the format must be "cumulative probability,value" (e.g. 0.1, -3).

Cumulative probabilities should be expressed as a number between 0 and 1. The first row must have a cumulative probability of 0 (minimum of the distribution). The last row must have a cumulative probability of 1 (maximum of the distribution).

Each cumulative probability gives the probability the outcome will be less than or equal to the corresponding value.

Cumulative probabilities must be increasing and unique. Values must also be increasing but duplicates values are allowed.

Probability	Value	Actions
<input type="text" value="0"/>	<input type="text" value="0"/>	Insert Delete
<input type="text" value="0.2"/>	<input type="text" value="1"/>	Insert Delete
<input type="text" value="0.6"/>	<input type="text" value="1.2"/>	Insert Delete
<input type="text" value="1"/>	<input type="text" value="2.5"/>	Insert Delete

Number of Rows to Add: [Add](#)

The chart below displays the cumulative distribution function (CDF) or probability histogram for average daily consumption based on the parameters above. The chart is only updated if the page is saved or the Refresh Chart button is clicked.

Cumulative Distribution

Note, only the CDF is displayed for Cumulative Empirical distributions.

[Refresh Chart](#)

For chronic multifood hazards, FDA-iRISK calculates a lifetime average daily dose based on exposure from several foods across a single common population. Therefore, FDA-iRISK requires each life stage defined for a specific food to include information on sex and age range. Sex may be specified as male, female or both. Age is defined in terms of years and months. Year 0 indicates infants. All years should include data from 1 month to 11 months (e.g. 5 years, 1 month to 10 years, 11 months to describe the life of a child from the 5th to 11th birthdays). When FDA-iRISK computes the overall lifetime average daily dose from all foods, it will use the maximum year defined for all groups across all foods included in the scenario. It also assumes exposure starts a year 0. If any consumption models do not include data for specific age ranges from the minimum to the maximum, zero consumption is assumed for those gaps.

Additionally, as the consumption must be applied to a common population and not all foods will be consumed by the same proportion of the population, users must include non-eaters in their consumption data. I.e. in some cases, consumption may only start in the 90th percentile of the population with the rest of the population having zero consumption. As such, consumption must be defined using the cumulative empirical distribution as it is the only distribution available in FDA-iRISK that can define such a pattern. Lastly, at this time only units of g/kg-day are available for the consumption data.

- 9 Under **Age and Sex** enter values for Sex, Start Year and Month and End Year and Month.
Note that units for Average Daily Consumption are grams per kg-day. As such, no body weight is required
- 10 Enter a cumulative empirical distribution for the average daily consumption for the current life stage.
- 11 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.
- 12 Continue adding life stages until consumption has been defined over the full lifespan.

Editing a Population Group / Life Stage

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food for which you want to edit a population group / life stage.
- 4 On the Edit Food page, click the **Consumption Models** tab.
- 5 Click the **Edit** link to the right of the consumption model for which you want to edit a population group / life stage.

- 6 Click the **Population Groups / Life Stages** tab, and then click the **Edit** link to the right of the population group / life stage that you want to edit.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> [Food \(Tortilla Chips\)](#) -> [Edit Chronic Consumption Model \(Tortilla Chip Consumption\)](#) -> [Life Stages Tab](#)

Edit Chronic Consumption Model

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

[Instructions](#) [Name and Parameters](#) [Life Stages \(5\)](#) [Scenarios \(2\)](#) [Notes \(0\)](#)

[Add Life Stage](#)

Life Stage	Span (Years)	Consumption	Body Weight	Actions
Adults aged 20 years and over	57	Fixed Value (Value: 15) g/day	Normal (Mean: 80, Standard deviation: 16) Kg	Edit Copy Delete
Children aged 1 to 5 years	5	Fixed Value (Value: 6) g/day	Uniform (Minimum: 10, Maximum: 30) Kg	Edit Copy Delete
Children aged 11 to 15	5	Fixed Value (Value: 13) g/day	Uniform (Minimum: 30, Maximum: 70) Kg	Edit Copy Delete
Children aged 6 to 10	5	Fixed Value (Value: 9) g/day	Uniform (Minimum: 20, Maximum: 60) Kg	Edit Copy Delete
Youth aged 16 to 20 years	5	Fixed Value (Value: 18) g/day	Uniform (Minimum: 60, Maximum: 90) Kg	Edit Copy Delete
Total Span in Years: 77				
u: Uncertainty distribution defined for this parameter				

Quick Links: [Tortilla Chips \(F\)](#)

- 7 On the Edit Population Group / Life Stage and Consumption page, make one or more of the following changes:
- When editing a population group for acute exposure, you can edit the name of the population group, the number of eating occasions per year, the amount per eating occasion, the number of servings per person, and (for exposure to a chemical hazard) body weight as appropriate.
 - When editing a life stage for chronic multifold exposure, you can edit the name of the life stage, sex, age range, and average daily consumption. (Note: To change the number of consumers, you must edit the associated risk scenario.)
 - When editing a life stage for chronic exposure, you can edit the name of the life stage, the span in years, the average daily consumption, and the body weight. (Note: To change the number of consumers you must edit the consumption model itself from the Edit Chronic Consumption Model page. See "Editing a Consumption Model" on page 57.)
- 8 Do one of the following:
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Population Group / Life Stage

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food for which you want to delete a population group / life stage.
- 4 On the Edit Food page, click the **Consumption Models** tab.
- 5 Click the **Edit** link to the right of the consumption model for which you want to delete a population group / life stage.
- 6 Click the **Population Groups / Life Stages** tab, and then click the **Delete** link to the right of the population group / life stage that you want to delete.
- 7 Do one of the following:
 - If there are no risk scenarios related to this population group / life stage, click **Delete**.
 - If there are risk scenarios defined using the population group / life stage, they are listed on the page. You must delete the risk scenarios before you can delete the population group / life stage. (The Delete button will not display until the risk scenarios have been deleted.) For more information, see *"Deleting a Risk Scenario" on page 131*. Once the elements are deleted, navigate back to this page and click **Delete**.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> [Food \(Tortilla Chips\)](#) -> [Consumption Model \(Tortilla Chip Consumption\)](#) -> [Delete Life Stage \(Children aged 11 to 15\)](#)

Delete Life Stage

Unable to delete life stage unless the related risk scenarios are deleted first.

Deleting Life Stage *Children aged 11 to 15* will also delete the following:

Risk Scenarios	Notes
Aflatoxin B1 in Tortilla Chips	None specified
Aflatoxin B1 in Tortilla Chips (Exposure Only)	

Copying a Population Group / Life Stage

When you are working with your own models, you have the option to copy a consumption population group / life stage. When you copy a consumption population group / life stage, all related elements are linked to the new consumption population group / life stage.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Foods** tab, and then click the **Edit** link to the right of the food for which you want to copy a population group / life stage.

- 4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.
- 5 Click the **Edit** link to the right of the consumption model for which you want to copy a population group / life stage.
- 6 Click the **Population Groups / Life Stages** tab, and then click the **Copy** link to the right of the population group / life stage that you want to copy.
- 7 On the Copy Population Group / Life Stage and Consumption page, switch between the tabs and review all element definitions associated with the population group / life stage.
- 8 Click the **Name and Parameters** tab to enter a new name. By default, the copied model will have the name *<name> Copy*.
- 9 Click the **Instructions** tab.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Tortilla Chips) -> Consumption Model (Tortilla Chip Consumption) -> Copy Life Stage and Consumption (Children aged 1 to 5 years) ->

Copy Life Stage and Consumption

Instructions Name and Parameters Notes (0)

Use this feature to make a copy of the selected life stage.

Use the checkboxes to include or exclude specific elements from being copied with the life stage.

Use the tabs to change the model name used for the copy and to review the data currently associated with the life stage.

Include with copy:

Notes: ☒

After creating the copy:

Open the edit page for the copy ☒

Return to the list of life stages ☐

Copy Cancel

- 10 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 11 Click **Copy**.

Importing a Population Group / Life Stage

Consumption population groups / life stages cannot be imported individually. Importing a consumption model will import all its population groups / life stages. For more information, see *"Importing a Consumption Model"* on page 60.

CHAPTER 4

Diets

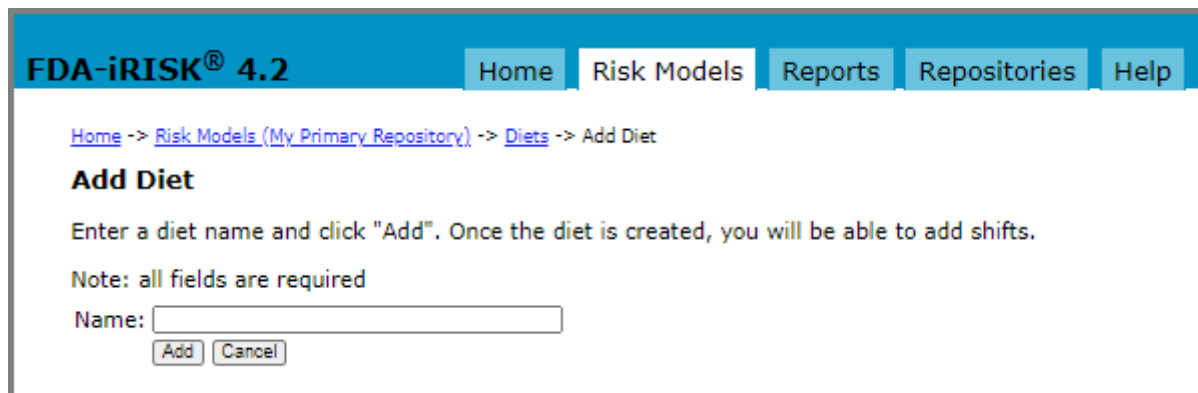
Diets allow you to explore the impact of shifts in diets between different foods. You specify diet shifts compared to a baseline diet by assigning modifiers that adjust the amount consumed for each food by a fixed multiplier (e.g., 0.5 for Food A, 1.4 for Food B) to shift average daily consumption from one food to another. A diet can be comprised of as many foods as are defined in the repository and multiple shifts can be defined for each diet.

For example, when you select a diet for a multifood scenario, the diet shifts are incorporated into the analysis to show the change in risk (or exposure) for each shift in the diet as compared to the baseline.

The diets are linked to select foods for maximum flexibility so that you can apply them to any consumption model. This allows you to define alternative baseline consumption models but still apply the same overall diet shifts in different scenarios to explore the impact of different initial estimates of consumption.

Adding a Diet

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Diets** tab, and then click the **Add Diet** link. The Add Diet page opens.



FDA-iRISK® 4.2

Home Risk Models Reports Repositories Help

Home -> Risk Models (My Primary Repository) -> Diets -> Add Diet

Add Diet

Enter a diet name and click "Add". Once the diet is created, you will be able to add shifts.

Note: all fields are required

Name:

Add Cancel

- 4 In the **Name** input field, enter a name for the food.

- 5 Click **Add**. The Edit Diet page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Diets](#) -> Edit Diet (Diet 1) -> Name and Parameters Tab

Edit Diet

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

Instructions

Name and Parameters

Notes (0)

Note: All fields are required

Name:

Add food to diet:

Food	Baseline	<input type="button" value="Add a Shift"/>
Soft Ripened Cheese	<input type="text" value="1"/>	<input type="button" value="Add"/>
Peanut Butter	<input type="text" value="1"/>	<input type="button" value="Add"/>

Last Modified: 16-Sep-2019 13:59:58

Quick Links: [Diets](#)

- 6 In the **Add food to diet** drop-down list, select a food and click **Add**. Repeat this step until you have added all of the required foods to the diet.

The initial baseline diet has a default multiplier of 1; however, you can set it to 0 to indicate that the food is not included in the baseline diet.

- 7 To define a diet shift, click **Add Shift**.

- 8 In the **Shift** box, type a name for the shift and enter a diet shift multiplier for each food.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Diets](#) -> Edit Diet (Diet 1) -> Name and Parameters Tab

Edit Diet

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

Instructions | Name and Parameters | Notes (0)

Note: All fields are required

Name:

Add food to diet:

Food	Baseline	Shift <input type="text" value=""/>	<input type="button" value="Add a Shift"/>
Soft Ripened Cheese	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="button" value="Add a Shift"/>
Peanut Butter	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="button" value="Add a Shift"/>

Last Modified: 16-Sep-2019 13:59:58

Quick Links: [Diets](#)

- 9 Do one of the following:
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Editing a Diet

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- Click the **Diets** tab, and then click the **Edit** link to the right of the diet that you want to edit.

Instructions | Hazards (8) | Foods (10) | Diets (1) | Process Models (7) | Risk Scenarios (11) | Notes

Diets

Select a diet from the list below to edit or delete, or add a new diet.
Shifts are defined as part of the diet.

[Add Diet](#)

Diet	Actions
Diet 1	Edit Copy Delete

- 4 On the **Edit Food** page, edit the diet name, the shift name, the foods in the diet, and the baseline (a multiplier of 1 is recommended) and shift multipliers as required.
- 5 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Diet

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Diets** tab, and then click the **Delete** link to the right of the diet that you want to delete.
- 4 On the **Delete Diet** page, do one of the following:
 - If there are no risk scenarios defined for the diet, click **Delete**.
 - If there are risk scenarios defined for the diet, they are listed on the page. You must delete these risk scenarios before you can delete the diet. (The Delete button will not display until the risk scenarios have been deleted.) For more information, see "Deleting a Risk Scenario" on page 131. Once the risk scenarios are deleted, navigate back to this page and click **Delete**.

Home -> Risk Models (My Primary Repository) -> Diets -> Delete Diet (Diet 1)

Delete Diet

Deleting the diet *Diet 1* will also delete the following:

Diet Shifts	Diet Food	Risk Scenarios	Notes
Shift	Peanut Butter	None specified	None specified
	Soft Ripened Cheese		

Copying a Diet

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.
- 3 Click the **Diets** tab, and then click the **Copy** link to the right of the diet that you want to copy.
- 4 On the **Copy Diet** page, switch between the tabs and review all element definitions associated with the diet.
- 5 Click the **Name and Parameters** tab to enter a new name. By default, the copied food will have the name `<diet_name> Copy`.

- 6 Click the **Instructions** tab.

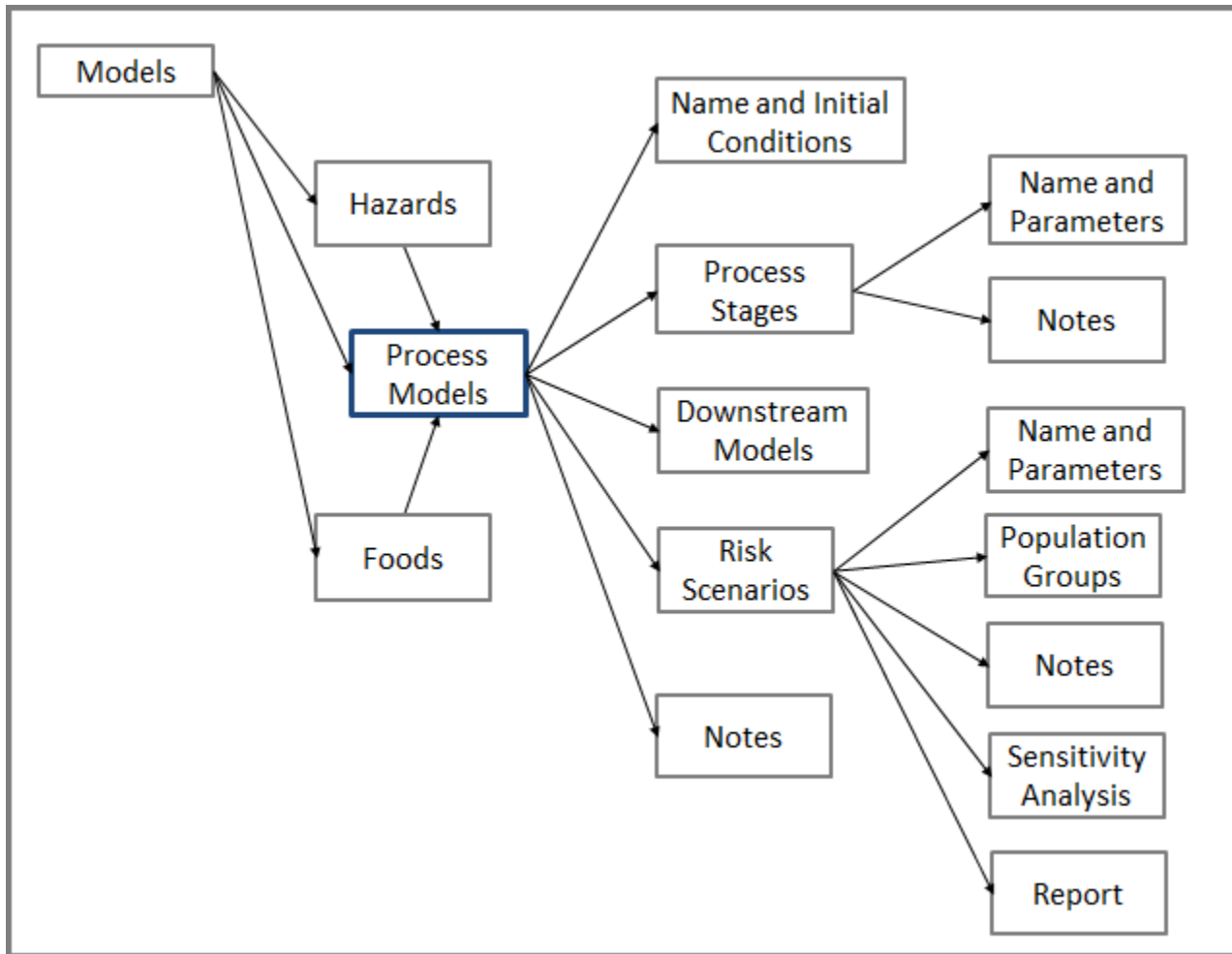
The screenshot shows a web interface for creating a copy of a diet. At the top, a breadcrumb trail reads: [Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Diets](#) -> [Copy Diet \(Diet 1\)](#) -> [Instructions Tab](#). Below this is the title 'Copy Diet'. A tabbed interface has three tabs: 'Instructions' (selected), 'Name and Parameters', and 'Notes (0)'. The 'Instructions' tab contains the following text: 'Use this feature to make a copy of the selected diet.', 'Use the checkboxes to include or exclude specific elements from being copied with the diet.', 'Use the tabs to change the diet name used for the copy and to review the data currently associated with the diet.', 'Include with copy:', 'Shifts: ☒', 'Notes (for all copied items): ☒', 'After creating the copy:', 'Open the edit page for the copy ☒', and 'Return to the list of diets ☐'. At the bottom left are 'Copy' and 'Cancel' buttons.

- 7 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 8 Click **Copy**.

CHAPTER 5

Process Models and Process Stages

The following illustration shows the edit pathways for process models in FDA-iRISK. Each arrow represents a potential one-to-many relationship; however, a process model can only be associated with one food hazard combination:



Navigating to Process Models

You navigate to the process models in the following ways:

- Click the **Process Models** tab on the Risk Models page. A complete list of process models displays; however, you can filter the list by food or hazard.

Home -> Risk Models (My Primary Repository) -> Process Models Tab

Risk Models

Select Repository:

Instructions Hazards (8) Foods (10) Diets (1) **Process Models (7)** Risk Scenarios (11) Notes

Process Models

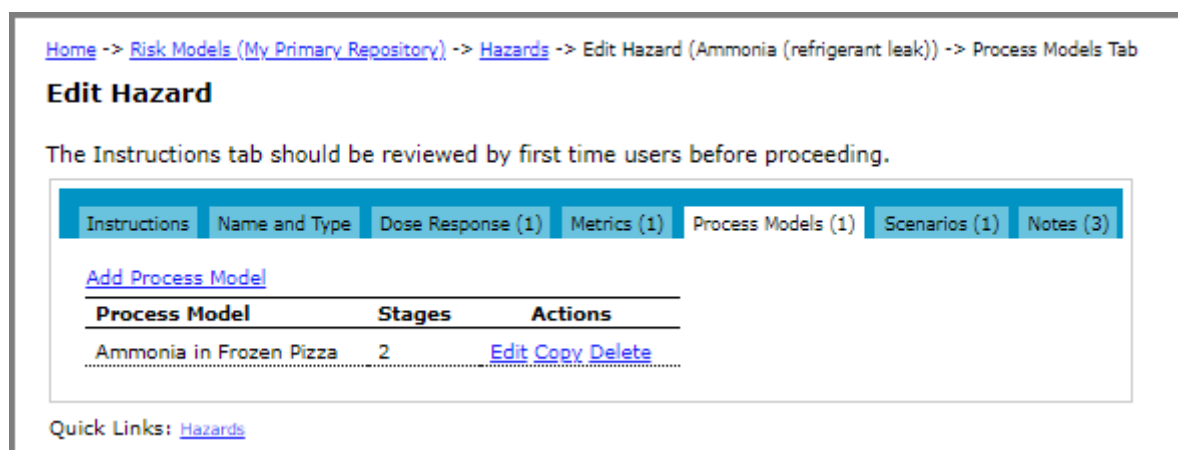
Select a process model from the list below to edit or delete, or add a new process model. To add a process model, the food and hazard under consideration must have already been defined.

[Add Process Model](#)

Filter by food: Filter by hazard:

Process Model	Stages	Actions
Aflatoxin B1 in Tortilla Chips	0	Edit Copy Delete
Ammonia in Frozen Pizza	2	Edit Copy Delete
L. monocytogenes in soft ripened cheese	1	Edit Copy Delete
OTA in Oats	0	Edit Copy Delete
OTA in Raisins	0	Edit Copy Delete
OTA in Rice	0	Edit Copy Delete
Salmonella in Peanut Butter	2	Edit Copy Delete

- To navigate to the process models associated with a particular hazard, click the **Hazards** tab on the Risk Models page. Then, click the **Edit** link to the right of the hazard for which you want to access the process models. On the Edit Hazard page, click the **Process Models** tab.



Adding a Process Model

Before you begin: The hazard and food that you want to select for the process model must be available. For information about adding them, see *Chapter 2, "Hazards, Dose Response Models, Health Metrics, and Predictive Models"* and *Chapter 3, "Foods, Consumption Models, and Population Groups"*.

The initial conditions and process stage(s) parameters that make up a process model, are referred to as a process model parameter set.

By default, there is a single process model parameter set for every process model. (See *"Adding a Process Model - Single Set of Parameters"* on page 81)

For process models with a microbial hazard, you can define multiple parameter sets for the same process model that reflect differences in a single process model between for example, geographic regions, or seasons. In this case, each parameter set is optionally assigned a proportion of the total number of eating occasions as defined in the associated consumption models. This allows the calculation of the relative risk in terms of DALYs for each parameter set. However, you can set this proportion to 1 if you do not wish to apply a proportion of consumption. (See *"Adding a Microbial Process Model - Multiple Parameter Sets (Parallel Model)"* on page 84)

For process models with multiple parameter sets, you can select which to include in the ranking reports. Scenarios that use the process models with multiple parameter sets are available for sensitivity analysis, but only for the primary parameter set. In addition, this type of process model cannot be linked to another process model.

Adding a Process Model - Single Set of Parameters

- 1 Navigate to the Process Models page. See *"Navigating to Process Models"* on page 80.

- Click the **Add Process Model** link. The Add Process Model page opens.

- In the **Name** input field, enter a name for the process model.
- In the **Hazard** drop-down list, select the hazard.
- In the **Food** drop-down list, select the food.
Note: The food and hazard cannot be changed once the process model is added.
- Click **Add**. The Edit Process Model page opens.
- In the **Model Name** input field, edit the process model name, if required.
- Under **Define Initial Conditions Using**, (if is not already selected) select **Single Set of Parameters** and then click **Change Method**.
- In the **Select Mass Units** drop-down list under **Initial Contamination, Unit Size and Prevalence**, select the mass unit.
- Under **Initial Unit Mass**, select a variability distribution from the drop-down list, and then enter a value for mass per unit of food.
Note: The distribution chart is not displayed when a fixed value is selected rather than a variability distribution.
- Do one of the following:
 - To describe a situation in which the food is already contaminated (e.g. raw milk to be used in cheese making), select the **Initial Units are Contaminated** check box. Then, enter the prevalence of the contaminated units in the **Initial Prevalence** input field and under **Initial Concentration**, enter values for the initial concentration of the hazard in the food among contaminated units only.

Prevalence represents the proportion of food units that are contaminated and is parameterized as a unitless value between 0 and 1. The prevalence value specified in each process model must be the proportion of contaminated food units for the unit size (i.e., mass or volume) specified. For example, if the unit size represents a head of lettuce, the prevalence must be the proportion of heads of lettuce that are contaminated and not the proportion of fields or shipping crates of lettuce that are contaminated.

Important: Do not enter an average concentration over both contaminated and uncontaminated units.

- To describe a situation in which the food is not contaminated, clear the **Initial Units are Contaminated** check box. When this check box is cleared, any values for prevalence and concentration are ignored and the values are set to zero when the process model is evaluated.

- 12 For process models with a microbial hazard, enter the values for a maximum population density, if required.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Process Models](#) -> Edit Process Model (Ammonia in Frozen Pizza) -> Name and Initial Conditions Tab

Edit Process Model

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

Instructions | **Name and Initial Conditions** | Process Stages (2) | Downstream Models (0) | Scenarios (1) | Notes (0)

Note: All fields are required

Model Name:

Define Initial Conditions Using:

Single Set of Parameters ☒
 Upstream Process Model ☐

[Change Method](#)

Initial Contamination, Unit Size and Prevalences:

Parameter	Value	Uncertainty
Hazard:	Ammonia (refrigerant leak)	N/A
Food:	Frozen Pizza	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/>	N/A
Initial Prevalence:	<input type="text" value="1E-6"/>	Uniform (Minimum: 0.9E-6, Maximum: 1.1E-6) Edit Delete
Select Mass Units:	<input type="text" value="g"/>	N/A

Initial Unit Mass:

Distribution Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="100"/>	Add

Chart is not displayed when the distribution is set to Fixed Value

Initial Concentration:

Parameter	Value	Uncertainty
Units:	<input type="text" value="mg"/> / <input type="text" value="g"/> Update	N/A
Variability Distribution:	<input type="text" value="Triangular"/>	N/A
Minimum:	<input type="text" value="0.7"/>	Add
Mode:	<input type="text" value="1.3"/>	Add
Maximum:	<input type="text" value="2"/>	Add

The chart below displays the probability density function (PDF) and cumulative distribution function (CDF) or probability histogram for the initial concentration based on the parameters above. Please note that the left vertical axis measures probability density and should not be interpreted as measuring probability. Values for probability density are not restricted to the interval (0,1). The chart is only updated if the page is saved or the Refresh Chart button is clicked.

[Refresh Chart](#)

[Save](#) [Save and Close](#) [Close](#)

Last Modified: 13-Aug-2020 12:11:52

Quick Links: [Frozen Pizza / 1](#) | [Ammonia \(refrigerant leak\) / 2](#)

13 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

The ultimate output of the process model must represent the concentration and prevalence of the hazard in the food at the time of consumption. If the defined initial conditions do not also represent the contamination at the time of consumption, you need to define process stages representing any changes between the initial conditions and consumption. See *"Adding a Process Stage (Single Definition)" on page 94*.

Adding a Microbial Process Model - Multiple Parameter Sets (Parallel Model)

For microbial process models, you can either create multiple parameter sets manually or import them from a text file (txt).

Adding a Microbial Process Model - Creating Multiple Parameter Sets

To create multiple parameter sets, you would create the first (i.e. primary) set by creating the process model and defining the initial conditions and process stages. Then, to create the next parameter set, you copy the primary parameter set, edit it accordingly, and then save it using a different name. Continue this process until you have created all of the necessary parameter sets.

For each parameter set, you must assign a weight or a proportion of the total number of eating occasions as defined in the associated consumption models. This allows the calculation of the relative risk in terms of DALYs for each parameter set. You can set this proportion to 1 if you do not wish to apply a proportion of consumption.

In addition, you can select which parameter sets to include in a scenario and ranking reports.

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 Click the **Add Process Model** link. The Add Process Model page opens.
- 3 In the **Name** input field, enter a name for the process model.
- 4 In the **Hazard** drop-down list, select the hazard.
- 5 In the **Food** drop-down list, select the food.
Note: The food and hazard cannot be changed once the process model is added.
- 6 Click **Add**. The Edit Process Model page opens.
- 7 In the **Model Name** input field, edit the process model name, if required.
- 8 Under **Define Initial Conditions Using**, select **Multiple Sets of Parameters** and then click **Change Method**. The first (i.e. primary) parameter set displays in the **Select Parameter Set to Edit** drop-down list. By default, the first (and primary) parameter set has the same name as the process model name.
- 9 Click the **Copy to New Parameter Set** button once for each variation of the model you want to define. The copies will populate the drop-down menu in the Select Parameter Set to Edit field.

- 10 Select the original set from the **Select Parameter Set to Edit** drop-down list, and click **Load Parameter Set**. The original set name displays in the Parameter Set Name field, where it can be edited. This will represent the primary (baseline) parameter set (which cannot be deleted from the parallel model). Edit the name if desired.
- 11 If the baseline set has already been defined, select an as-yet undefined parameter set from the **Select Parameter Set to Edit** drop-down menu and click **Load Parameter Set**.
- 12 In the **Parameter Set Weight (0-1)** input field, enter the weight of the total number of eating occasions as defined in the associated consumption models, or leave the value at 1.
- 13 To include the data model parameter set in a risk scenario or the ranking reports, select the **Include in Ranking Reports** check box.
- 14 Define the initial conditions for the parameter set and click **Save** to stay on the Edit Process Model Page. The values are saved to the name you have loaded or typed in the **Parameter Set Name** field (which is automatically be included in the Select Parameter Set to Edit drop-down list.).
- 15 Repeat [Step 12](#) to [Step 14](#) for each variant parameter set.
Note: The parameter set displayed in the Parameter Set Name field is the one that is being edited. The Copy to New Parameter Set button is only used when initially copying the name.
- 16 On the Edit Process Model page, click the **Process Stages** tab.
- 17 Click the **Add Process Stage** link. The Add Process Stage page opens.
- 18 In the **Stage Name** input field, enter a name for the process stage.
- 19 In the **Process Type** drop-down list, select the process type.
- 20 Click **Add**. The Edit Process Stage page opens.
- 21 On the Edit Process Stage page, select **Multiple Definitions** from the **Define Using** drop-down list, and then click **Update Method**.
- 22 Select a parameter set from the **Select Definition to Edit** drop-down list and click **Load Definition**. The loaded parameter set name displays in the Process Model field.
- 23 If required, edit the specific stage name to be associated with the loaded parameter set (e.g., Growth during Storage, Baseline). Alternatively the same stage name can be used for all parameter sets.
- 24 Enter the appropriate value(s) to define the stage for the loaded parameter set.
- 25 To save the changes and remain on the page, click **Save**.
- 26 Repeat [Step 21](#) to [Step 25](#) (numbers 1 to 5 on the following figure) for each parameter set.
- 27 Repeat [Step 16](#) to [Step 26](#) for each process stage to be added.
- 28 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

When you are finished, the Process Stages list on the Edit Process Model page will display the stages and one definition per stage; the stage names and specific definition(s) displayed on the Process Stages list on the Edit

Process Model page will pertain to the parameter set loaded most recently, either from within an Edit Process Stage page or from the Select Parameter Set to Edit menu on the Edit Process Model page.

To delete a process model parameter set

Note: You cannot delete the primary process model parameter set. (The Delete button is not available when the primary parameter set is loaded into the Parameter Set Name field.)

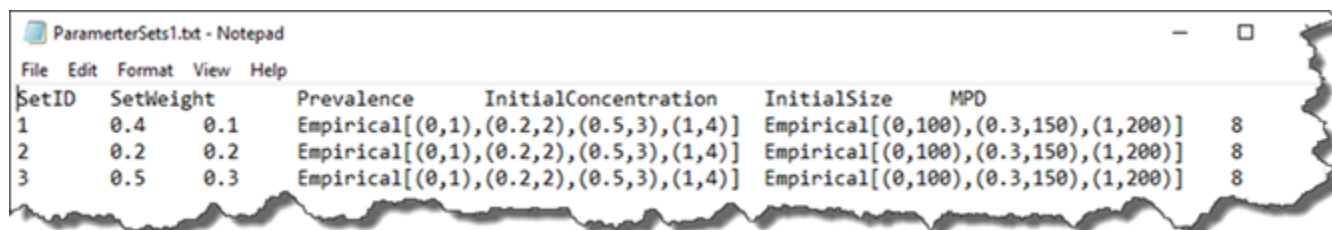
- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 On the **Process Models** tab, click the **Edit** link to the right of the process model.
- 3 In the **Select Parameter Set to Edit** drop-down list, select the parameter set to delete and then click **Load Parameter Set**.
- 4 To the right of the **Parameter Set Name** input field, click **Delete Parameter Set**.

Adding a Process Model - Importing Multiple Parameter Sets

You define the parameter sets in a tab-delimited text file (.txt) that includes the following information:

- SetID (should be unique)
- SetWeight (should be >0 and <=1)
- Prevalance
- InitialConcentration
- InitialSize
- MPD

For example:



SetID	SetWeight	Prevalance	InitialConcentration	InitialSize	MPD
1	0.4	0.1	Empirical[(0,1),(0.2,2),(0.5,3),(1,4)]	Empirical[(0,100),(0.3,150),(1,200)]	8
2	0.2	0.2	Empirical[(0,1),(0.2,2),(0.5,3),(1,4)]	Empirical[(0,100),(0.3,150),(1,200)]	8
3	0.5	0.3	Empirical[(0,1),(0.2,2),(0.5,3),(1,4)]	Empirical[(0,100),(0.3,150),(1,200)]	8

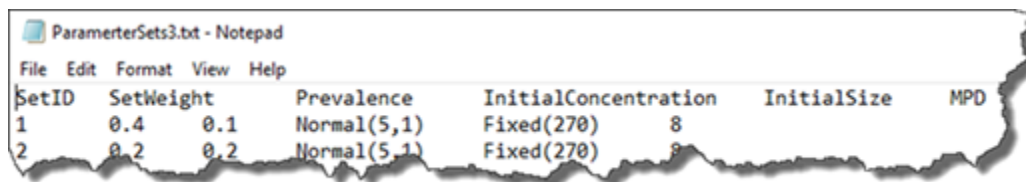
Size units and concentration units are copied from the existing primary set. Any existing process stages are also copied from the existing primary set.

The following distributions can be specified for InitialConcentration and InitialSize:

Distribution	Format	Example
Empirical	Empirical[(probability, value), (probability, value) , ..., (probability, value)]	Empirical[(0,1),(0.2,2),(0.5,3),(1,4)]
Chance	Chance[(probability, value), (probability, value) , ..., (probability, value)]	Chance[(0.3,1),(0.2,2),(0.5,3)]
BetaGeneral	BetaGeneral(alpha, beta, Lower bound, Upper bound)	BetaGeneral(5,1,1,8)

BetaPert	BetaPert(Minimum, Mode, Maximum)	BetaPert(2,5,9)
Fixed	Fixed (Value)	Fixed (0.5)
Normal	Normal(Mean, Standard Deviation)	Normal(5,2)
NormalTruncated	NormalTruncated(Mean, Standard Deviation, Lower Bound, Upper Bound)	NormalTruncated(5,2,1,8)
Triangular	Triangular(Minimum, Mode, Maximum)	Triangular(2,5,9)
TriangularPercentiles	TriangularPercentiles(5 th Percentile, Mode, 95 th Percentile)	TriangularPercentiles(3,5,8)
TriangularTruncated	TriangularTruncated(Minimum, Mode, Maximum, Lower Bound, Upper Bound)	TriangularTruncated(2,5,9,3,7)
Uniform	Uniform(Minimum, Maximum)	Uniform(1,9)
UniformPercentiles	UniformPercentiles(5 th Percentile, 95 th Percentile)	UniformPercentiles(2,8)

For example,



SetID	SetWeight	Prevalence	InitialConcentration	InitialSize	MPD
1	0.4	0.1	Normal(5,1)	Fixed(270)	8
2	0.2	0.2	Normal(5,1)	Fixed(270)	8

Imported parameter sets are added to any existing sets. Once the sets are imported, you may wish to select another set as primary and delete the default set.

You can also select which parameter sets to include in a scenario and ranking reports.

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 Click the **Add Process Model** link. The Add Process Model page opens.
- 3 In the **Name** input field, enter a name for the process model.
- 4 In the **Hazard** drop-down list, select the hazard.
- 5 In the **Food** drop-down list, select the food.
Note: The food and hazard cannot be changed once the process model is added.
- 6 Click **Add**. The Edit Process Model page opens.
- 7 In the **Model Name** input field, edit the process model name, if required.
- 8 Under **Define Initial Conditions Using**, select **Multiple Sets of Parameters** and then click **Change Method**.
- 9 Click **Import Multiple Parameter Sets**, and then **Choose File**.
- 10 Navigate to and select the text file (.txt). Click **Import**. The imported parameter sets are listed in the Select Parameter Set to Edit drop-down list.

- 11 On the Edit Process Model page, click the **Process Stages** tab.
- 12 Click the **Add Process Stage** link. The Add Process Stage page opens.
- 13 In the **Stage Name** input field, enter a name for the process stage.
- 14 In the **Process Type** drop-down list, select the process type.
- 15 Click **Add**. The Edit Process Stage page opens.
- 16 On the Edit Process Stage page, select **Multiple Definitions** from the **Define Using** drop-down list, and then click **Update Method**.
- 17 Select a parameter set from the **Select Definition to Edit** drop-down list and click **Load Definition**. The loaded parameter set name displays in the Process Model field.
- 18 If required, edit the specific stage name to be associated with the loaded parameter set (e.g., Growth during Storage, Baseline). Alternatively the same stage name can be used for all parameter sets.
- 19 Enter the appropriate value(s) to define the stage for the loaded parameter set.
- 20 To save the changes and remain on the page, click **Save**.
- 21 Repeat [Step 16](#) to [Step 20](#).
- 22 Repeat [Step 11](#) to [Step 21](#) for each process stage to be added.
- 23 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

When you are finished, the Process Stages list on the Edit Process Model page will display the stages and one definition per stage; the stage names and specific definition(s) displayed on the Process Stages list on the Edit Process Model page will pertain to the parameter set loaded most recently, either from within an Edit Process Stage page or from the Select Parameter Set to Edit menu on the Edit Process Model page.

To delete a process model parameter set

Note: You cannot delete the primary process model parameter set. (The Delete button is not available when the primary parameter set is loaded into the Parameter Set Name field.)

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 On the **Process Models** tab, click the **Edit** link to the right of the process model.
- 3 In the **Select Parameter Set to Edit** drop-down list, select the parameter set to delete and then click **Load Parameter Set**.
- 4 To the right of the **Parameter Set Name** input field, click **Delete Parameter Set**.

Adding a Process Model - Define Initial Conditions Using Existing Process Model Results (Linked Models)

You can use the results of an existing process model as the initial conditions for a new process model. For example, a process model for fluid milk could be used to provide the initial conditions for a cheese process model.

You can also model microbial toxins in FDA-iRISK in which a microbial hazard generates a chemical toxin within the process model. To do this, you must use the results of an existing process model with a microbial hazard as the initial conditions for a process model with a chemical hazard. You will need to specify a conversion rate from the microbial concentration to the corresponding toxin concentration.

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 Click the **Add Process Model** link. The Add Process Model page opens.
- 3 In the **Name** input field, enter a name for the process model.
- 4 In the **Hazard** drop-down list, select the hazard.
- 5 In the **Food** drop-down list, select the food.
Note: The food and hazard cannot be changed once the process model is added.
- 6 Click **Add**. The Edit Process Model page opens.
- 7 In the **Model Name** input field, edit the process model name, if required.
- 8 Under **Initial Conditions**, select **Upstream Process Model** and then click **Change Method**.

Home -> Risk Models (My Primary Repository) -> Process Models -> Edit Process Model (Ammonia in Frozen Pizza) -> Name and Initial Conditions Tab

Edit Process Model

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

Instructions
Name and Initial Conditions
Process Stages (2)
Downstream Models (0)
Scenarios (1)
Notes (0)

Note: All fields are required

Model Name:

Define Initial Conditions Using:

Single Set of Parameters ☐

Upstream Process Model ☒

Process Model:

Quick Links: [Frozen Pizza \(F\)](#) | [Ammonia \(refrigerant leak\) \(H\)](#)

- 9 In the **Process Model** drop-down list, select the process model to use and then click **Select**. (You can easily edit the selected process model by selecting the **Edit** link below the drop-down list.)

- 10 For a microbial-toxin process model, under **Conversion Rate**, select the conversion type, units and rate, and the intercept. If required, select the **Use Threshold** check box and then enter the threshold below which no toxin is produced.

Conversion Rate:	
Conversion Type:	Linear <input type="button" value="Update"/>
Converted Units:	cfu/g to <input type="text" value="mg"/> / g
Conversion Rate: (cfu/g to mg/g)	<input type="text" value="0"/>
Intercept: (mg/g)	<input type="text" value="0"/>
Use Threshold:	<input type="checkbox"/>
Threshold: (cfu/g)	<input type="text" value="0"/>

- 11 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

The ultimate output of the process model must represent the level and prevalence of the hazard in the food at the time of consumption. If the defined initial conditions do not represent the contamination at the time of consumption, you need to define process stages between the initial conditions and consumption. See *"Adding a Process Stage (Single Definition)"* on page 94.

Editing a Process Model

- 1 Navigate to the Process Models page. See *"Navigating to Process Models"* on page 80.

- On the **Process Models** tab, click the **Edit** link to the right of the process model that you want to edit.

Home -> Risk Models (My Primary Repository) -> Process Models Tab

Risk Models

Select Repository:

Instructions Hazards (8) Foods (10) Diets (1) **Process Models (7)** Risk Scenarios (11) Notes

Process Models

Select a process model from the list below to edit or delete, or add a new process model. To add a process model, the food and hazard under consideration must have already been defined.

[Add Process Model](#)

Filter by food: Filter by hazard:

Process Model	Stages	Actions
Aflatoxin B1 in Tortilla Chips	0	Edit Copy Delete
Ammonia in Frozen Pizza	2	Edit Copy Delete
L. monocytogenes in soft ripened cheese	1	Edit Copy Delete
OTA in Oats	0	Edit Copy Delete
OTA in Raisins	0	Edit Copy Delete
OTA in Rice	0	Edit Copy Delete
Salmonella in Peanut Butter	2	Edit Copy Delete

- On the Edit Process Model page, make one or more of the following changes:
 - The process model name.
 - The initial concentration, prevalence, and unit size for the food-hazard combination.
 - For process models with a microbial hazard, you may optionally include a maximum population density.
 - The method used to define initial conditions. (Click Update Method to save the change.)
- Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Process Model

- Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- On the **Process Models** tab, click the **Delete** link to the right of the process model that you want to delete.
- On the Delete Process Model page, do one of the following:
 - If there are no risk scenarios defined using the process model, click **Delete**.

- If there are risk scenarios defined using the process model, they are listed on the page. You must delete the risk scenarios before you can delete the process model. (The Delete button will not display until the risk scenarios have been deleted.) For more information, see *"Deleting a Risk Scenario" on page 131*. Once the risk scenarios are deleted, navigate back to this page and click **Delete**.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Process Models](#) -> Delete Process Model (Ammonia in Frozen Pizza)

Delete Process Model

Please correct the following:

Unable to delete process model unless the related risk scenarios are deleted first.

Deleting this process model *Ammonia in Frozen Pizza* will also delete the following:

Process Stages	Child Process Models	Risk Scenarios	Notes
Cooking	None specified	Ammonia in Frozen Pizza in Children	None specified
Storage			

Copying a Process Model

When you are working with your own models, you have the option to copy a process model. When you copy a process model, all related elements are linked to the new process model.

- Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- On the **Process Models** tab, click the **Copy** link to the right of the process model that you want to copy.
- On the Copy Process Model page, switch between the tabs and review all element definitions associated with the process model.
- Click the **Name and Initial Conditions** tab to enter a new name. By default, the copied process model will have the name `<process_model_name> Copy`.

- Click the **Instructions** tab.

Home -> Risk Models (My Primary Repository) -> Process Models -> Copy Process Model (Ammonia in Frozen Pizza) -> Instructions Tab

Copy Process Model

Instructions
Name and Initial Conditions
Process Stages (2)
Notes (0)

Use this feature to make a copy of the selected model. The copy will be linked with the same food and hazard as the original.

Use the checkboxes to include or exclude specific elements from being copied with the model.

Use the tabs to change the model name used for the copy and to review the data currently associated with the model.

Choose hazard:
Use same hazard ☒
Create new hazard: ☐ New Hazard
Link to existing hazard: ☐ Aflatoxin B1

Choose food:
Use same food ☒
Create new food: ☐ New Food
Link to existing food: ☐ Frozen Pizza

Include with copy:
Process Stages: ☒
Notes (for all selected items): ☒

After creating the copy:
Open the edit page for the copy ☒
Return to the list of process models ☐

Copy
Cancel

- Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- Click **Copy**.

Importing a Process Model

When you are viewing models shared from others, you have the option to import a process model into your own models. When you import a process model, all associated elements are also imported, including processing stages and notes.

The imported process model will have the name: *<process_model_name> Imported*.

- Click the **Risk Models** tab on the main tab bar.
- In the **Select Repository** drop-down list, select a repository that is being shared with you.
- Navigate to the Process Models page. See "Navigating to Process Models" on page 80.
- Click the **Import** link to the right of the process model that you want to import.
- On the Import Process Model page, switch between the tabs and review all element definitions associated with the process model.
- Click the **Instructions** tab.

- 7 In the **Select Repository** drop-down list, select a model repository to which to import the process model.
- 8 Choose the hazard to link the process model to. Do one of the following:
 - To link the imported process model to a hazard in your repository, select the **Link to my hazard** option and select the hazard from the drop-down list. Note that the hazard type (i.e., microbial vs. chemical) of the selected hazard must be the same as the hazard that is linked to the process model that you are importing.
 - To import the hazard with the process model, select the **Import hazard with process model** option. The related dose response models and health metrics are imported as well.
- 9 Choose the food to link the process model to. Do one of the following:
 - To link the imported process model to a food in your repository, select the **Link to my food** option and select the food from the drop-down list. Note that the unit type of the selected food (i.e., mass vs. volume) must be the same as the food that is linked to the process model that you are importing.
 - To import the food with the process model, select the **Import food with process model** option. The related consumption models are imported as well.
- 10 Click **Import**.
- 11 Do one of the following:
 - To edit the dose response model, click the **View Imported Process Model** link.
 - To return to the list of shared dose response models, click **Close**.

Process Stages

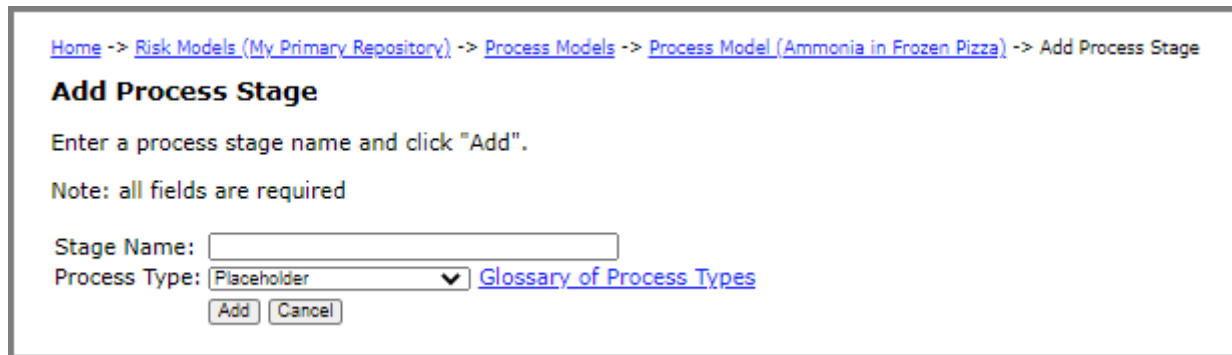
Adding a Process Stage (Single Definition)

For multiple definition process stages (within parallel models) see *"Adding a Microbial Process Model - Multiple Parameter Sets (Parallel Model)" on page 84*.

Before you begin: When adding a process stage for the Decrease by Inactivation Model or Increase by Growth Model process types, the predictive model(s) that you want to select must be available. For more information, see the section, *"Predictive Models" on page 44*

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 On the Process Models tab, click the **Edit** link to the right of the process model where you want to add a process stage.
- 3 On the Edit Process Model page, click the **Process Stages** tab.

- Click the **Add Process Stage** link. The Add Process Stage page opens.



Home -> Risk Models (My Primary Repository) -> Process Models -> Process Model (Ammonia in Frozen Pizza) -> Add Process Stage

Add Process Stage

Enter a process stage name and click "Add".

Note: all fields are required

Stage Name:

Process Type: Placeholder ▼ [Glossary of Process Types](#)

- In the **Stage Name** input field, enter a name for the process stage.
- In the **Process Type** drop-down list, select the process type that describes the impact of the processing step under evaluation on either the concentration or prevalence of the hazard, or the size of the unit of food.

Tip: Click the **Glossary of Process Types** link to view a list and description of the process types. For more information about the process types, see the *FDA-iRISK Technical Document*.

Notes:

- To include a process step that has no impact on these values, select **No Change** from the **Process Type** drop-down list.
 - If you are building a process model framework prior to data collection, select **Placeholder** from the **Process Type** drop-down list. You can change it to any other type by editing later, as required.
- Click **Add**. The Edit Process Stage page opens.
(The input fields that display on this page are determined by the process type that you selected on the previous page.)
 - Enter the appropriate values to define the effect of the process stage on the concentration or prevalence of hazard in the food, or the size of the food unit.

In the following example, the mass of the food unit becomes 250 g as the peanut butter is portioned into jars.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Process Models](#) -> [Process Model \(Salmonella in Peanut Butter\)](#) -> [Edit Process Stage \(Packaging\)](#) -> [Name and Parameters Tab](#)

Edit Process Stage

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

Instructions

Name and Parameters

Notes (0)

Note: All fields are required

Stage Name:

Process Model: Salmonella in Peanut Butter

Process Type: Partitioning

Parameter	Value	Uncertainty
Food Units:	<input type="text" value="g"/> <input type="button" value="Update"/>	N/A

Final Unit Size:

Distribution Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="250"/>	Add

Chart is not displayed when the distribution is set to Fixed Value

Last Modified: 03-Sep-2019 11:15:04

Quick Links: [Peanut Butter \(F\)](#) | [Salmonella \(H\)](#) | [Salmonella in Peanut Butter \(PM\)](#)

Similarly, the following is an example of a process stage describing the decrease of the hazard during storage:

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Process Models](#) -> [Process Model \(Salmonella in Peanut Butter\)](#) -> [Edit Process Stage \(Storage\)](#) -> [Name and Parameters Tab](#)

Edit Process Stage

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

Instructions | **Name and Parameters** | **Notes (1)**

Note: All fields are required

Stage Name:

Process Model: Salmonella in Peanut Butter

Process Type: Decrease

Reduction in Microbial Population (log10 scale):

Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Uniform"/>	N/A
Minimum:	<input type="text" value="0.49"/>	Add
Maximum:	<input type="text" value="3.47"/>	Add

The chart below displays the probability density function (PDF) and cumulative distribution function (CDF) or probability histogram for the variability distribution based on the parameters above. Please note that the left vertical axis measures *probability density* and should not be interpreted as measuring probability. Values for probability density are not restricted to the interval (0,1). The chart is only updated if the page is saved or the Refresh Chart button is clicked.

[Refresh Chart](#)

[Save](#) [Save and Close](#) [Close](#)

Last Modified: 03-Sep-2019 11:15:04

Quick Links: [Peanut Butter \(F\)](#) | [Salmonella \(H\)](#) | [Salmonella in Peanut Butter \(PM\)](#)

9 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.

- To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.
- 10 Continue adding process stages until the impact of processing on the concentration and prevalence of the hazard, or the mass of the food, up to the point of consumption, have been defined.

Editing a Process Stage

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 On the Process Models tab, click the **Edit** link to the right of the process model where you want to edit a process stage.
- 3 On the Edit Process Model page, click the **Process Stages** tab.
- 4 If applicable (i.e., if the process stage belongs to a parallel process model), select the process model definition for the process stage that you want to edit from the **Select Definition to Edit** drop down list box. Click **Load Definition**.
- 5 Click the **Edit** link to the right of the process stage that you want to edit.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Process Models](#) -> Edit Process Model (Salmonella in Peanut Butter) -> Process Stages Tab

Edit Process Model

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

Instructions	Name and Initial Conditions	Process Stages (2)	Downstream Models (0)	Scenarios (1)	Notes (0)
Add Process Stage					
Stage Name	Process Type	Definition	Unit Size	Actions	
Packaging	Partitioning	Fixed Value (Value: 250) g	250 g	Edit	Copy Delete ↑ ↓
Storage	Decrease	Uniform (Minimum: 0.49, Maximum: 3.47)	250 g	Edit	Copy Delete ↑ ↓

u: Uncertainty distribution defined for this parameter

Quick Links: [Peanut Butter \(F\)](#) | [Salmonella \(H\)](#)

- 6 On the Edit Process Stage page, make one or more of the following changes:
 - The process stage name.
 - The values of any of the parameters.
- 7 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Process Stage

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 On the Process Models tab, click the **Edit** link to the right of the process model where you want to delete a process stage.
- 3 On the Edit Process Model page, click the **Process Stages** tab.
- 4 If applicable (i.e., if the process stage belongs to a parallel process model), select the process model definition for the process stage that you want to delete from the **Select Definition to Edit** drop down list box. Click **Load Definition**.
- 5 Click the **Delete** link to the right of the process stage that you want to delete.
- 6 On the Delete Process Stage page, click **Delete**.

Copying a Process Stage

When you are working with your own models, you have the option to copy a process stage. The copy is linked to the same process model as the original and appended to the end of the current list of process stages.

- 1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.
- 2 On the Process Models tab, click the **Edit** link to the right of the process model for which you want to copy a process stage.
- 3 On the Edit Process Model page, click the **Process Stages** tab.
- 4 Click the **Copy** link to the right of the process stage that you want to copy.
- 5 On the Copy Process Stage page, do one of the following:
 - To copy a process stage defined within a parallel model, on the Instructions tab, select the **Open the edit page for the copy** option, and then click **Copy**. Then, perform [Step 21](#) to [Step 25](#) of the section *"Adding a Microbial Process Model - Multiple Parameter Sets (Parallel Model)" on page 84*. Omit the remaining steps below.

- To copy a process stage defined for non-parallel process models, switch between the tabs and review all element definitions associated with the process stage.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Process Models](#) -> [Process Model \(Salmonella in Peanut Butter\)](#) -> Copy Process Stage (Packaging) -> Instructions Tab

Copy Process Stage

Instructions

Name and Parameters

Notes (0)

Use this feature to make a copy of the selected stage. The copy will be linked with the same process model as the original and appended to the end of the current list of stages.

Use the checkboxes to include or exclude specific elements from being copied with the stage.

Use the tabs to change the stage name used for the copy and to review the data currently associated with the stage.

Include with copy:

Notes: ☒

After creating the copy:

Open the edit page for the copy ☒

Return to the list of process stages ☐

Copy Cancel

- 6 Click the **Name and Parameters** tab to enter a new name. By default, the copied process stage will have the name `<process_stage_name> Copy`.
- 7 Click the **Instructions** tab.
- 8 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 9 Click **Copy**.

Importing a Process Stage

Process stages cannot be imported individually. Importing a process model will import all its process stages.

CHAPTER 6

Notes

Notes occupy the right-most tab on the Edit Page of every element in FDA-iRISK. To view the list of notes (if any) defined for an element, click the Notes tab on any Edit page. For example, here is a sample of how notes are displayed:

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> Edit Hazard (Ammonia (refrigerant leak)) -> Notes Tab

Edit Hazard

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

Instructions

Name and Type

Dose Response (1)

Metrics (1)

Process Models (1)

Scenarios (1)

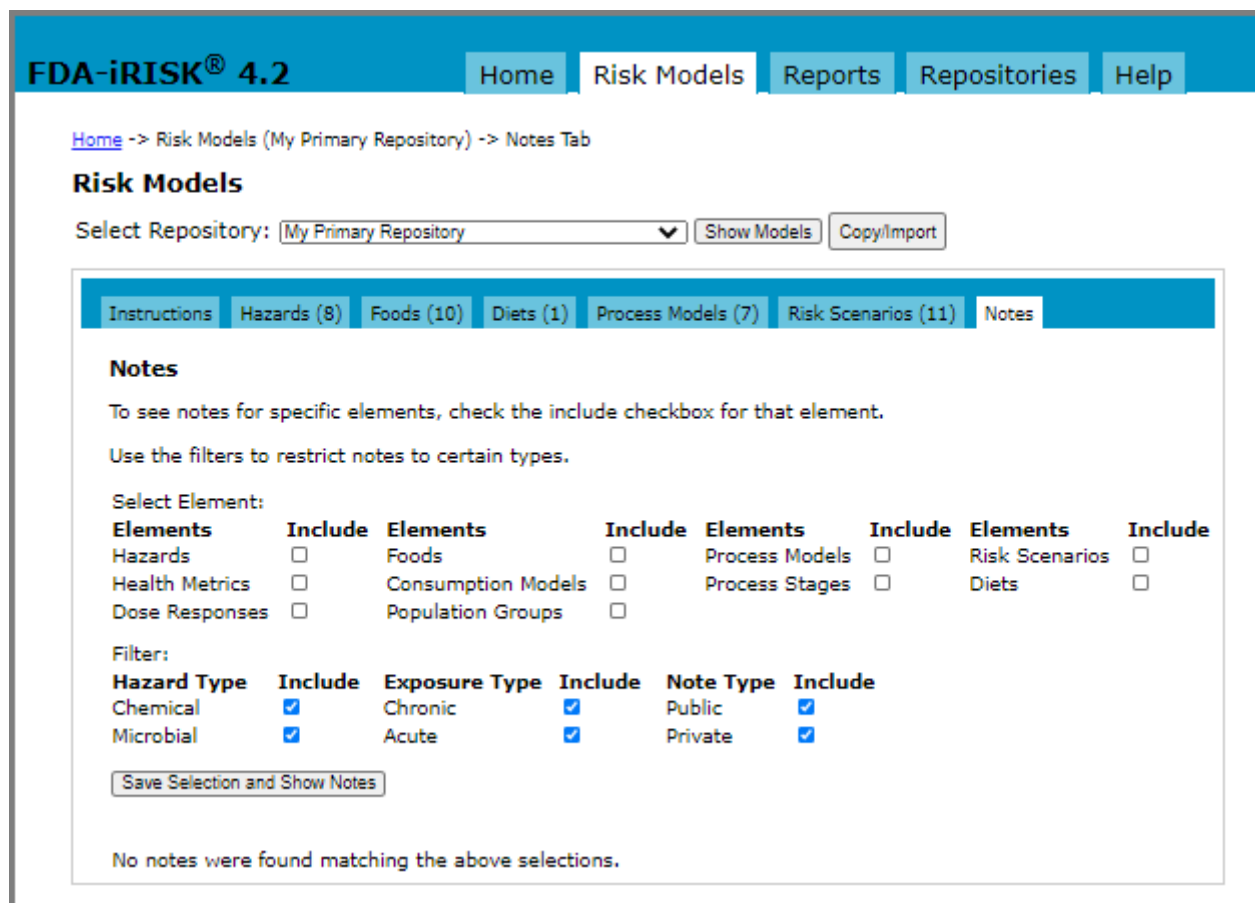
Notes (3)

[Add Note](#)

Type	Heading	Text	Actions
Public	Description	Ammonia is a corrosive alkaline gas at room temperature, with an acrid odor that can be detected at concentrations of 35 mg per cubic metre of air (IPCS, 1990). It is used industrially and is also associated with normal biological activity, and typical levels range from less than 25	Edit Copy Delete ↑ ↓
Public	References	International Programme on Chemical Safety (IPCS). 1990. Ammonia Health and Safety Guide. Available at: http://www.inchem.org/documents/hsg/hsg0.37.htm . Accessed Aug. 31, 2012	Edit Copy Delete ↑ ↓
Public	Context	The assumption behind inclusion of this hazard, which is not a typical food contaminant, is that a refrigeration system failed and resulted in spillage of ammonia onto package of food. This occurrence was reported in Dworkin et al., 2004. Dworkin MS, Patel A, Fennell M, Collmer M, Bailey S, Bloom...	Edit Copy Delete ↑ ↓

Quick Links: [Hazards](#)

Alternately, you can use the filters on the Notes tab on the Risk Models page to restrict the list of notes to certain types and then edit, copy, and delete them as required. The filter selections are saved.



FDA-iRISK® 4.2 Home Risk Models Reports Repositories Help

Home -> Risk Models (My Primary Repository) -> Notes Tab

Risk Models

Select Repository: My Primary Repository Show Models Copy/Import

Instructions Hazards (8) Foods (10) Diets (1) Process Models (7) Risk Scenarios (11) **Notes**

Notes

To see notes for specific elements, check the include checkbox for that element.
Use the filters to restrict notes to certain types.

Select Element:

Elements	Include	Elements	Include	Elements	Include	Elements	Include
Hazards	<input type="checkbox"/>	Foods	<input type="checkbox"/>	Process Models	<input type="checkbox"/>	Risk Scenarios	<input type="checkbox"/>
Health Metrics	<input type="checkbox"/>	Consumption Models	<input type="checkbox"/>	Process Stages	<input type="checkbox"/>	Diets	<input type="checkbox"/>
Dose Responses	<input type="checkbox"/>	Population Groups	<input type="checkbox"/>				

Filter:

Hazard Type	Include	Exposure Type	Include	Note Type	Include
Chemical	<input checked="" type="checkbox"/>	Chronic	<input checked="" type="checkbox"/>	Public	<input checked="" type="checkbox"/>
Microbial	<input checked="" type="checkbox"/>	Acute	<input checked="" type="checkbox"/>	Private	<input checked="" type="checkbox"/>

Save Selection and Show Notes

No notes were found matching the above selections.

When editing a note, you can type or paste text into the Notes input field. (When pasting, be sure to review the pasted text to ensure that all symbols and special text have been correctly carried over.)

When viewing the list of notes on the Notes tab of an Edit Page, you can order the notes in the list (using the up and down arrows to the far right of the note). This will affect the order of the notes in the list view and in reports.

Adding a Note

- 1 Navigate to the Notes tab for the element where you want to add a note.
- 2 Click the **Add Note** link.
- 3 On the **Add Note** page, enter a heading for the note.
- 4 If required, to prevent sharing the note and exclude it from reports, select the **Private** check box.

- 5 Click **Add**. The window expands and you can enter the note.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Ammonia (refrigerant leak)) -> Edit Note (Rationale)

Edit Note

Private notes will not be shared and will be excluded from reports.

Note: all fields are required

Private: ☐

Heading:

Note:

Last Modified: 18-Aug-2020 13:37:52

- 6 In the **Note** input field, enter the note.
Note: FDA-iRISK times out after a certain period of inactivity. Therefore, it is good practice to save regularly to avoid losing any work since the last save.
- 7 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Editing a Note

- 1 Do one of the following:
 - Navigate to the **Notes** tab on the Risk Models page. Use the check boxes at the top of the page to select the element(s) and filter(s) to locate the note that you want to edit.
 - Navigate to the **Notes** tab for the element where you want to edit a note.

- Click the **Edit** link to the right of the note that you want to edit.

Home -> Risk Models (My Primary Repository) -> Hazards -> Edit Hazard (Ammonia (refrigerant leak)) -> Notes Tab

Edit Hazard

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

[Instructions](#)
[Name and Type](#)
[Dose Response \(1\)](#)
[Metrics \(1\)](#)
[Process Models \(1\)](#)
[Scenarios \(1\)](#)
[Notes \(3\)](#)

[Add Note](#)

Type	Heading	Text	Actions
Public	Description	Ammonia is a corrosive alkaline gas at room temperature, with an acrid odor that can be detected at concentrations of 35 mg per cubic metre of air (IPCS, 1990). It is used industrially and is also associated with normal biological activity, and typical levels range from less than 25	Edit Copy Delete ↑ ↓
Public	References	International Programme on Chemical Safety (IPCS). 1990. Ammonia Health and Safety Guide. Available at: http://www.inchem.org/documents/hsg/hsg0.37.htm . Accessed Aug. 31, 2012	Edit Copy Delete ↑ ↓
Public	Context	The assumption behind inclusion of this hazard, which is not a typical food contaminant, is that a refrigeration system failed and resulted in spillage of ammonia onto package of food. This occurrence was reported in Dworkin et al., 2004. Dworkin MS, Patel A, Fennell M, Collmer M, Bailey S, Bloom...	Edit Copy Delete ↑ ↓

Quick Links: [Hazards](#)

- On the Edit Note page, make the required changes.
- Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Note

- Do one of the following:
 - Navigate to the **Notes** tab on the Risk Models page. Use the check boxes at the top of the page to select the element(s) and filter(s) to locate the note that you want to delete.
 - Navigate to the **Notes** tab for the element where you want to delete the note.
- Click the **Delete** link to the right of the note that you want to delete.
- Click **Delete**.

Copying a Note

When you are working with your own models, you have the option to copy a note.

- 1 Do one of the following:
 - Navigate to the **Notes** tab on the Risk Models page. Use the check boxes at the top of the page to select the element(s) and filter(s) to locate the note that you want to copy.
 - Navigate to the **Notes** tab for the element where you want to copy the note.
- 2 Click the **Copy** link to the right of the note that you want to copy.
- 3 On the Copy Note page, enter a new heading and if required, edit the note text.
- 4 Click **Copy**.

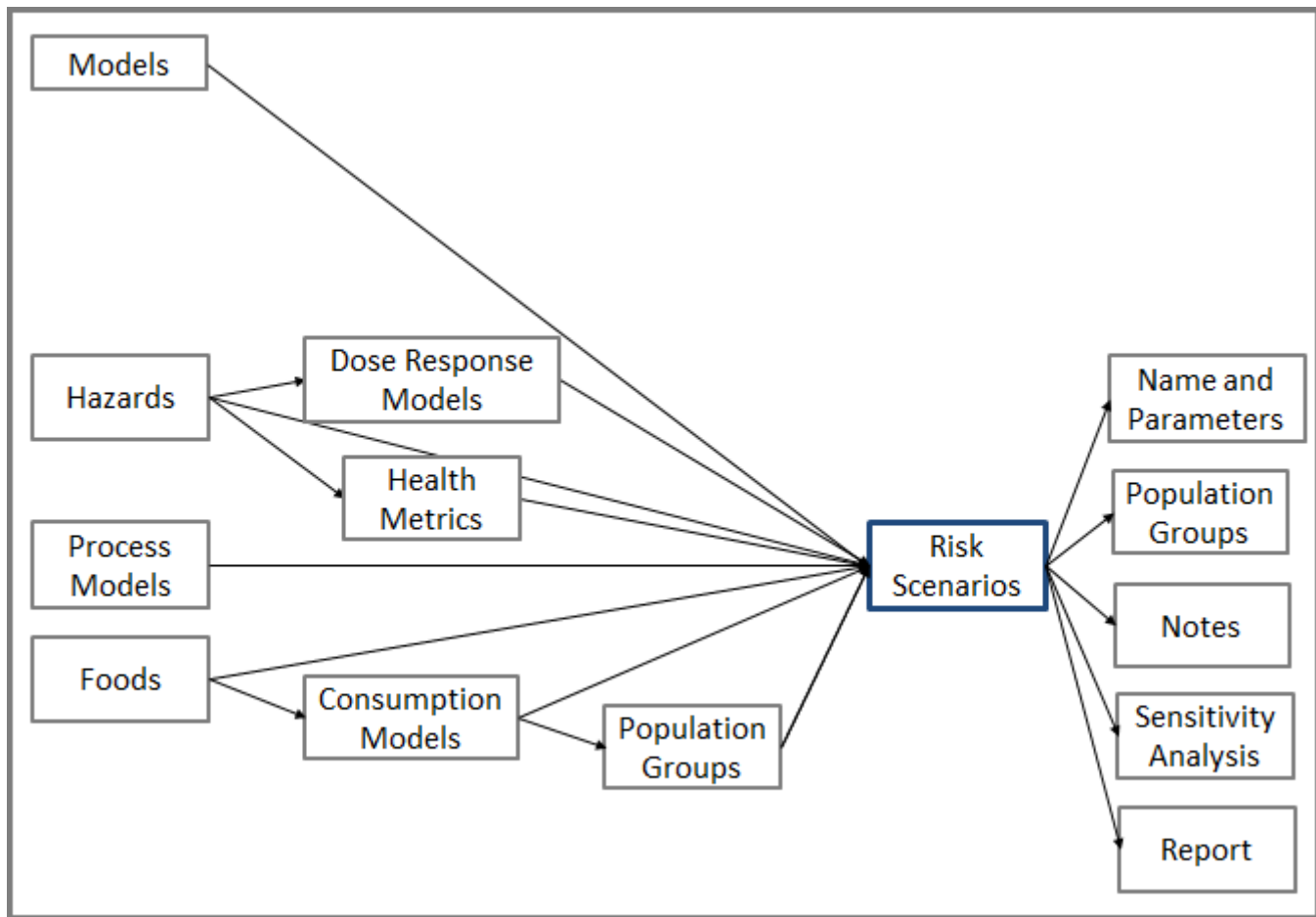
Importing a Note

Notes must be imported with their associated model element; they cannot be imported individually.

CHAPTER 7

Risk Scenarios

The following illustration shows the edit pathways for acute exposure risk scenarios in FDA-iRISK. Each arrow represents a potential one-to-many relationship:



For risk scenarios involving chronic exposures, a "full lifetime" set of life stages take the place of the population groups shown here.

Navigating to Risk Scenarios

You navigate to the risk scenarios in the following ways:

- Click the **Risk Scenarios** tab on the Risk Models page. Select a repository and click **Show Models**. A complete list of risk scenarios displays; however, you can filter the list by food or hazard. (The number on the tab, e.g. (10) indicates the number of risk scenarios.)

Home -> Risk Models (My Primary Repository) -> Risk Scenarios Tab

Risk Models

Select Repository:

Instructions Hazards (8) Foods (10) Diets (1) Process Models (7) Risk Scenarios (11) Notes

Risk Scenarios

Select a risk scenario from the list to edit or delete, or add a new risk scenario.
Computed risk scenarios must be linked to an existing food, hazard, dose response, health metric, consumption and process model. Specified risk scenarios must be linked to an existing food and hazard.

[Add Risk Scenario](#) [Validate Scenarios](#)

Filter by food: Filter by hazard:

Shared	Scenario	Validation	Actions
*	Aflatoxin B1 in Tortilla Chips (Tortilla Chips, Aflatoxin B1, DALY, Chronic, Computed)	Not Checked	Edit Copy Delete
*	Aflatoxin B1 in Tortilla Chips (Exposure Only) (Tortilla Chips, Aflatoxin B1, No Metric - Exposure Only, Chronic, Computed)	Not Checked	Edit Copy Delete
*	Ammonia in Frozen Pizza in Children (Frozen Pizza, Ammonia (refrigerant leak), DALY, Acute, Computed)	Not Checked	Edit Copy Delete
	Campylobacter spp. in Poultry (Poultry, Campylobacter, DALY, Acute, Specified)	Not Checked	Edit Copy Delete
	Enterobacteriaceae in Soft Shelled Shrimp	Not Checked	Edit Copy Delete

- To navigate to the risk scenarios associated with a particular food, click the **Foods** tab on the Risk Models page. Then, click the **Edit** link to the right of the food for which you want to access the scenarios. On the Edit Food page, click the **Risk Scenarios** tab.

Home -> Risk Models (My Primary Repository) -> Foods -> Edit Food (Frozen Pizza) -> Scenarios Tab

Edit Food

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

Instructions Name and Type Consumption Models (1) Process Models (1) Scenarios (1) Notes (0)

[Add Risk Scenario](#)

Shared	Name	Actions
*	Ammonia in Frozen Pizza in Children	Edit Copy Delete

Quick Links: [Foods](#)

- To navigate to the risk scenarios associated with a particular hazard, click the **Hazards** tab on the Risk Models page. Then, click the **Edit** link to the right of the hazard for which you want to access the risk scenarios. On the Edit Hazard page, click the **Scenarios** tab.

Home -> Risk Models (My Primary Repository) -> Hazards -> Edit Hazard (Aflatoxin B1) -> Scenarios Tab

Edit Hazard

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

Instructions | Name and Type | Dose Response (1) | Metrics (6) | Process Models (1) | Scenarios (2) | Notes (0)

[Add Risk Scenario](#)

Shared	Name	Actions
*	Aflatoxin B1 in Tortilla Chips	Edit Copy Delete
*	Aflatoxin B1 in Tortilla Chips (Exposure Only)	Edit Copy Delete

Quick Links: [Hazards](#)

Adding a Risk Scenario

Before you begin: For scenarios requiring the results to be computed by FDA-iRISK, ensure the required food(s), hazard, consumption model(s), dose response model(s), health metric(s) and process model(s) are available.

Adding a Risk Scenario, Computed (Single Food)

- Navigate to the Risk Scenarios page. See "Navigating to Risk Scenarios" on page 107.
- Click the **Add Risk Scenario** link. The Add Risk Scenario page opens.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario

Add Risk Scenario

Step 1: Enter a name for the risk scenario, and select the risk scenario type.

If results are to be computed by FDA-iRISK, ensure you have already created the required food, hazard, consumption model, dose response model, health metric and process model. For scenarios specified from external sources, ensure you have created the required food and hazard.

Note: all fields are required

Name:

Type: ☒ Computed using FDA-iRISK model for single hazard and single food
☐ Computed using FDA-iRISK model for single hazard and MULTIPLE foods
☐ Computed using FDA-iRISK model for MULTIPLE hazards and MULTIPLE foods
☐ Specified from external source for single hazard and single food

Exposure only ☐

- In the **Name** input field, enter a name for the risk scenario.

- Select the **Computed using FDA-iRISK model for single hazard and single food** option to indicate that the risk will be computed using FDA-iRISK model for a single hazard and single food.

To define a full risk scenario providing results in terms of health burden, leave the **Exposure only** check box unselected. For information about defining an "exposure-only" scenario providing results in terms of dose, see the section, "Adding a Risk Scenario, Computed (Single Food, Exposure Only)" on page 114.

- Click **Next**. The Add Risk Scenario page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Add Risk Scenario

Add Risk Scenario

Step 2: Select the process model, exposure type and metric type.

Food and Hazard will be determined from the process model selected. Exposure type is automatically set to Acute when the hazard is microbial.

A list of available supporting models is provided at the bottom of the page for the selected process model. Ensure that the required components exist before proceeding. If any required element displays "No Models" then you will not be able to complete the scenario*.

Name: Aflatoxin B1
 Type: Results Computed for Single Food
 Filter Process Models by: All
 Process Model: Aflatoxin B1 in Tortilla Chips
 Food: Tortilla Chips, Hazard: Aflatoxin B1
 Exposure Type: Acute
 Metric Type: DALY
 Previous Next Cancel

Available Models:

Health Metrics	for Acute Exposure	for Chronic Exposure
DALY <ul style="list-style-type: none"> Liver Cancer Liver Cancer (computed) Liver Cancer Imported Cost Per Illness <ul style="list-style-type: none"> Liver Cancer (COI) Liver Cancer (COI, computed) QALY <ul style="list-style-type: none"> Liver Cancer (QALY Loss) 	Consumption Models No Models* Dose Response Models No Models*	Consumption Models <ul style="list-style-type: none"> Tortilla Chip Consumption Tortilla Chip Consumption - Multifood Dose Response Models <ul style="list-style-type: none"> Linear by Slope Factor

*For example, if a DALY health metric exists but a Cost of Illness metric does not, you will not be able to create a scenario using Cost of Illness as the metric for the selected process model. You will be able to create a scenario using the DALY metric. Similarly, if an acute consumption model exists but not a chronic one, you will not be able to create a chronic exposure scenario. The same applies to dose response models.

Note: If the Available Models boxes at the bottom of the page indicate that no appropriate models exist for your risk scenario, the risk scenario cannot be defined until the missing elements are added.

- In the **Process Model** drop-down list, select the process model. The process model that you select determines which food and hazard to include in the risk scenario.
- In the **Exposure Type** drop-down list, select the exposure type that the risk scenario will evaluate. (This is fixed as Acute if the process model selected involves a microbial hazard.)

- 8 In the **Metric Type** drop-down list, select the metric that determines how the result will be expressed.
- 9 Click **Next**. The Add Risk Scenario page opens.
- 10 In the **Consumption Model** drop-down list, select the consumption model. The Consumption Model drop-down list is filtered to contain only models that match the exposure type of the scenario.
- 11 Click **Add**. The Edit Risk Scenario page opens. Either a Population Groups tab (for acute exposure scenarios) or a Life Stages tab (for chronic exposure scenarios) is displayed on the page.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> [Edit Risk Scenario \(Aflatoxin B1 in Tortilla Chips\)](#) -> [Name and Parameters Tab](#)

Edit Risk Scenario

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

Instructions	Name and Parameters	Life Stages (5/5)	Dose Responses (1/1)	Notes (0)	Sensitivity Analysis	Report
<p>Note: All fields are required</p> <p>Shared: <input checked="" type="checkbox"/></p> <p>Name: <input type="text" value="Aflatoxin B1 in Tortilla Chips"/></p> <p>Type: Results Computed</p> <p>Process Model: Aflatoxin B1 in Tortilla Chips</p> <p>Food: Tortilla Chips</p> <p>Hazard: Aflatoxin B1</p> <p>Exposure Type: Chronic</p> <p>Metric Type: DALY</p> <p>Consumption Model: Tortilla Chip Consumption</p> <p><input type="button" value="Save"/> <input type="button" value="Save and Close"/> <input type="button" value="Close"/></p> <p><small>Last Modified: 25-Sep-2014 22:05:01</small></p>						

Quick Links: [Tortilla Chips \(F\)](#) | [Aflatoxin B1 \(H\)](#) | [Aflatoxin B1 in Tortilla Chips \(PM\)](#)

Note: Messages appearing in green text on this page serve as a reminder of any remaining step(s) necessary to define the scenario.

- 12 Select the **Shared** check box to indicate that the risk scenario (and its component elements) will be shared with others whom you invite to share your repository. If you choose not to share the risk scenario, clear the **Shared** check box.
- 13 To complete this procedure, depending on the exposure type do one of the following:
 - **For chronic exposure type:** FDA-iRISK applies the selected dose response model(s) and associated health metric(s) to an entire cohort of consumers in a chronic exposure. Click the **Life Stages** tab and select the **Include** check box for each life stage from the consumption model that you want to include in the risk scenario.

Note: By default, no life stages are selected; however, the risk scenario cannot be simulated until at least one has been selected. Typically, a dose response model for a chronic hazard will assume a “lifetime exposure”. To calculate and display the total span in years covered by the selected life stages, click **Save**.

In the following example, five groups have been defined for the consumption model called “TortillaChipConsumption”. Because the groups have been defined in order to describe the (chronic)

lifetime exposure, all must be selected. The total span in years covered by the selected life stages is calculated when the Save button is clicked.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> [Edit Risk Scenario \(Aflatoxin B1 in Tortilla Chips\)](#) -> [Life Stages Tab](#)

Edit Risk Scenario

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

[Instructions](#)
[Name and Parameters](#)
[Life Stages \(5/5\)](#)
[Dose Responses \(1/1\)](#)
[Notes \(0\)](#)
[Sensitivity Analysis](#)
[Report](#)

Annual Consumers: 25E6

Life Stage	Consumption	Span In Years	Include
Adults aged 20 years and over	Fixed Value (Value: 15) g/day	57	<input checked="" type="checkbox"/>
Children aged 1 to 5 years	Fixed Value (Value: 6) g/day	5	<input checked="" type="checkbox"/>
Children aged 11 to 15	Fixed Value (Value: 13) g/day	5	<input checked="" type="checkbox"/>
Children aged 6 to 10	Fixed Value (Value: 9) g/day	5	<input checked="" type="checkbox"/>
Youth aged 16 to 20 years	Fixed Value (Value: 18) g/day	5	<input checked="" type="checkbox"/>
Total Span Included:			77

[Save](#)
[Save and Close](#)
[Close](#)

Last Modified: 25-Sep-2014 22:05:01

Quick Links: [Tortilla Chips \(F\)](#) | [Aflatoxin B1 \(H\)](#) | [Aflatoxin B1 in Tortilla Chips \(PM\)](#)

Click the **Dose Responses** tab. For each listed dose response that you want to apply in the scenario, select the health metric from the **Health Metric** drop-down list and select the **Include** check box.

Note: By default, no dose responses are selected; however, the risk scenario cannot be simulated until at least one has been selected.

Continuing the example, one dose response model has been defined for Aflatoxin B1. A health metric is selected and the check box indicates that this dose response will be applied to the risk scenario. Optionally, to measure the exceeded lifetime average daily dose (LADD), enter the LADD threshold value

(LADD Value) and LADD units. To include the result in the report, select the Include in Results check box. Save and close.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Edit Risk Scenario (Aflatoxin B1 in Tortilla Chips) -> Dose Responses Tab

Edit Risk Scenario

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

Instructions	Name and Parameters	Life Stages (5/5)	Dose Responses (1/1)	Notes (0)	Sensitivity Analysis	Report														
<table border="1"> <thead> <tr> <th>Dose Response</th> <th>Health Metric</th> <th>Include</th> </tr> </thead> <tbody> <tr> <td>Linear by Slope Factor</td> <td>Liver Cancer (computed) (19.4)</td> <td><input checked="" type="checkbox"/></td> </tr> </tbody> </table> <p>Lifetime Average Daily Dose Threshold:</p> <table border="1"> <thead> <tr> <th>Parameter</th> <th>Value</th> </tr> </thead> <tbody> <tr> <td>Include in Results:</td> <td><input type="checkbox"/></td> </tr> <tr> <td>LADD Value:</td> <td>0</td> </tr> <tr> <td>LADD Units:</td> <td>ug / g</td> </tr> </tbody> </table> <p> <input type="button" value="Save"/> <input type="button" value="Save and Close"/> <input type="button" value="Close"/> </p> <p><small>Last Modified: 25-Sep-2014 22:05:01</small></p>							Dose Response	Health Metric	Include	Linear by Slope Factor	Liver Cancer (computed) (19.4)	<input checked="" type="checkbox"/>	Parameter	Value	Include in Results:	<input type="checkbox"/>	LADD Value:	0	LADD Units:	ug / g
Dose Response	Health Metric	Include																		
Linear by Slope Factor	Liver Cancer (computed) (19.4)	<input checked="" type="checkbox"/>																		
Parameter	Value																			
Include in Results:	<input type="checkbox"/>																			
LADD Value:	0																			
LADD Units:	ug / g																			

Quick Links: [Tortilla Chips \(E\)](#) | [Aflatoxin B1 \(H\)](#) | [Aflatoxin B1 in Tortilla Chips \(PM\)](#)

- **For acute exposure type:** Whereas FDA-iRISK applies selected the dose response models and associated health metrics to an entire cohort of consumers in a chronic exposure, you can customize these definitions for each population group in an acute exposure scenario. Click the **Population Groups** tab and select the **Include in Analysis** check box for each population group that you want to include in the risk scenario. For each population group select the appropriate dose response model and health metric from the respective drop-down list.

In the following example, three population groups have been defined based on differences in probability (Dose Response Models) and severity (Health Metrics) of illness caused by exposure to the hazard. The three groups are designed to collectively represent the population at risk (i.e. they are mutually exclusive);

therefore, they should all be included in the risk scenario to compute the burden for each group as it contributes to the total population burden (i.e. the Include in Analysis check box is selected for all three).

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Edit Risk Scenario (L. monocytogenes in soft ripened cheese) -> Population Groups Tab

Edit Risk Scenario

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

Population Group	Consumption	Dose Response & Health Metric Model	Include in Analysis
Adults 60+	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eq; 1.8E+08 eq/yr	Dose Response: Adults 60+ DR Health Metric: Adults 60+ DALY (2.6)	<input checked="" type="checkbox"/>
Intermediate Aged (5-59)	Triangular (Minimum: 10, Mode: 28, Maximum: 168) g/eq; 1.7E+09 eq/yr	Dose Response: Intermediate Aged (5-59) DR Health Metric: Intermediate Aged (5-59) DALY (5.0)	<input checked="" type="checkbox"/>
Perinatal	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eq; 1.2E+07 eq/yr	Dose Response: Perinatal DR Health Metric: Perinatal DALY (14)	<input checked="" type="checkbox"/>

[Save](#) [Save and Close](#) [Close](#)

Last Modified: 11-Dec-2013 16:00:05

Quick Links: [Soft Ripened Cheese \(F\)](#) | [L. monocytogenes \(H\)](#) | [L. monocytogenes in soft ripened cheese \(PM\)](#)

More typically, a single population group (e.g., "General Population") is defined for an acute exposure risk scenario, as shown below. The dose response model and health metric must still be selected to ensure the models applied are valid for the population group named.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Edit Risk Scenario (Salmonella in peanut butter) -> Population Groups Tab

Edit Risk Scenario

Issues detected for this scenario. Please check the following:
Error: Dose response model uncertainty invalid [Edit Salmonella Beta-Poisson DR](#)

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

Population Group	Consumption	Dose Response & Health Metric Model	Include in Analysis
General Population	Fixed Value (Value: 30) g/eq; 1.7E10 eq/yr	Dose Response: Salmonella Beta-Poisson DR Health Metric: Salmonella DALY (0.019)	<input checked="" type="checkbox"/>

[Save](#) [Save and Close](#) [Close](#)

Last Modified: 16-Dec-2013 12:07:09

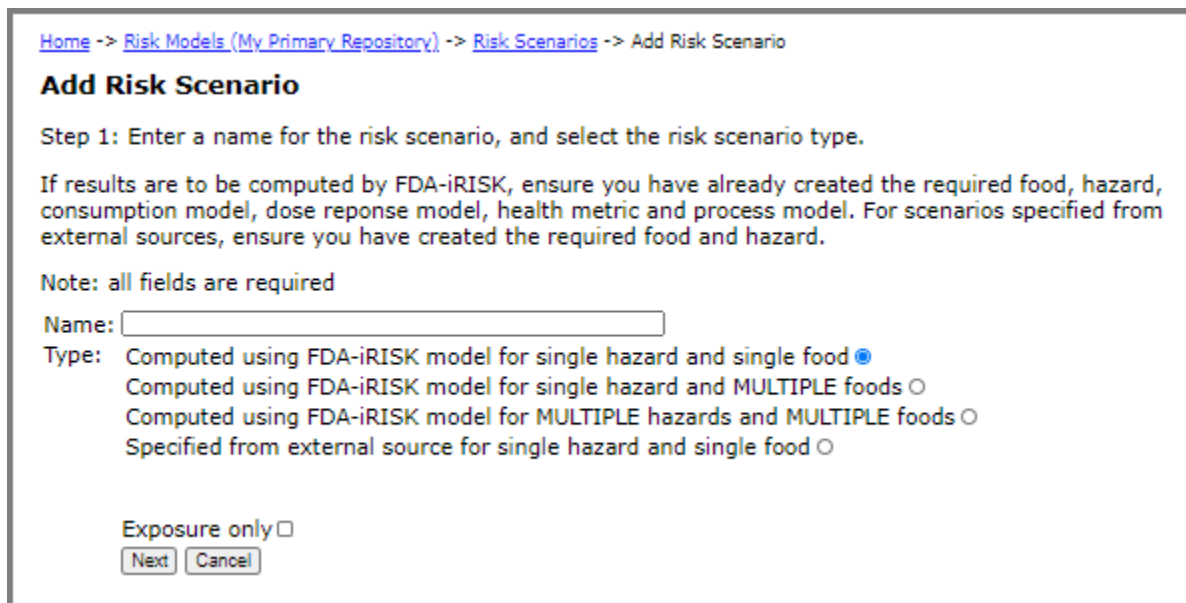
Quick Links: [Peanut Butter \(F\)](#) | [Salmonella \(H\)](#) | [Salmonella in Peanut Butter \(PM\)](#)

14 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

Adding a Risk Scenario, Computed (Single Food, Exposure Only)

- 1 Navigate to the Risk Scenarios page. See "Navigating to Risk Scenarios" on page 107.
- 2 Click the **Add Risk Scenario** link. The Add Risk Scenario page opens.



The screenshot shows a web browser window with the breadcrumb path: Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario. The page title is "Add Risk Scenario". Below the title, it says "Step 1: Enter a name for the risk scenario, and select the risk scenario type." A paragraph of instructions follows: "If results are to be computed by FDA-iRISK, ensure you have already created the required food, hazard, consumption model, dose response model, health metric and process model. For scenarios specified from external sources, ensure you have created the required food and hazard." A note states "Note: all fields are required". There is a "Name:" label followed by a text input field. Below that, the "Type:" label is followed by four radio button options: "Computed using FDA-iRISK model for single hazard and single food" (which is selected), "Computed using FDA-iRISK model for single hazard and MULTIPLE foods", "Computed using FDA-iRISK model for MULTIPLE hazards and MULTIPLE foods", and "Specified from external source for single hazard and single food". At the bottom, there is an "Exposure only" checkbox and two buttons labeled "Next" and "Cancel".

- 3 In the **Name** input field, enter a name for the risk scenario.
- 4 Select the **Computed using FDA-iRISK model for single hazard and single food** option to indicate that the risk will be computed using FDA-iRISK model for a single hazard and single food.
- 5 Select the **Exposure only** check box.

- 6 Click **Next**. The Add Risk Scenario page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Add Risk Scenario

Add Risk Scenario

Step 2: Select the process model, exposure type and metric type.

Food and Hazard will be determined from the process model selected. Exposure type is automatically set to Acute when the hazard is microbial.

A list of available supporting models is provided at the bottom of the page for the selected process model. Ensure that the required components exist before proceeding. If any required element displays "No Models" then you will not be able to complete the scenario*.

Name: Aflatoxin B1 in Tortilla Chips
 Type: Results Computed for Single Food (Exposure Only)

Filter Process Models by:

Process Model:
 Food: Tortilla Chips, Hazard: Aflatoxin B1

Exposure Type:

Available Models:

for Acute Exposure	for Chronic Exposure
Consumption Models No Models*	Consumption Models <ul style="list-style-type: none"> Tortilla Chip Consumption Tortilla Chip Consumption - Multifood

*For example, if a DALY health metric exists but a Cost of Illness metric does not, you will not be able to create a scenario using Cost of Illness as the metric for the selected process model. You will be able to create a scenario using the DALY metric. Similarly, if an acute consumption model exists but not a chronic one, you will not be able to create a chronic exposure scenario. The same applies to dose response models.

Note: If the Available Models boxes at the bottom of the page indicate that no appropriate models exist for your risk scenario, the risk scenario cannot be defined until the missing elements are added.

- 7 In the **Process Model** drop-down list, select the process model. The process model that you select determines which food and hazard to include in the risk scenario.
- 8 In the **Exposure Type** drop-down list, select the exposure type that the risk scenario will evaluate. Notice that the Metric Type does not appear on this page as it is not required for exposure only scenarios.

- 9 Click **Next**. The Add Risk Scenario page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Add Risk Scenario

Add Risk Scenario

Step 3: Select consumption model.

Name: Aflatoxin B1 in Tortilla Chips
 Type: Results Computed For Single Food (Exposure Only)
 Process Model: Aflatoxin B1 in Tortilla Chips
 Food: Tortilla Chips
 Hazard: Aflatoxin B1
 Exposure Type: Chronic
 Consumption Model: Tortilla Chip Consumption ▼

[Previous](#) [Add](#) [Cancel](#)

- 10 In the **Consumption Model** drop-down list, select the consumption model. The Consumption Model drop-down list is filtered to contain only models that match the exposure type of the scenario.
- 11 Click **Add**. The Edit Risk Scenario page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Edit Risk Scenario (Aflatoxin B1 in Tortilla Chips (Exposure Only)) -> Name and Parameters Tab

Edit Risk Scenario

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

[Instructions](#) [Name and Parameters](#) [Life Stages \(5/5\)](#) [Notes \(0\)](#) [Sensitivity Analysis](#) [Report](#)

Note: All fields are required

Shared: ☒

Name: Aflatoxin B1 in Tortilla Chips (Exposure Only)

Type: Results Computed (Exposure Only)

Process Model: Aflatoxin B1 in Tortilla Chips

Food: Tortilla Chips

Hazard: Aflatoxin B1

Exposure Type: Chronic

Metric Type: N/A (Exposure only)

Consumption Model: Tortilla Chip Consumption

[Save](#) [Save and Close](#) [Close](#)

Last Modified: 26-Sep-2014 09:39:11

Quick Links: [Tortilla Chips \(F\)](#) | [Aflatoxin B1 \(H\)](#) | [Aflatoxin B1 in Tortilla Chips \(PM\)](#)

Note: Messages appearing in green text on this page serve as a reminder of any remaining step(s) necessary to define the scenario.

- 12 To indicate that the risk scenario and its component elements will be shared with others whom you invite, to share your scenario, select the **Shared** check box.

13 To complete this procedure, do one of the following:

- **For chronic exposure type:** Click the **Life Stages** tab and select the **Include** check box for each life stage from the consumption model that you want to include in the risk scenario.

Note: By default, no life stages are selected; however, the risk scenario cannot be simulated until at least one has been selected.

To calculate and display the total span in years covered by the selected life stages, click **Save**.

In the following example, five groups have been defined for the consumption model. Because the groups have been defined in order to describe the (chronic) lifetime exposure, all must be selected. The total span in years covered by the selected life stages is calculated when the **Save** button is clicked.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (Aflatoxin B1 in Tortilla Chips (Exposure Only)) -> Life Stages Tab

Edit Risk Scenario

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

Life Stage	Consumption	Span In Years	Include
Adults aged 20 years and over	Fixed Value (Value: 15) g/day	57	<input checked="" type="checkbox"/>
Children aged 1 to 5 years	Fixed Value (Value: 6) g/day	5	<input checked="" type="checkbox"/>
Children aged 11 to 15	Fixed Value (Value: 13) g/day	5	<input checked="" type="checkbox"/>
Children aged 6 to 10	Fixed Value (Value: 9) g/day	5	<input checked="" type="checkbox"/>
Youth aged 16 to 20 years	Fixed Value (Value: 18) g/day	5	<input checked="" type="checkbox"/>
Total Span Included:			77

Annual Consumers: 25E6

Save Save and Close Close

Last Modified: 26-Sep-2014 09:39:11

Quick Links: [Tortilla Chips \(E\)](#) | [Aflatoxin B1 \(H\)](#) | [Aflatoxin B1 in Tortilla Chips \(PM\)](#)

- **For acute exposure type:** Click the **Population Groups** tab and select the **Include in Analysis** check box for each population group that you want to include in the risk scenario.

In the following example, three population groups have been defined because of differences in probability (Dose Response Models) and severity (Health Metrics) of illness, even though these will not be used in the exposure only model. The three groups are designed to collectively represent the population at risk (i.e.

they are mutually exclusive); therefore, they should all be included in the risk scenario to compute the exposure for each group (i.e. The **Include in Analysis** check box is selected for all three).

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (L. monocytogenes in soft ripened cheese (Exposure Only)) -> Population Groups Tab

Edit Risk Scenario

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

Population Group	Consumption	Include in Analysis
Adults 60+	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eq; 1.8E+08 eq/yr	<input checked="" type="checkbox"/>
Intermediate Aged (5-59)	Triangular (Minimum: 10, Mode: 28, Maximum: 168) g/eq; 1.7E+09 eq/yr	<input checked="" type="checkbox"/>
Perinatal	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eq; 1.2E+07 eq/yr	<input checked="" type="checkbox"/>

Save Save and Close Close

Last Modified: 26-Sep-2014 10:28:13

Quick Links: [Soft Ripened Cheese \(F\)](#) | [L. monocytogenes \(H\)](#) | [L. monocytogenes in soft ripened cheese \(PM\)](#)

14 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

Adding a Risk Scenario, Computed (Multifood)

- 1 Navigate to the Risk Scenarios page. See "Navigating to Risk Scenarios" on page 107.
- 2 Click the **Add Risk Scenario** link. The Add Risk Scenario, Step 1 page opens.
- 3 In the **Name** input field, enter a name for the risk scenario.
- 4 Select the **Computed using FDA-iRISK model for single hazard and MULTIPLE foods** option to indicate that the risk will be computed using FDA-iRISK model for a single hazard and multiple foods.

- 5 Click **Next**. The Add Risk Scenario, Step 2 page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Add Risk Scenario

Add Risk Scenario

Step 2: Select the hazard and metric type, then click Next.

Exposure type is automatically set to Chronic for multifood scenarios.

Note, the hazard must be associated with process models for foods that already have multifood consumption models defined.

Name: Ochratoxin A from Oats, Rice and Raisins
 Type: Results Computed for Multiple Foods

Hazard:
 Exposure Type: Chronic
 Metric Type:

- 6 In the **Hazard** drop-down list, select the hazard. Note that only hazards associated with process models that have foods that have multifood consumption models appear in the list.
- 7 In the **Metric Type** drop-down list, select the metric that determines how the result will be expressed.
- 8 Click **Next**. The Add Risk Scenario, Step 3 page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Add Risk Scenario

Add Risk Scenario

Step 3: Select the process models for the foods to include in the scenario, then click Next.

Exposure type is automatically set to Chronic for multifood scenarios.

Note, only process models for the selected hazard and for foods that already have multifood consumption models defined are shown.

Name: Ochratoxin A from Oats, Rice and Raisins
 Type: Results Computed for Multiple Foods

Hazard: Ochratoxin A
 Exposure Type: Chronic
 Metric Type: DALY

Process Models: ☐ OTA in Oats
☐ OTA in Raisins
☐ OTA in Rice

- 9 Select the process models for the foods to include in the scenario. Only process models for the selected hazard and that have multifood consumption models defined are provided as options.

- 10 Click **Add**. The Edit Chronic Multifood Risk Scenario page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Edit Risk Scenario (Ochratoxin A from Oats, Rice and Raisins) -> Name and Parameters Tab

Edit Chronic Multifood Risk Scenario

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

[Instructions](#)
[Name and Parameters](#)
[Consumption Models \(3/3\)](#)
[Dose Responses \(1/1\)](#)
[Diets](#)
[Notes \(0\)](#)
[Sensitivity Analysis](#)
[Report](#)

Note: All fields are required

Shared: ☐

Name:

Type: Results Computed Multifood

Hazard: Ochratoxin A

Process Models: OTA in Oats, OTA in Raisins , OTA in Rice

Foods: Oats, Raisins, Rice

Exposure Type: Chronic

Metric Type: DALY

Last Modified: 26-Sep-2014 10:42:06

Quick Links: [Ochratoxin A \(H\)](#) | [Food \(Oats\)](#) | [Food \(Raisins\)](#) | [Food \(Rice\)](#) | [Process Model \(OTA in Oats\)](#) | [Process Model \(OTA in Raisins\)](#) | [Process Model \(OTA in Rice\)](#)

Note: Messages appearing in green text on this page serve as a reminder of any remaining step(s) necessary to define the scenario.

- 11 On the Edit Chronic Multifood Risk Scenario page, select the **Shared** check box to indicate that the risk scenario (and its component elements) will be shared with others whom you invite to share your repository. If you choose not to share the risk scenario, clear the **Shared** check box.
- 12 Click the **Consumption Models** tab and do the following:
- Enter the number of annual consumers to apply to every food. The same cohort size is applied to each food.
 - Enter the percentage of the population that is female. The percentage of the population that is male is computed from this value.

- Select the consumption models to include in the scenario by clicking the **Include** check box to the right of the name. Note that at least one must be selected in order for the scenario to be simulated.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (Ochratoxin A from Oats, Rice and Raisins) -> Consumption Models Tab

Edit Chronic Multifood Risk Scenario

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

[Instructions](#)
[Name and Parameters](#)
[Consumption Models \(3/3\)](#)
[Dose Responses \(1/1\)](#)
[Diets](#)
[Notes \(0\)](#)
[Sensitivity Analysis](#)
[Report](#)

Annual Consumers:

% Female:

% Male: 50

Select which consumption models to use for each food.

Food	Consumption Model	Life Stage	Include
Oats	Oats (Multifood)	1 year olds, both genders	<input checked="" type="checkbox"/>
		2 - 8 year olds, both genders	
		61 - 85, both genders	
		9 - 60 year olds, both genders	
Raisins	Raisins (Multifood)	1 - 8 years, both genders	<input checked="" type="checkbox"/>
		26 - 55 years, both genders	
		56 - 85, both genders	
		9 - 25 years, both genders	
Rice	Rice (Multifood)	1 year olds, both genders	<input checked="" type="checkbox"/>
		18 - 55 year olds, both genders	
		2 - 8 year olds, both genders	
		56 - 85 year olds, both genders	
		9 - 17 year olds, both genders	

Last Modified: 26-Sep-2014 10:42:06

Quick Links: [Ochratoxin A \(H\)](#) | [Food \(Oats\)](#) | [Food \(Raisins\)](#) | [Food \(Rice\)](#) | [Process Model \(OTA in Oats\)](#) | [Process Model \(OTA in Raisins\)](#) | [Process Model \(OTA in Rice\)](#)

13 Click the **Dose Response** tab and do the following

- Select the dose response models associated with the hazard that you want to apply to the scenario. By default, none are selected and the scenario cannot be simulated until at least one is selected.
- From the drop-down lists, select the health metric for each selected dose response. Click the **Include** check box to the right of the dose response model.

Note: The counts on both tabs indicate how many elements are currently selected from the total available. For a new scenario, the number is zero.

14 Click the **Diets** tab and do the following:

- Select the diet from the drop-down list and then click **Update**.
- Select the diet shifts to include.

15 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

Adding a Risk Scenario, Computed (Multifood, Exposure Only)

- 1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.
- 2 Click the **Add Risk Scenario** link. The Add Risk Scenario Step, 1 page opens.
- 3 In the **Name** input field, enter a name for the risk scenario.
- 4 Select the **Computed using FDA-iRISK model for single hazard and MULTIPLE foods** option to indicate that the risk will be computed using FDA-iRISK model for a single hazard and multiple foods.
- 5 Select the **Exposure only** check box.
- 6 Click **Next**. The Add Risk Scenario, Step 2 page opens.
- 7 In the **Hazard** drop-down list, select the hazard. Note that only hazards associated with process models that have foods that have chronic multifood consumption models appear in the list.
- 8 Click **Next**. The Add Risk Scenario, Step 3 page opens.
- 9 Select the process models for the foods to include in the scenario. Only process models for the selected hazard and that have multifood consumption models defined are provided as options. For information about adding a multifood consumption model, see the section, *"Adding a Consumption Model, Chronic Multifood Exposure" on page 56*.
- 10 Click **Add**. The Edit Chronic Multifood Risk Scenario page opens.

Note: Messages appearing in green text on this page serve as a reminder of any remaining step(s) necessary to define the scenario.
- 11 On the Edit Chronic Multifood Risk Scenario page, select the **Shared** check box to indicate that the risk scenario (and its component elements) will be shared with others whom you invite to share your scenario. If you choose not to share the risk scenario, clear the **Shared** check box.
- 12 Click the **Consumption Models** tab and do the following:
 - Enter the number of annual consumers to apply to every food. The same cohort size is applied to each food.
 - Enter the percentage of the population that is female. The percentage of the population that is male is computed from this value.
 - Select the consumption models to include in the scenario by clicking the **Include** check box to the right of the name. Note that at least one must be selected in order for the scenario to be simulated.

Note: The count on this tab indicates how many elements are currently selected from the total available. For a new scenario, it is zero.
- 13 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Adding a Risk Scenario, Computed (Multiple Hazards and Multiple Foods)

- 1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.

- 2 Click the **Add Risk Scenario** link. The Add Risk Scenario, Step 1 page opens.
- 3 In the **Name** input field, enter a name for the risk scenario.
- 4 Select the **Computed using FDA-iRISK model for MULTIPLE hazards and MULTIPLE foods** option to indicate that the risk will be computed using FDA-iRISK model for multiple hazards and multiple foods.
- 5 Click **Next**. The Add Risk Scenario, Step 2 page opens.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario

Add Risk Scenario

Step 2: Select the metric type and process models to include in the scenario, then click Next.

Exposure type is automatically set to Chronic for multifood scenarios.

Note, only process models for chronic hazards and for foods that already have multifood consumption models defined are shown. The hazard(s) must also have at least one chronic dose response model and one health metric defined.

Name: MultiHazard Multifood Assessment

Type: Results Computed for Multiple Hazards and Multiple Foods

Exposure Type: Chronic

Metric Type:

Process Models: ☐ Aflatoxin B1 in Tortilla Chips
☐ OTA in Oats
☐ OTA in Raisins
☐ OTA in Rice

- 6 In the **Metric Type** drop-down list, select the metric that determines how the result will be expressed.
- 7 Select the process models to include in the scenario. Only process models for chronic hazards and for foods that include multifood consumption models defined are shown. For information about adding a multifood consumption model, see the section, *"Adding a Consumption Model, Chronic Multifood Exposure"* on page 56.

- 8 Click **Add**. The Edit Chronic Multihazard Risk Scenario page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Edit Risk Scenario (MultiHazard Multifood Assessment) -> Name and Parameters Tab

Edit Chronic Multihazard Risk Scenario

Issues detected for this scenario. Please check the following:
 Error: No consumption model selected for food Oats
 Error: No consumption model selected for food Raisins
 Error: No consumption model selected for food Rice
 Error: No hazard dose response model selected for hazard Ochratoxin A
 Error: Annual consumers = 0

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

Instructions	Name and Parameters	Consumption Models (0/3)	Dose Responses (0/1)	Process Models (3/3)	Diets	Notes (0)	Report
<p>Note: All fields are required</p> <p>Shared: <input type="checkbox"/></p> <p>Name: <input type="text" value="MultiHazard Multifood Assessment"/></p> <p>Type: Results Computed Multihazard</p> <p>Process Models: OTA in Oats, OTA in Raisins , OTA in Rice</p> <p>Foods: Oats, Raisins, Rice</p> <p>Hazards: Ochratoxin A</p> <p>Exposure Type: Chronic</p> <p>Metric Type: DALY</p> <p><input type="button" value="Save"/> <input type="button" value="Save and Close"/> <input type="button" value="Close"/></p> <p><small>Last Modified: 30-Aug-2019 11:04:36</small></p>							

Quick Links: [Food \(Oats\)](#) | [Food \(Raisins\)](#) | [Food \(Rice\)](#) | [Hazard \(Ochratoxin A\)](#) | [Process Model \(OTA in Oats\)](#) | [Process Model \(OTA in Raisins\)](#) | [Process Model \(OTA in Rice\)](#)

Note: Messages appearing in green text on this page serve as a reminder of any remaining step(s) necessary to define the scenario.

- 9 On the Edit Chronic Multihazard Risk Scenario page, select the **Shared** check box to indicate that the risk scenario (and its component elements) will be shared with others whom you invite to share your repository. If you choose not to share the risk scenario, clear the **Shared** check box.
- 10 Click the **Consumption Models** tab and do the following:
 - Enter the number of annual consumers to apply to every food. The same cohort size is applied to each food.
 - Enter the percentage of the population that is female. The percentage of the population that is male is computed from this value.

- Select the consumption models to include in the scenario by clicking the **Include** check box to the right of the name. Note that at least one must be selected in order for the scenario to be simulated.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> [Edit Risk Scenario \(MultHazard Multifood Assessment\)](#) -> [Consumption Models Tab](#)

Edit Chronic Multihazard Risk Scenario

Issues detected for this scenario. Please check the following:
 Error: No consumption model selected for food Oats
 Error: No consumption model selected for food Raisins
 Error: No consumption model selected for food Rice
 Error: No hazard dose response model selected for hazard Ochratoxin A
 Error: Annual consumers = 0

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

Instructions	Name and Parameters	Consumption Models (0/3)	Dose Responses (0/1)	Process Models (3/3)	Diets	Notes (0)	Report																																				
<p>Annual Consumers: <input type="text" value="0"/></p> <p>% Female: <input type="text" value="50"/></p> <p>% Male: <input type="text" value="50"/></p> <p>Select which consumption models to use for each food.</p> <table border="1"> <thead> <tr> <th>Food</th> <th>Consumption Model</th> <th>Life Stage</th> <th>Include</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Oats</td> <td rowspan="4">Oats (Multifood)</td> <td>1 year olds, both genders</td> <td><input type="checkbox"/></td> </tr> <tr> <td>2 - 8 year olds, both genders</td> <td></td> </tr> <tr> <td>61 - 85, both genders</td> <td></td> </tr> <tr> <td>9 - 60 year olds, both genders</td> <td></td> </tr> <tr> <td rowspan="4">Raisins</td> <td rowspan="4">Raisins (Multifood)</td> <td>1 - 8 years, both genders</td> <td><input type="checkbox"/></td> </tr> <tr> <td>26 - 55 years, both genders</td> <td></td> </tr> <tr> <td>56 - 85, both genders</td> <td></td> </tr> <tr> <td>9 - 25 years, both genders</td> <td></td> </tr> <tr> <td rowspan="5">Rice</td> <td rowspan="5">Rice (Multifood)</td> <td>1 year olds, both genders</td> <td><input type="checkbox"/></td> </tr> <tr> <td>18 - 55 year olds, both genders</td> <td></td> </tr> <tr> <td>2 - 8 year olds, both genders</td> <td></td> </tr> <tr> <td>56 - 85 year olds, both genders</td> <td></td> </tr> <tr> <td>9 - 17 year olds, both genders</td> <td></td> </tr> </tbody> </table> <p><input type="button" value="Save"/> <input type="button" value="Save and Close"/> <input type="button" value="Close"/></p> <p>Last Modified: 30-Aug-2019 11:04:36</p> <p>Quick Links: Food (Oats) Food (Raisins) Food (Rice) Hazard (Ochratoxin A) Process Model (OTA in Oats) Process Model (OTA in Raisins) Process Model (OTA in Rice)</p>								Food	Consumption Model	Life Stage	Include	Oats	Oats (Multifood)	1 year olds, both genders	<input type="checkbox"/>	2 - 8 year olds, both genders		61 - 85, both genders		9 - 60 year olds, both genders		Raisins	Raisins (Multifood)	1 - 8 years, both genders	<input type="checkbox"/>	26 - 55 years, both genders		56 - 85, both genders		9 - 25 years, both genders		Rice	Rice (Multifood)	1 year olds, both genders	<input type="checkbox"/>	18 - 55 year olds, both genders		2 - 8 year olds, both genders		56 - 85 year olds, both genders		9 - 17 year olds, both genders	
Food	Consumption Model	Life Stage	Include																																								
Oats	Oats (Multifood)	1 year olds, both genders	<input type="checkbox"/>																																								
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		9 - 17 year olds, both genders																																									

11 Click the **Dose Response** tab and do the following

- Select the dose response models associated with the hazard that you want to apply to the scenario. By default, none are selected and the scenario cannot be simulated until at least one is selected.
- From the drop-down lists, select the health metric for each selected dose response. Click the Include check box to the right of the dose response model.

Note: The counts on both tabs indicate how many elements are currently selected from the total available. For a new scenario, the number is zero.

12 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.

- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

Adding a Risk Scenario, Specified

- 1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.
- 2 Click the **Add Risk Scenario** link. The Add Risk Scenario page opens.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario

Add Risk Scenario

Step 1: Enter a name for the risk scenario, and select the risk scenario type.

If results are to be computed by FDA-iRISK, ensure you have already created the required food, hazard, consumption model, dose response model, health metric and process model. For scenarios specified from external sources, ensure you have created the required food and hazard.

Note: all fields are required

Name:

Type:
 Computed using FDA-iRISK model for single hazard and single food ☒
 Computed using FDA-iRISK model for single hazard and MULTIPLE foods ☐
 Computed using FDA-iRISK model for MULTIPLE hazards and MULTIPLE foods ☐
 Specified from external source for single hazard and single food ☐

Exposure only ☐

- 3 In the **Name** input field, enter a name for the risk scenario.
- 4 Select the **Specified from external source for single hazard and single food** option.
- 5 Click **Next**. The Add Risk Scenario page opens.
- 6 Select the food and hazard from the drop-down lists.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario

Add Risk Scenario

Step 2: Select food and hazard.

Name: Campylobacter spp. in Poultry

Type: Results Specified for Single Food

Food:

Hazard:

- 7 Click **Next**. The Add Risk Scenario page opens.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Add Risk Scenario

Add Risk Scenario

Step 3: Select exposure type.

Name: Campylobacter spp. in Poultry
 Type: Results Specified For Single Food
 Food: Poultry
 Hazard: Campylobacter
 Exposure Type: Acute
 Health Metric Type: DALY

- 8 Click **Add**.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Risk Scenarios](#) -> Edit Risk Scenario (Campylobacter spp. in Poultry) -> Name and Parameters Tab

Edit Risk Scenario

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

Instructions | Name and Parameters | Notes (0) | Report

Note: All fields are required

Shared: ☐

Name: Campylobacter spp. in Poultry

Type: Results Specified

Food: Poultry

Hazard: Campylobacter

Exposure Type: Acute

Mean Exposure: 0 cfu

Number of cases: 0

Health Metric: 0 DALY per case

Total DALY: 0.00

Last Modified: 11-Dec-2013 12:24:45

Quick Links: [Poultry \(F\)](#) | [Campylobacter \(H\)](#)

- 9 Select the **Shared** check box to indicate that the risk scenario and its components will be shared with others whom you invite to share your repository.
- 10 In the **Mean Exposure** input field, enter the value for the mean exposure.
- 11 In the **Number of cases** input field, enter the value for the number of cases.
- 12 In the **Health Metric** input field, enter the value for the health metric for DALY per Case (or Cost per Illness or QALY Loss, if one of those metric types were chosen).

- 13 To calculate and display one of the following, click **Save**.
 - The total DALY incurred according to the entered values for incidence and burden per case.
 - The total cost incurred if the entered values refer to incidence and cost per illness.
 - The total QALY loss incurred according to the entered values for incidence and QALY loss per case.
- 14 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Adding a Risk Scenario, Specified (Exposure -Only, Microbial)

- 1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.
- 2 Click the **Add Risk Scenario** link. The Add Risk Scenario page opens.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario

Add Risk Scenario

Step 1: Enter a name for the risk scenario, and select the risk scenario type.

If results are to be computed by FDA-iRISK, ensure you have already created the required food, hazard, consumption model, dose response model, health metric and process model. For scenarios specified from external sources, ensure you have created the required food and hazard.

Note: all fields are required

Name:

Type:
 Computed using FDA-iRISK model for single hazard and single food ☒
 Computed using FDA-iRISK model for single hazard and MULTIPLE foods ☐
 Computed using FDA-iRISK model for MULTIPLE hazards and MULTIPLE foods ☐
 Specified from external source for single hazard and single food ☐

Exposure only ☐

- 3 In the **Name** input field, enter a name for the risk scenario.
- 4 Select the **Specified from external source for single hazard and single food** option.
- 5 Select the **Exposure only** check box.
- 6 Click **Next**. The Add Risk Scenario page opens.

- 7 Select the food and hazard from the drop-down lists.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario

Add Risk Scenario

Step 2: Select food and hazard.

Name: Campylobacter spp. in Poultry

Type: Results Specified for Single Food

Food: Poultry

Hazard: Campylobacter

Previous Next Cancel

- 8 Click **Next**. The Add Risk Scenario page opens.
- 9 Click **Add**.
- 10 In the **Mean Exposure** field, enter the mean exposure in the units of the hazard.
- 11 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Adding a Risk Scenario, Specified (Exposure - Only, Chemical)

- 1 Navigate to the Risk Scenarios page. See "Navigating to Risk Scenarios" on page 107.
- 2 Click the **Add Risk Scenario** link. The Add Risk Scenario page opens.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Add Risk Scenario

Add Risk Scenario

Step 1: Enter a name for the risk scenario, and select the risk scenario type.

If results are to be computed by FDA-iRISK, ensure you have already created the required food, hazard, consumption model, dose response model, health metric and process model. For scenarios specified from external sources, ensure you have created the required food and hazard.

Note: all fields are required

Name:

Type:

Computed using FDA-iRISK model for single hazard and single food ☒

Computed using FDA-iRISK model for single hazard and MULTIPLE foods ☐

Computed using FDA-iRISK model for MULTIPLE hazards and MULTIPLE foods ☐

Specified from external source for single hazard and single food ☐

Exposure only ☐

Next Cancel

- 3 In the **Name** input field, enter a name for the risk scenario.

- 4 Select the **Specified from external source for single hazard and single food** option.
- 5 Select the **Exposure only** check box.
- 6 Click **Next**. The Add Risk Scenario page opens.
- 7 Select the food and hazard from the drop-down lists.
- 8 Click **Next**. The Add Risk Scenario page opens.
- 9 In the **Exposure Type** drop-down list, select **Acute** or **Chronic**.
- 10 Click **Add**.
- 11 In the **Mean Exposure** field, enter the mean exposure and, if required, select the units.
- 12 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Editing a Risk Scenario

- 1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.

- On the **Risk Scenarios** tab, click the **Edit** link to the right of the risk scenario that you want to edit.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios Tab

Risk Models

Select Repository:

Instructions Hazards (8) Foods (10) Diets (1) Process Models (7) **Risk Scenarios (11)** Notes

Risk Scenarios

Select a risk scenario from the list to edit or delete, or add a new risk scenario.
Computed risk scenarios must be linked to an existing food, hazard, dose response, health metric, consumption and process model. Specified risk scenarios must be linked to an existing food and hazard.

[Add Risk Scenario](#) [Validate Scenarios](#)

Filter by food: Filter by hazard:

Shared	Scenario	Validation	Actions
*	Aflatoxin B1 in Tortilla Chips (Tortilla Chips, Aflatoxin B1, DALY, Chronic, Computed)	Not Checked	Edit Copy Delete
*	Aflatoxin B1 in Tortilla Chips (Exposure Only) (Tortilla Chips, Aflatoxin B1, No Metric - Exposure Only, Chronic, Computed)	Not Checked	Edit Copy Delete
*	Ammonia in Frozen Pizza in Children (Frozen Pizza, Ammonia (refrigerant leak), DALY, Acute, Computed)	Not Checked	Edit Copy Delete
	Campylobacter spp. in Poultry (Poultry, Campylobacter, DALY, Acute, Specified)	Not Checked	Edit Copy Delete
	L. monocytogenes in soft ripened cheese	Not	Edit Copy Delete

- Make the required changes. For more information about which elements may be edited see "Adding a Risk Scenario" on page 108.
- Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Risk Scenario

Deleting a scenario does not delete any of the component models used in its creation.

- Navigate to the Risk Scenarios page. See "Navigating to Risk Scenarios" on page 107.
- On the **Risk Scenarios** tab, click the **Delete** link to the right of the risk scenario that you want to delete.
- On the Delete Risk Scenario page, click **Delete**.

Copying a Risk Scenario

When you are working with your own models, you have the option to copy a risk scenario. When you copy a risk scenario, its population groups / life stages (associated with the consumption model selected for the scenario) and dose response models are also copied. The copied risk scenario is linked to the original process model, food, and hazard.

- 1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.
- 2 On the **Risk Scenarios** tab, click the **Copy** link to the right of the risk scenario that you want to copy.
- 3 On the Copy Risk Scenario page, switch between the tabs and review all element definitions associated with the risk scenario.
- 4 Click the **Name and Parameters** tab to enter a new name. By default, the copied risk scenarios will have the name `<risk_scenario_name> Copy`.
- 5 Click the **Instructions** tab.
- 6 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.
- 7 Click **Copy**.

Running a Report for a Risk Scenario

- 1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.
- 2 On the **Risk Scenarios** tab, click the **Edit** link to the right of the risk scenario for which you want to generate a report.
- 3 Click the Report tab.
- 4 In the **Report Title** input field, enter a name for the report, and enter an abstract in the **Report Abstract** input field (optional).
- 5 To receive an email notification when the report completes, select the **Send Email** check box.
Note: To set the default for this option (i.e. the **Send Email** check box is selected or cleared by default), click the **My Account** link at the top right of the FDA-iRISK main page, and then select or clear the **Send Email when Reports Complete (Default)** check box.
- 6 click **Generate Report for Risk Scenario**.

CHAPTER 8

Reports

There are two types of reports:

- **Risk Estimates and Scenario Ranking** Creates a report with risk estimates and ranking results for one or more scenarios including full documentation of model inputs.
- **Summary of Model Elements** Creates a report summarizing model elements with no risk estimates. The scenarios are not computed.

FDA-iRISK evaluates the parameters for all risk scenarios before they can be run. If a scenario does not meet the necessary requirements to run (usually due to incomplete model parameterization), it will not appear in the list of available scenarios. Instead, it will appear in the list of Incomplete Scenarios at the bottom of the page. The list provides the reason the scenario was excluded. Once the issue is resolved, the scenario becomes available to run.

Creating the Summary of Model Elements Report

- 1 Click the **Reports** tab on the main tab bar.

- Click the **Create** link to the left of the Summary of Model Elements report type. The Summary of Model Elements page opens.

[Home](#) -> [Reports](#) -> Summary of Model Elements -> Report Tab

Summary of Model Elements

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

Instructions | **Report**

Note: All fields are required

Show models for: My Primary Repository

Report Title: FDA-iRISK Summary of Model Elements

Report Abstract:

The selected options will only be reported when the corresponding food and/or hazard are selected.

Hazard Name	Select	Food Name	Select	Diet Name	Select	Options	Select
Aflatoxin B1	<input checked="" type="checkbox"/>	Chocolate-flavored Dairy Beverage	<input checked="" type="checkbox"/>	Diet 1	<input checked="" type="checkbox"/>	Show Consumption Model	<input checked="" type="checkbox"/>
Ammonia (refrigerant leak)	<input checked="" type="checkbox"/>	Dairy Beverage	<input checked="" type="checkbox"/>			Show Dose Response	<input checked="" type="checkbox"/>
Inorganic Arsenic Imported	<input checked="" type="checkbox"/>	Frozen Pizza	<input checked="" type="checkbox"/>			Show Health Metric	<input checked="" type="checkbox"/>
Inorganic Arsenic Imported	<input checked="" type="checkbox"/>	Oats	<input checked="" type="checkbox"/>			Show Predictive Model	<input checked="" type="checkbox"/>
Ochratoxin A	<input checked="" type="checkbox"/>	Peanut Butter	<input checked="" type="checkbox"/>			Show Process	<input checked="" type="checkbox"/>
		Poultry	<input checked="" type="checkbox"/>				
		Quinoa	<input checked="" type="checkbox"/>				

The Download Acrobat Reader link will open a PDF in a new window. To return to the application, close the window.
[Download Acrobat Reader to view PDF files](#)

Generate Report

Quick Links: [Report History](#) | [Risk Estimates and Scenario Ranking](#)

- In the **Select Repository** drop-down list, select the model repository to view.
- In the **Report Title** input field, enter a name for the report, and enter an abstract in the **Report Abstract** input field (optional).
- Select the check boxes beside the hazards and foods that you want to include in the report.
- Select the check boxes beside the elements listed under Options that you want to include in the report.
- Click **Generate Report**. The report is created in PDF format.

Creating the Risk Estimates and Scenario Ranking Report

- Click the **Reports** tab on the main tab bar.

- Click the **Create** link to the left of the Risk Estimates and Scenario Ranking report type. The Risk Estimates and Scenario Ranking page opens.

Home -> Reports -> Risk Estimates and Scenario Ranking -> Report Tab

Risk Estimates and Scenario Ranking

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

Instructions Report

Note: All fields are required

List scenarios for: ☒ (R1) My Primary Repository ☐ (R2) My Second Repository

Update Selections

Filters: Use the following filters to select a subset of the scenarios available for ranking.

Food Hazard Metric Exposure Type

All All All All All

Load Risk Scenarios

Quick Links: [Report History](#) | [Summary of Model Elements](#)

- In the **List scenarios for** section, select one or more model repositories and click **Update Selections**.
- You can use the drop-down list filters (i.e. Food, Hazard, Metric, Exposure, Type) to refine the list of available scenarios.
- Click **Load Risk Scenarios**.
- Select the check boxes beside the scenarios that you want to include in the report.
For information about the using the Group ID input fields to group scenarios, see *"Grouping Scenarios" on page 136*.
For information about using the Scenario Weight input fields, see *"Including Weighted Scenarios" on page 136*.
- If required, do one of the following:
 - To edit a scenario, click the **Edit** link to the right of the scenario.
 - To view details for a shared scenario, click the **View** link to the right of the scenario.
- To include uncertainty in the analysis and results, select the **Include Uncertainty** check box for those scenarios with uncertainty defined. Otherwise, the model will use variability only. Note that the value of this check box is saved between report runs. (Does not apply to shared scenarios.)
- In the **Report Title** input field, enter a name for the report, and enter an abstract in the **Report Abstract** input field (optional).
- To receive an email notification when the report completes, select the **Send Email** check box.
Note: To set the default for this option (i.e. the **Send Email** check box is selected or cleared by default), click the **My Account** link at the top right of the FDA-iRISK main page, and then select or clear the **Send Email when Reports Complete (Default)** check box.

- 11 By default, results for chronic exposure scenarios are annualized by dividing the lifetime risk by the length of the lifespan in years (e.g. 70). To report results for the full lifespan, clear the **Annualize Chronic Results** check box.

Note: As annualized results are required to rank acute and chronic scenarios together, the check box can only be cleared when all the selected scenarios are chronic.

- 12 Do one of the following:
- To generate a report of the selected scenarios, click **Generate Report for Checked**.
 - To generate a report of all scenarios, click **Generate Report for All Listed**.

A message displays the number of scenarios submitted and includes a link to the Report History section of FDA-iRISK. See *"Viewing Reports" on page 137*.

Grouping Scenarios

For information about how to create a Risk Estimates and Scenario Ranking report, see *"Creating the Risk Estimates and Scenario Ranking Report" on page 134*.

On the Risk Estimates and Scenario Ranking page, enter a user-defined ID in the respective Group ID input fields to identify mutually exclusive scenarios that collectively represent the risk(s) you want to evaluate. In the following example, the acute and chronic exposure from the same hazard in the same food are grouped:



<input checked="" type="checkbox"/>	OTA	n/a	OTA Acute (Wheats and wheat products, Ochratoxin A, DALY, Acute, Computed)
<input checked="" type="checkbox"/>	OTA	n/a	OTA Chronic (Wheats and wheat products, Ochratoxin A, DALY, Chronic, Computed)

Alternatively, you could group across different pathogens in the same food, or the same hazard in different foods. The resulting report provides a value for the summed DALY value across each identified group, as well as the results and information contained in a standard ranking report.

Grouping is ignored when the Include Uncertainty check box is selected for a scenario assigned to a group as uncertain results cannot be merged across scenarios.

Including Weighted Scenarios

For information about how to create a Risk Estimates and Scenario Ranking report, see *"Creating the Risk Estimates and Scenario Ranking Report" on page 134*.

In some situations, two or more scenarios may be required to characterize fully the risk for a food-hazard combination, with each scenario contributing a proportion of the risk. To achieve this, you might apply the appropriate population sizes to each scenario or try some other mechanism.

Alternatively, you can specify a weight between 0 and 1 for each scenario in the Scenario Weight input fields, and then group them together. This instructs FDA-iRISK to apply that weight to the results before aggregating them.

Viewing Reports

You can view pending and completed reports on the Report History tab. You can navigate to the Report History page in the following ways:

- Click the **Reports** tab on the main tab bar and then click the **Report History** tab. The list of generated reports display, newest to oldest.

FDA-iRISK® 4.2 Home Risk Models Reports Repositories Help

Home -> Reports -> Report History Tab

Reports

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

Instructions Report History New Report Simulation Settings

The following links, Download Acrobat Reader, View PDF, View Word and View Excel will open a PDF, Word or Excel document in a new window. To return to the application, close the window.

[Download Acrobat Reader to view PDF files](#)

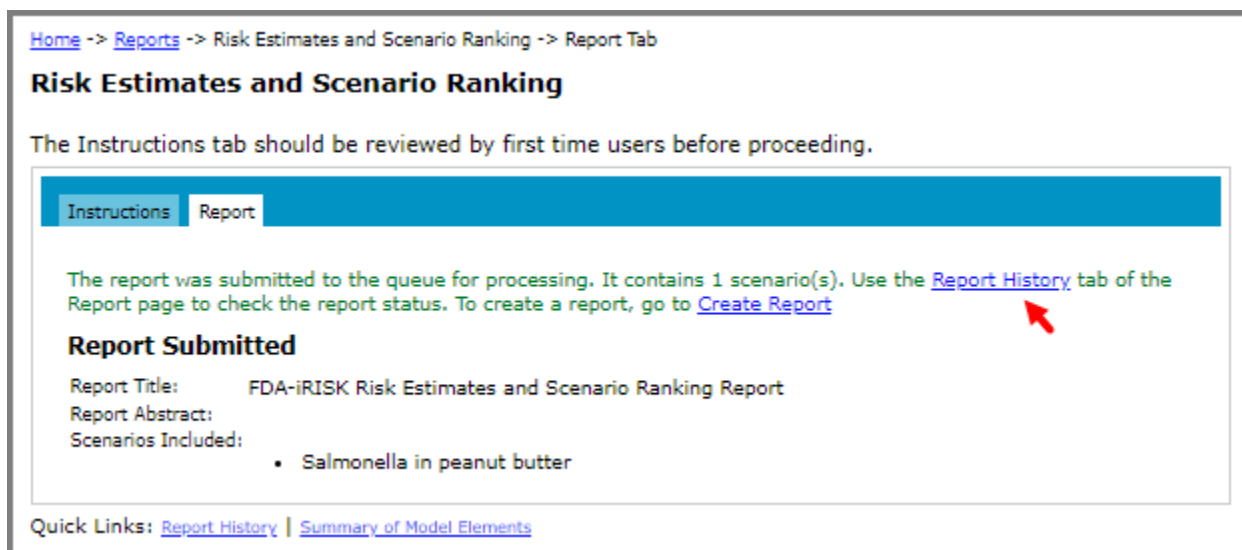
[Refresh Lists](#)

Completed Reports

Rank by: Filter by date: Filter by status: Append Repository Name: ☐

Name & Abstract	Scenarios	Completed	PDF	Word	Excel	Edit	Delete
FDA-iRISK Risk Estimates and Scenario Ranking Report	1	17-Aug-2020 07:48:14	Details <input type="checkbox"/> Notes <input type="checkbox"/> View PDF	Details <input type="checkbox"/> Notes <input type="checkbox"/> View Word	View Excel Convergence	Edit	Delete
Sensitivity Analysis for Salmonella in peanut butter	3	16-Aug-2020 10:08:56	Details <input type="checkbox"/> Notes <input type="checkbox"/> View PDF	Details <input type="checkbox"/> Notes <input type="checkbox"/> View Word	View Excel Convergence	Edit	Delete

- Create and generate a report on the New Report tab. (See "Creating the Summary of Model Elements Report" on page 133 and "Creating the Risk Estimates and Scenario Ranking Report" on page 134.) Click the **Report History** link.



The Report History page displays both pending and completed reports. The Status column in the list of pending reports, shows the report status. Click the Refresh Lists button to update report statuses. While a report is in process, the Status column provides feedback about the progress of the scenario simulations. Once a report completes, it is moved to the Completed Reports list.

Click the Cancel link under Pending Reports to cancel a report.

Home -> Reports -> Report History Tab

Reports

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

Instructions Report History **New Report** Simulation Settings

The following links, Download Acrobat Reader, View PDF, View Word and View Excel will open a PDF, Word or Excel document in a new window. To return to the application, close the window.

[Download Acrobat Reader to view PDF files](#)
[Refresh Lists](#)

Pending Reports

Name & Abstract	Scenarios	Submitted	Status	Cancel Report
FDA-iRISK Risk Estimates and Scenario Ranking Report	1	17-Aug-2020 08:24:04	Pending (1st in Queue)	Cancel

Completed Reports

Rank by: Filter by date: Filter by status: Append Repository Name: ☐

Name & Abstract	Scenarios	Completed	PDF	Word	Excel	Edit	Delete
FDA-iRISK Risk Estimates and Scenario Ranking Report	1	17-Aug-2020 08:21:16	Details <input type="checkbox"/> Notes <input type="checkbox"/> View PDF	Details <input type="checkbox"/> Notes <input type="checkbox"/> View Word	View Excel Convergence	Edit	Delete

The Completed Reports list includes the following options:

- **Rank by** lets you select the metric used to rank results within the reports (the selection does not affect the order of the reports in the list). The options are Health Metric (e.g. Total DALYs), Health Metric per Eating Occasion or Consumer, Total Illnesses, Total Illnesses per Eating Occasion or Consumer, and Exposure (Dose).
- **Filter by date** and **Filter by status** let you filter the list of completed reports by a selected date and status.
- Sort the report list by the **Name & Abstract** and **Completed** columns. Click the header to apply the sort. Click again to reverse the sort direction.
- The **Details** and/or **Notes** check boxes let you include or exclude details and/or notes in the report in PDF or Word format. (You can also see a basic summary report in Excel).
- To view a report, click the **View** link of the format in which you want to view the report.
- To edit the report name or abstract, click the **Edit** link to the right of the report that you want to edit. A page opens where you make the edit and save the changes.
- To export the simulation convergence report in Excel format, click the **Convergence** link to the right of the report.
- To export chemical exposure results for variability-only scenarios included in the report in Excel format, click the **Exposure** link to the right of the report.
- To delete a report, click the **Delete** link to the right of the report that you want to delete.

Interpreting the Risk Estimates and Scenario Ranking Report

The report has a cover page with the report title, the abstract if provided, and a disclaimer.

The summary of the rankings starts on the second page. In the example shown below, three scenarios have been ranked by Health Metric (Total DALYs). Note that the scenarios are ranked in descending order. The Uncertainty Results column does not display results when no scenarios include uncertainty. Otherwise, it includes the Minimum, 5th Percentile, Median, Mean, 95th Percentile and Maximum values. The median value is used for ranking for scenarios with uncertainty.

Ranking Summary		
<i>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.</i>		
Scenario or Scenario Group	Total DALYs per Year	Uncertainty Results
Salmonella in peanut butter - Specified	64.6	N/A
L. monocytogenes in soft ripened cheese	15.7	N/A
Ammonia in Frozen Pizza in Children	0.262	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.

If a group ID was provided when submitting the report (see "Grouping Scenarios" on page 136), it will appear in the Scenario or Scenario Group column, and the names of all the scenarios in the group will be listed for each row (group).

The summary is followed on the next page by an ungrouped ranking summary with additional details. That is, it shows the rankings by individual scenario in descending order. Since no groups had been defined in this example, the ungrouped ranking summary is the same as the main ranking summary shown above.

Ranking Summary for Risk Scenarios (Ungrouped)							
<i>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.</i>							
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
Ammonia in Frozen Pizza in Children	N/A	1.30E+9	262	2.02E-7	0.262	2.02E-10	0.262

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.

If the scenarios include more than one ranking variable type (e.g. DALYs, Cost per Illness, QALY Loss), a ranking is performed for each metric type.

In the summary sections, several results are provided. All are per year values unless the Annualize Chronic Results check box was cleared.

The columns show the following:

- **Lifecourse Duration:** This applies to chronic chemical hazard scenarios and is the total lifespan (i.e. exposure duration) considered by the scenario (e.g. 70 years).
- **Eating Occasions or # Consumers:** “Eating occasions” is used for acute hazards and is the annual total for all population groups / life stages 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 (for acute exposures) or consumers (for chronic exposures).
- **Total DALYs per Year:** As this is a DALY scenario, the total number of DALYs for the year.
- **DALYs per Eating Occasion or Consumer:** The DALYs divided by the number of eating occasions (or consumers).
- **Total DALYs per Year (Weighted):** If a scenario weight was added, the value from the DALY column is multiplied by the specified weight.

Notes:

- For process models that include the Threshold Exceedance Test process stage, which measures the frequency of exceeding a user defined concentration threshold (fixed value only, no uncertainty) for acute scenarios, the results follow the ungrouped ranking summary in the report. For more information about the threshold exceedance process stage, see the *Technical Document*.

Concentration Threshold Exceedance Results:					
Scenario	Hazard	Food	Process Stage & Concentration Threshold Value	Proportion of Contaminated Servings Exceeding Threshold	Proportion of All Servings Exceeding Threshold
S. aureus Growth	Staphylococcus aureus	Batter (hypothetical formulation)	Threshold Exceedance Test 5 log ₁₀ cfu/g	0.0217	0.000867

- For chronic exposure scenarios (single food) that include the lifetime average daily dose (LADD) threshold for measuring the exceeded LADD in the report, the result is shown in the Exposure by Percentile chart, and summarized in the Lifetime Average Daily Dose Threshold section.

If you selected the Details check box, 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.

Convergence is tested by evaluating the change in mean total of DALYs for the scenario over batches of iterations. The model is considered to have converged if the change in mean is less than 1%. By default, three sequential batches must pass this test for the model to be considered as converged. A slightly different algorithm is used when the model includes uncertainty.

For more information about convergence, see the section, *Interpreting the Convergence Report on page 144* and the *Technical Document*.

Scenario Details for: Ammonia in Frozen Pizza in Children			
Type:	Results Computed	Scenario Weight:	N/A
Hazard:	Ammonia (refrigerant leak) (Chemical)	Metric Type:	DALY
Food:	Frozen Pizza	Exposure Type:	Acute
Process Model:	Ammonia in Frozen Pizza	Converged:	Yes (by 18000 variability samples)
Consumption Model:	Frozen Pizza Consumption by Children	Include Uncertainty:	No

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

Process Model: Ammonia in Frozen Pizza				
	Initial Conditions	Model Outputs*		
Prevalence:	1E-6	1.00E-6		
Concentration:	Triangular (Units: mg/g)	0.000617 g/g		
	Minimum: 0.7 Mode: 1.3 Maximum: 2			
	Computed Mean: 1.33 mg/g			
Unit Mass:	Fixed Value (g)	150 g		
	Value: 150			
* Final prevalence and Prevalence-Weighted mean concentration				
Process Stages for Ammonia in Frozen Pizza:				
Process Stage	Process Type	Definition	Concentration (g/g)	Prevalence
Storage	Decrease	Uniform Minimum: 0.05 Maximum: 0.1	0.00123	1.00E-6
Cooking	Decrease	Fixed Value Value: 0.5	0.000617	1.00E-6

The initial values that you provide are shown, and model output reported. As well, the concentration and prevalence are reported for the end of each process stage.

Note that for microbial hazards, while you can specify initial concentration on the log scale, FDA-iRISK converts all log10 units to arithmetic units when performing calculations. FDA-iRISK then computes the arithmetic mean of concentration results but converts these means back to the log10 scale for the report. This can result in the reported mean concentration (also referred to as computed mean) having a value different than the mean that you specified. For example, if you specify an initial concentration in log10 cfu/g as a Normal distribution with a mean of

3 and a standard deviation of 1, the computed arithmetic mean concentration is 13,035 cfu/g. When converted back to the log10 scale, this results in a value of 4.12 log10 cfu/g. For microbial hazards, the text 'Computed Mean:' in the above screenshot is replaced with 'Computed Mean (Arithmetic)' to reflect this.

Also note that for the process stage and final results, food units are converted to grams or milliliters. In addition, all mean concentration values are computed as prevalence-weighted average results. That is, across model iterations, the concentrations generated by iterations associated with higher proportions of contaminated units will have a higher weight in determining the overall average concentration across all iterations.

This raises a key concept on the definition of prevalence used by FDA-iRISK. Prevalence is always taken to mean the proportion of contaminated units in a batch. The actual number of units in the batch is undefined.

The next section summarizes the risk estimates generated for the population groups / life stages based on the final concentration and prevalence, as well as serving size (amount consumed). If selected for inclusion in the report (via a checkbox on the Edit Population Group and Consumption page), the consumption according to the number of servings per person is also included.

The definitions for the population groups / life stages are presented first, followed by the results:

Result Summary					
Mean Exposure: See population groups		Total Number of Illnesses:		262	
		Total DALY/Year:		0.262	
Population Group Definitions:					
Population Group	Consumption	Dose Response		Health Metric	
Children 6 to 12	Eating Occasions: 1.3E9 eo/yr	Ammonia Non-Threshold Linear		Ammonia (oral) DALY (0.001 DALYs)	
Body Weight: Fixed Value (Units: Kg)	Per Eating Occasion: Triangular (Units: g/eo)	Non-Threshold Linear (Dose unit: mg)			
Value: 0	Minimum: 100 Mode: 150 Maximum: 300	Risk at Reference Point: 0.21 Reference Point: 118			
		Probability of adverse effect: 100%			
Correlation Option: No Correlation					
Population Group Results:					
Population Group	Mean Dose* (mg)	Mean** Prevalence in Servings	Mean Probability of Illness	Number of Illnesses per year	Total Metric Per Year (DALYs)
Children 6 to 12	0.0648	1.75E-6	2.02E-7	262	0.262
* Mean dose per Contaminated serving		** Proportion of contaminated servings			
Health Metric Details: Ammonia (oral) DALY					
				DALY/Case:	0.001

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

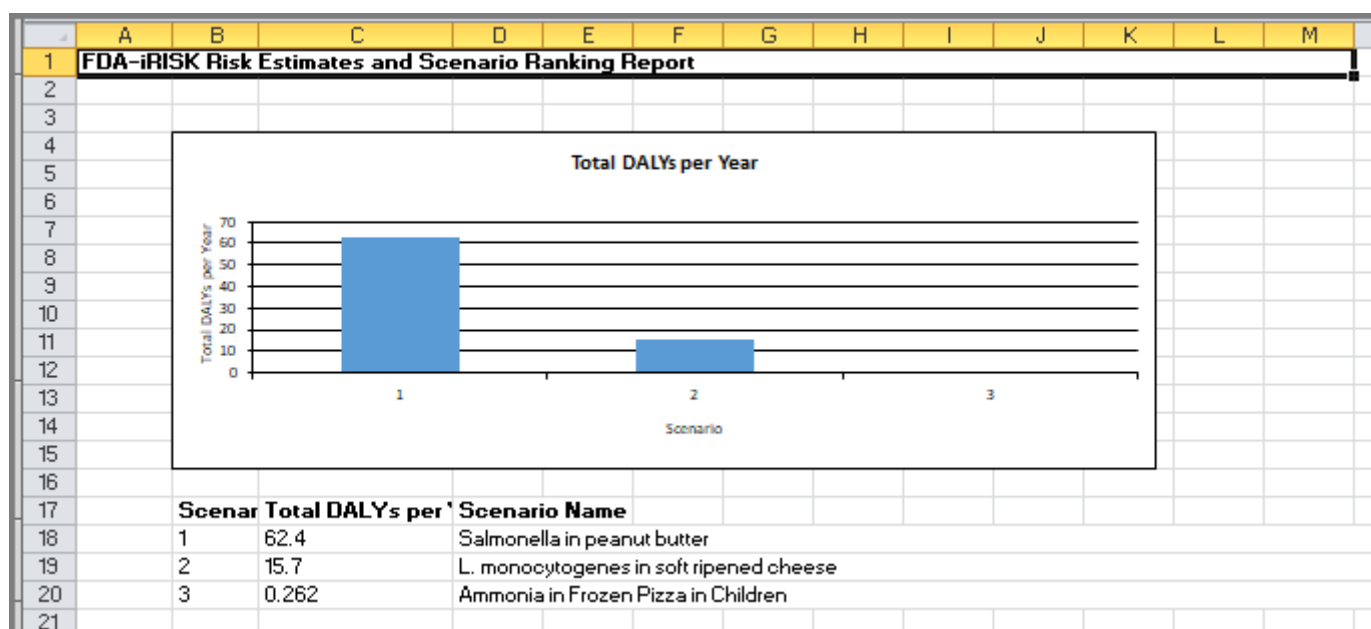
The next section summarizes the health metric details.

If you select the Notes check box, any non-private notes associated with the scenario and its elements would be included at the end of the scenario's summary.

Interpreting the Convergence Report

The FDA-iRISK Convergence report is an Excel file.

The first sheet provides a summary of the results and a list of scenarios in the report:



The second sheet provides a list of the simulation settings used to generate the report:

FDA-iRISK Risk Estimates and Scenario Ranking Report Simulation Settings						
Variability Settings			Uncertainty Settings			
Initial Batch Size	9,000		Batch Size	100		
Running Batch Size	3,000		Maximum Batches	100		
Maximum Batches	100		Convergence Tests	1		
Convergence Tests	3		Convergence Criterion - Mean (%)	5		
Convergence Criterion (%)	1		Test Median	Yes		
Endpoint	Risk (if available)		Convergence Criterion - Median (%)	5		
			Test Confidence Interval	Yes		
			Convergence Interval (%)	90		
			Convergence Criterion - CI (%)	10		

Following the second sheet, there is one sheet per scenario.

For single food scenarios, only one set of results is displayed:

	A	B	C	D	E	F	G
1	Salmonella in peanut butter Variability Convergence Results						
2							
3							
4		Batch	Batch Mean	Running Mean	Change In Mean	Test Result	Batch Duration (Minutes)
5		1	62.23828777	62.23828777	0	FALSE	0.014066667
6		2	62.44116701	62.28900758	0.000814266	TRUE	0.005199997
7		3	63.26087214	62.48338049	0.003110794	TRUE	0.004949996
8		4	61.82344154	62.37339066	0.001763409	TRUE	0.004950006
9						Total Duration:	0.029166666
10							

For multifood scenarios, the results for the exposure/risk model is displayed, in addition to one set for each process model used (where it converged on concentration).

For variability scenarios, the following fields are displayed:

- **Batch** The variability batch run.
- **Batch Mean** The mean result for that batch, in isolation.
- **Running Mean** The running mean over all batches.
- **Change in Mean** The change from the previous running mean.
- **Test Result** Whether the change is less than the threshold specified in the settings.
- **Batch Duration** The time required to complete the batch, in minutes.

For scenarios with uncertainty, the following fields are displayed:

- **Batch** The uncertainty batch run (which includes 2 or more variability batches)
- **Batch Mean** The mean result for that uncertainty batch, in isolation
- **Running Mean*** The running mean over all uncertainty batches
- **Change in Mean*** the change from the previous running mean
- **Test Result Mean*** if the change is less than the threshold specified in the settings.

*These fields repeat for the Median and the Confidence interval.

Each uncertainty batch will include several variability convergence tests (e.g., 100). The Iteration columns indicate the minimum, mean, median, and maximum number of variability iterations required to converge for each of the uncertainty iterations. The Batch Duration column indicates the time required to complete the uncertainty batch, in minutes.

Note: For multifood, some process models may have uncertainty while others do not, and it will show as appropriate. However, if any process models or the exposure models have uncertainty, the exposure model will also be uncertain.

Interpreting the Exposure Report

This report contains any percentile exposure results that are included in the main report for any chronic chemical, variability only scenarios.

It reports the scenario name, food, hazard, and diet if applicable. It also shows the 1st to 99th percentiles for exposure for the associated combination. Exposure units are g/kg-day.

Simulation Settings

You can manage the settings used for variability and uncertainty for risk estimates and ranking reports on the Simulation Settings tab.

The settings on this tab are used for any subsequent reports sent for simulation and can be changed at any time. You can define multiple sets of simulation settings to quickly switch between settings.

As you develop a model, you may wish to reduce the batch size and convergence tests used to speed up test runs, in particular for simulations with uncertainty. Note, the model will aim for convergence using the settings defined. Convergence on more relaxed settings should not be assumed to provide results equivalent to more stringent simulation settings, and in some cases, may result in risk scenarios that do not converge during simulation. However, this process should nevertheless produce reports providing some insight into the scenario's behavior.

Note: Increasing values beyond the default values (of the selected set) will result in longer running simulations.

For information about how the simulation settings are applied, see the *Technical Document*.

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:

Selected: True

Variability Settings		Uncertainty Settings	
Variability Initial Batch Size:	<input type="text" value="9,000"/>	Uncertainty Batch Size:	<input type="text" value="100"/>
Variability Running Batch Size:	<input type="text" value="3,000"/>	Uncertainty Convergence Tests:	<input type="text" value="1"/>
Variability Convergence Tests:	<input type="text" value="3"/>	Uncertainty Maximum Batches:	<input type="text" value="100"/>
Variability Maximum Batches:	<input type="text" value="100"/>	Uncertainty Convergence Criterion - Mean (%):	<input type="text" value="5"/>
Variability Convergence Criterion (%):	<input type="text" value="1"/>	Test Uncertainty Median:	Yes ▼
Endpoint to Test:	Risk (if available) ▼	Uncertainty Convergence Criterion - Median (%):	<input type="text" value="5"/>
		Test Uncertainty Confidence Interval:	Yes ▼
		Uncertainty Confidence Interval:	90% ▼
		Uncertainty Convergence Criterion - Confidence Interval (%):	<input type="text" value="10"/>

Save Set Selected

Last Modified: 09-Dec-2015 11:22:45

Loading a Simulation Set

- 1 Click the **Reports** tab on the main tab bar.
- 2 Click the **Simulation Settings** tab.
- 3 In the **Select Set** drop-down list, select the set to load, and then click **Load Set**.

Adding a Simulation Set

- 1 Click the **Reports** tab on the main tab bar.
- 2 Click the **Simulation Settings** tab.
- 3 Click **Create New Set**.
- 4 In the **Set Name** input field, type a name for the new set and click **Save**.
- 5 Specify the variability and uncertainty settings for the new set, and then click **Save**.

Editing a Simulation Set

- 1 Click the **Reports** tab on the main tab bar.
- 2 Click the **Simulation Settings** tab.
- 3 In the **Select Set** drop-down list, select the set, and then click **Load Set**.
- 4 Edit the settings are required and then click **Save**.

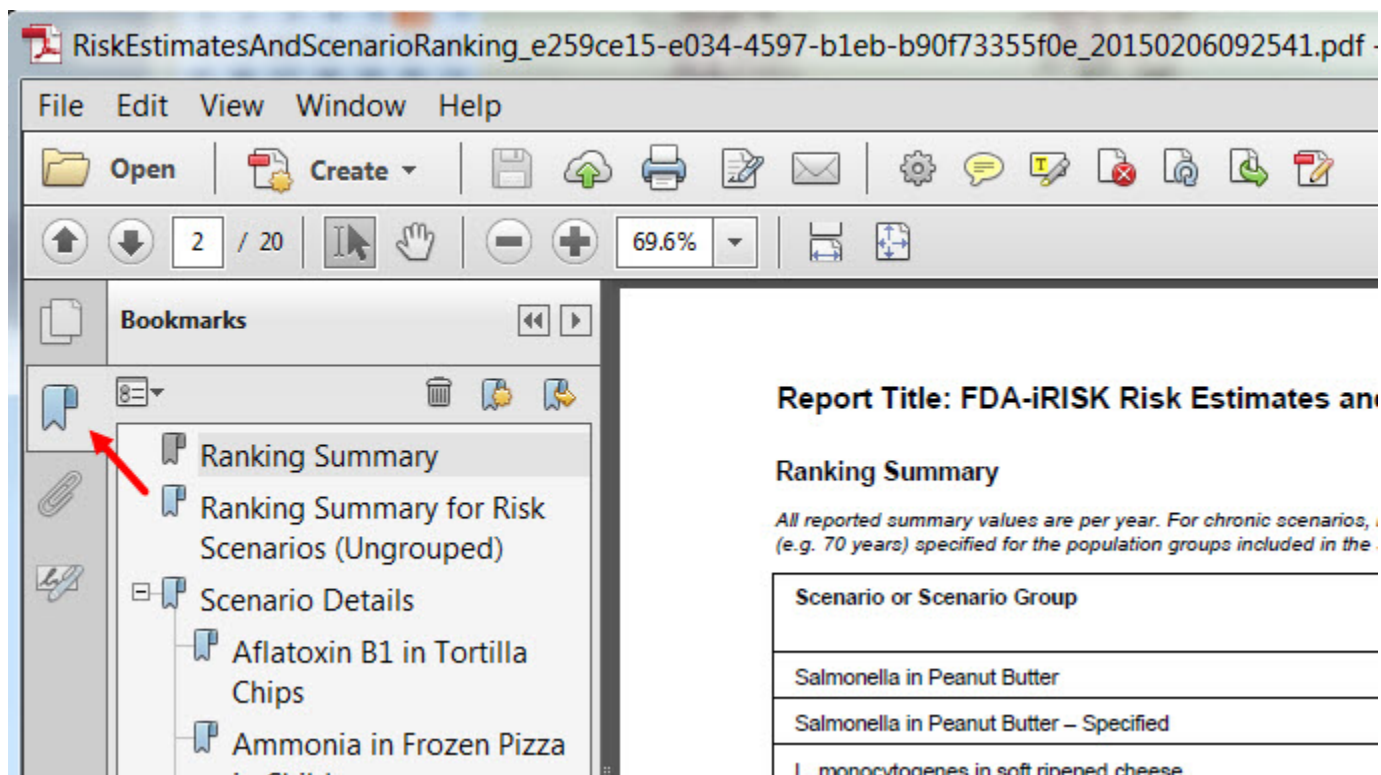
Deleting a Simulation Set

Note: To delete a simulation set marked as “selected”, select another set as “selected” first.

- 1 Click the **Reports** tab on the main tab bar.
- 2 Click the **Simulation Settings** tab.
- 3 In the **Select Set** drop-down list, select the set, and then click **Load Set**.
- 4 Click **Delete**.

Report Bookmarks

In the PDF report, bookmarks have been added to link to individual sections of the report and each scenario's detailed results. These bookmarks are not available in the Word report.



CHAPTER 9

Sensitivity Analysis

In developing risk scenarios, you may make assumptions that are necessary because of data gaps. FDA-iRISK offers a sensitivity analysis feature to explore the impact of different assumptions. Moreover, you can use sensitivity analysis to evaluate the impact on risk estimates of proposed control measures and interventions applied at any step of the process model, or the impact on risk estimates from changes in consumption patterns. You can use this feature to explore uncertainty (e.g. in the dose-response model) in a step-wise process.

For example, the level of a hazard in a food may decrease during cooking, but the extent of the decrease is unknown. A value based on expert opinion may be used in characterizing the cooking step in the process model, and sensitivity analysis can then be applied to obtain results using alternate values for this “decrease during cooking” parameter.

You can define sets of grouped parameter values for testing. For example:

- Sensitivity Analysis Set #1
 - Reduce prevalence by 50%
 - Change “growth” to “no growth”
 - Increase consumption 100%
- Sensitivity Analysis Set #2
 - Reduce prevalence by 10%
 - Change “growth” to “2x growth”
 - Increase consumption 50%

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

Running Sensitivity Analysis

Before you begin: One or more sensitivity analysis sets on which to run sensitivity analysis must exist. For more information, see *“Sensitivity Analysis Sets” on page 152*.

- 1 Navigate to the Risk Scenarios page. See *“Navigating to Risk Scenarios” on page 107*.

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

Instructions Hazards (8) Foods (10) Diets (1) Process Models (7) Risk Scenarios (11) Notes

Risk Scenarios

Select a risk scenario from the list to edit or delete, or add a new risk scenario.
 Computed risk scenarios must be linked to an existing food, hazard, dose response, health metric, consumption and process model. Specified risk scenarios must be linked to an existing food and hazard.

[Add Risk Scenario](#) [Validate Scenarios](#)

Filter by food: Filter by hazard:

Shared	Scenario	Validation	Actions
*	Aflatoxin B1 in Tortilla Chips (Tortilla Chips, Aflatoxin B1, DALY, Chronic, Computed)	Not Checked	Edit Copy Delete
*	Aflatoxin B1 in Tortilla Chips (Exposure Only) (Tortilla Chips, Aflatoxin B1, No Metric - Exposure Only, Chronic, Computed)	Not Checked	Edit Copy Delete
*	Ammonia in Frozen Pizza in Children (Frozen Pizza, Ammonia (refrigerant leak), DALY, Acute, Computed)	Not Checked	Edit Copy Delete
	Campylobacter spp. in Poultry (Poultry, Campylobacter, DALY, Acute, Specified)	Not Checked	Edit Copy Delete
	L. monocytogenes in soft ripened cheese (Soft Ripened Cheese, L. monocytogenes, DALY, Acute, Computed)	Not Checked	Edit Copy Delete
	L. monocytogenes in soft ripened cheese (Exposure Only) (Soft Ripened Cheese, L. monocytogenes, No Metric - Exposure Only, Acute, Computed)	Not Checked	Edit Copy Delete
	MultHazard Multifood Assessment (Multifood, Multihazard, DALY, Chronic, Computed Multihazard)	Not Checked	Edit Copy Delete
	Ochratoxin A from Oats, Rice and Raisins (Multifood, Ochratoxin A, DALY, Chronic, Computed Multifood)	Not Checked	Edit Copy Delete
	Ochratoxin A from Oats, Rice and Raisins (Exposure Only) (Multifood, Ochratoxin A, No Metric - Exposure Only, Chronic, Computed Multifood)	Not Checked	Edit Copy Delete
	Salmonella in peanut butter (Peanut Butter, Salmonella, DALY, Acute, Computed)	Not Checked	Edit Copy Delete
	Salmonella in peanut butter - Specified (Peanut Butter, Salmonella, DALY, Acute, Specified)	Not Checked	Edit Copy Delete

1

Display Records:

- Click the **Sensitivity Analysis** tab. The Sensitivity Analysis tab lists existing sensitivity analysis sets as well as all scenario model elements for which sensitivity analysis may be defined, and any sensitivity analysis sets currently associated with the sensitivity analysis.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (Salmonella in peanut butter) -> Sensitivity Analysis Tab

Edit Risk Scenario

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

[Instructions](#)
[Name and Parameters](#)
[Population Groups \(1/1\)](#)
[Notes \(0\)](#)
[Sensitivity Analysis](#)
[Report](#)

Run Sensitivity Analysis Report

Sensitivity Analysis Set	Include in Report
Dose-response parameters lower uncertainty bound	<input type="checkbox"/>
Dose response parameters upper uncertainty bound	<input type="checkbox"/>

Send Email Notifications: ☐

Define Sensitivity Analysis Parameter Sets

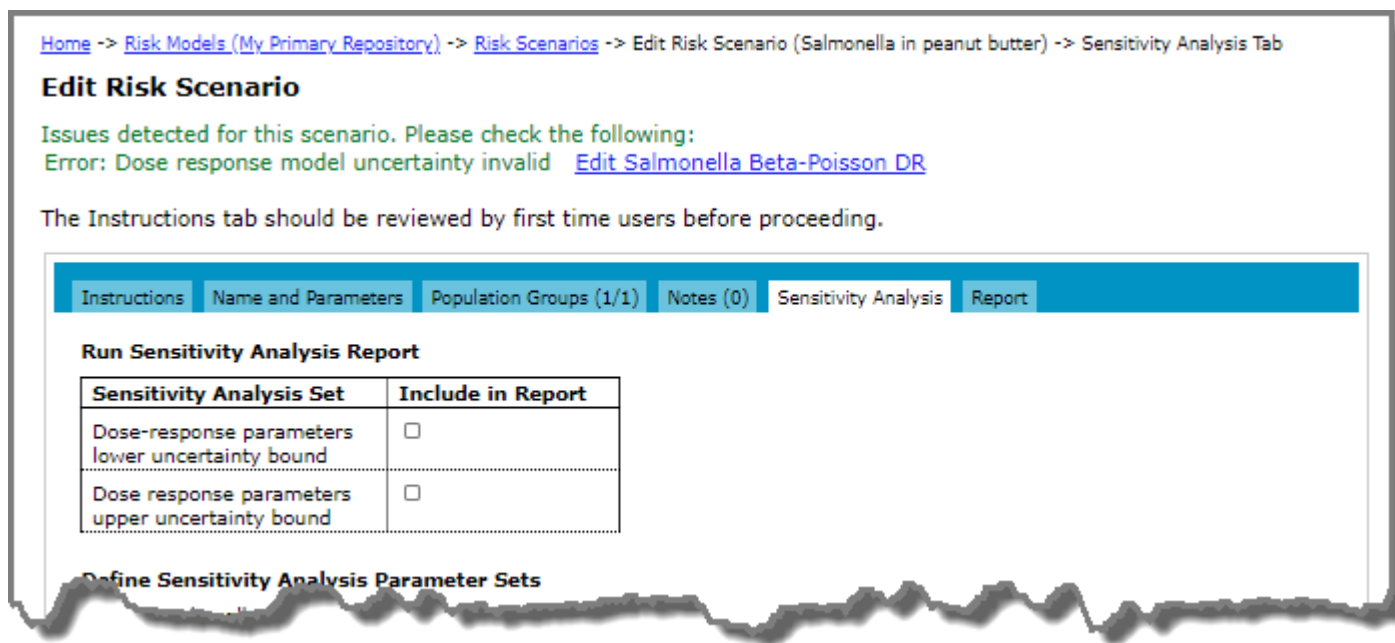
[Add Sensitivity Analysis Set](#)

Scenario Model Element	Parameter	Current Definition	Set: Dose-response parameters lower uncertainty bound Edit Delete	Set: Dose response parameters upper uncertainty bound Edit Delete
Salmonella in Peanut Butter - Initial Conditions	Initial Prevalence	5.5E-6 Edit	Add	Add
	Initial Concentration	Uniform (Minimum:-1.52, Maximum:2.55) Edit	Add	Add
	Initial Unit Mass	Fixed Value (Value:6.85E3) Edit	Add	Add

Notes:

- Sensitivity analysis is available for most scenario types; however, if the Sensitivity Analysis tab is not visible on the Edit Risk Scenario page, then sensitivity analysis is not available for the selected type of scenario.

- Issues detected for the scenario appear at the top of the page. You must resolve the errors before you can add sensitivity analysis sets or run sensitivity analysis reports.



- Select the check box to the right of the sets to include in the report.
- To receive an email notification when the sensitivity analysis completes, select the **Send Email Notifications** check box.
- Do the following:
 - To run selected sets, select the check boxes for the sensitivity analysis sets that you want to include, and then click **Run Selected Sets**.
 - To run all sets, click **Run All Sets**.

The report request is submitted and a link to the Report History page is provided.

- Click the **Report History** link.

For sensitivity analysis reports, the Excel report is often the preferred option to select as it provide a graphical summary of the results for the different values defined. For more information about reports, see *"Viewing Reports"* on page 137.

Sensitivity Analysis Sets

Adding a Sensitivity Analysis Set

- Navigate to the Sensitivity Analysis tab. See *"Running Sensitivity Analysis"* on page 149.

- Click the **Add Sensitivity Analysis Set** link. The Add Sensitivity Analysis Set page opens.

Home -> Risk Models (My Primary Repository) -> Risk Scenario (Salmonella in peanut butter) -> Add Sensitivity Analysis Set

Add Sensitivity Analysis Set

Enter a set name, and click "Add".

Note: all fields are required

Set Name:

- In the **Set Name** input field, enter a name for the set.
- Click **Add**. A column for the new set is added to the table.

Edit Risk Scenario

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

Instructions | Name and Parameters | Population Groups (1/1) | Notes (0) | Sensitivity Analysis | Report

Run Sensitivity Analysis Report

Sensitivity Analysis Set	Include in Report
Dose-response parameters lower uncertainty bound	<input type="checkbox"/>
Dose response parameters upper uncertainty bound	<input type="checkbox"/>
Set 1	<input type="checkbox"/>

Send Email Notifications: ☐

Define Sensitivity Analysis Parameter Sets

[Add Sensitivity Analysis Set](#)

Scenario Model Element	Parameter	Current Definition	Set: Dose-response parameters lower uncertainty bound Edit Delete	Set: Dose response parameters upper uncertainty bound Edit Delete	Set: Set 1 Edit Delete
Salmonella in Peanut Butter - Initial Conditions	Initial Prevalence	5.5E-6 Edit	Add	Add	Add

- To add the parameter set to one or more of the scenario model element parameters in the table, click **Add** in the Sensitivity Analysts Parameter Set column to the right of the parameter. The Edit Sensitivity Analysis Set Parameter page opens, displaying the current value defined for your chosen parameter to vary.
- Enter an alternate value for the parameter as part of the sensitivity analysis set you are building.
- Click **Save and Close** to return to the Edit Sensitivity Analysis Set page where you can add the parameter set to another scenario model element parameters in the table. Repeat the steps until you have built your desired set.

Editing a Sensitivity Analysis Set

- 1 Navigate to the Sensitivity Analysis tab. See *"Running Sensitivity Analysis" on page 149*.
- 2 Click the **Edit** link just below the title of the set that you want to edit.
- 3 On the Edit Sensitivity Analysis Set page, edit the set name and then click **Save** or **Save and Close**.

Deleting a Sensitivity Analysis Set

- 1 Navigate to the Sensitivity Analysis tab. See *"Running Sensitivity Analysis" on page 149*.
- 2 Click the **Delete** link just below the title of the set that you want to delete.
- 3 Click **Delete** to confirm the action.

Editing a Sensitivity Analysis Set Parameters

- 1 Navigate to the Sensitivity Analysis tab. See *"Running Sensitivity Analysis" on page 149*.
- 2 Click **Edit** in the Sensitivity Analysts Parameter Set column to the right of the parameter.
- 3 Edit the parameter and do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting a Sensitivity Analysis Set Parameters

- 1 Navigate to the Sensitivity Analysis tab. See *"Running Sensitivity Analysis" on page 149*.
- 2 Click the **Edit** link to the right of the set that you want to edit.
- 3 On the Edit Sensitivity Analysis Set page, click the **Delete** link to the right of the parameter that you want to delete.
- 4 Click **Delete** to confirm the action.

Editing the Current Definition of a Scenario Model Element Parameter

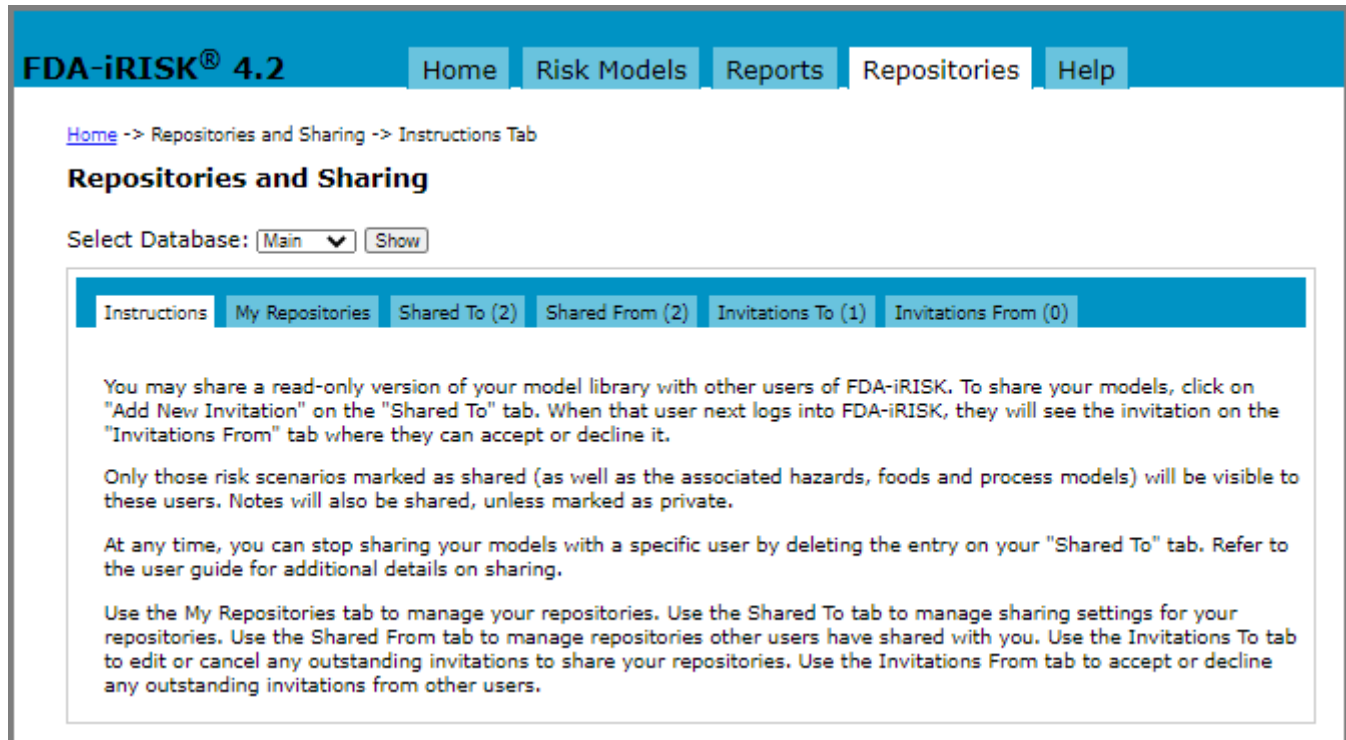
- 1 Navigate to the Sensitivity Analysis tab. See *"Running Sensitivity Analysis" on page 149*.
- 2 Click **Edit** in the Current Definition column to the left of the parameter. The associated edit page opens.
- 3 Edit the parameter and do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

CHAPTER 10

Repositories

The repositories page is used to manage model repositories by creating and deleting your own repositories, and sharing read-only access to model repositories with other users.

To navigate to the Repositories page, click the Repositories tab on the main tab bar.



The Repositories page includes the following tabs:

- **My Repositories** To create, rename, and delete your model repositories.
- **Shared To** To manage who can view your repositories.
- **Shared From** To manage repositories shared with you by other users.
- **Invitations To** To manage invitations to other users.
- **Invitations From** To manage invitations from other users.

Adding a Repository

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **My Repositories** tab and click the **Add New Repository** link. The Add Repository page opens.
- 3 In the **Repository Name** input field, enter a name for the new repository.
- 4 Click **Add**. The Edit Repository page opens.

- 5 In the **Description** input field, enter a description, if required.
- 6 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The Edit Repository page remains open.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

The new repository displays in the list on the My Repositories tab. In addition, the new repository is added to the drop-down list on the pages where you are required to select a repository.

When you have more than one repository, you can select the default repository that is always loaded first, using the **Set as Default** button. You must log out and log in again for this change to take effect.

Editing a Repository

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **My Repositories** tab and click the **Edit** link to the right of the repository that you want to edit.
- 3 On the Edit Repository page, edit the name and/or description.
- 4 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The Edit Repository page remains open.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

1

Deleting a Repository

Note that deleting a repository will delete all its models and cannot be undone.

You cannot delete the repository that is selected as the default. In order to delete a default repository, you must first select another repository as the default.

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **My Repositories** tab and click the **Delete** link to the right of the repository that you want to delete.
- 3 On the Delete Repository Page, click **Delete**.

Copying a Repository

You can only copy your own repositories on the Risk Models page. For shared repositories, see *"Importing a Repository"* on page 157.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select the repository that you want to copy.

- 3 Click **Copy/Import**.
- 4 On the Copy Repository page, do one of the following:
 - To create a new repository, select the **Copy to new repository** option and edit the name.
 - To copy all model elements from the selected repository into an existing repository, select the **Copy to selected repository** option and select the repository from the drop-down list.
- 5 Click **Copy**.

All elements of the repository are included in the copy. Once the copy completes, the confirmation page displays.
- 6 Click **Close** to return to the Risk Models page. The new copy is selected in the **Select Repository** drop-down list.

Importing a Repository

You have the option to import shared repositories on the Risk Models page. Note that only shared elements of the repository are included in the import. For more information, see *"Sharing a Risk Scenario" on page 158*.

For information about copying repositories, see *"Copying a Repository" on page 156*.

- 1 Click the **Risk Models** tab on the main tab bar.
- 2 In the **Select Repository** drop-down list, select the shared repository that you want to import.
- 3 Click **Copy/Import**. The Import Repository page opens.
- 4 Do one of the following:
 - To create a new repository, select the **Import to new repository** option and edit the name.
 - To import all model elements from the selected repository into an existing repository, select the **Import to selected repository** option and select the repository from the drop-down list.
- 5 Click **Import**.

All elements of the repository are included in the import. Once the import completes, the confirmation page displays.
- 6 Click **Close** to return to the Risk Models page. The new repository is selected in the **Select Repository** drop-down list.

Sharing Repositories

You have the option to share your model repositories with other users of FDA-iRISK.

Only content associated with a shared risk scenario will be visible to these users. However, once a hazard is associated with a shared risk scenario, all its elements are shared even if they are not used in that scenario (e.g., all the hazard's dose response models).

Sharing is read-only. Other users can view the repository that you share with them, but they cannot make changes. Similarly, any changes that you make are immediately visible to the other users. However, any copies of the shared repository are not updated.

When you invite another user to share a repository, they must log into FDA-iRISK and accept the invitation.

The next few sections discuss the different steps required to share your models.

Sharing a Risk Scenario

On the Risk Models page with the Risk Scenarios tab selected, scenarios in the list that have been designated as “to be shared” are indicated by an asterisk in the “Shared” column. Risk scenarios not marked by an asterisk are not accessible to people to whom you extend sharing invitations. See *“Inviting Others To Shared Risk Scenarios (Invitations To)”* on page 159.

Sharing is “read-only”, and those with whom you share definitions (risk scenarios and notes) cannot edit or delete them.

- 1 Navigate to the Risk Scenarios page. See *“Navigating to Risk Scenarios”* on page 107.
- 2 Click the **Edit** link to the right of the risk scenario that you want to share.
- 3 On the Risk Scenario page, select the **Shared** check box to indicate that you want to share this risk scenario.



All element definitions associated with the risk scenario (including all hazard elements as described above) will be shared with those to whom you extend a sharing invitation, with the exception of notes that have been designated as “Private”. For more information, see *“Adding a Note”* on page 102.

- 4 Do one of the following:
 - To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

The scenario now has an asterisk beside its name in the “Shared” column:

To make the Risk Scenarios that you have designated as “to be shared” accessible (on a read-only basis) to specific individuals, you must extend an invitation to share to those individuals. See *“Inviting Others To Shared Risk Scenarios (Invitations To)”* on page 159.

Inviting Others To Shared Risk Scenarios (Invitations To)

Adding an Invitations

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **Invitations To** tab and click the **Add New Invitation to Share** link. The Add Invitation to Share Repository page opens.
Note: the Add New Invitation link is also provided when the Shared To tab is selected.
- 3 In the **Select Repository** drop-down list, select the repository you wish to share.
- 4 In the **Invitee Email Address** input field, type the email address of the person with whom you want to share the repository.
- 5 Click **Add**.

You are returned to the Repositories page where the email address of the invitee appears in the list of invitations. It will remain in the list until it is accepted or declined, or if you delete it before that time. If it is accepted, it will move to the list on the Shared To tab.

Editing an Invitation

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **Invitations To** tab and click the **Edit** link to the right of the email address of the person whose invitation you want to edit.
- 3 On the Edit Invitation page, make the required changes.
- 4 Do one of the following:
 - To save the changes and remain on the page, click **Save**.
 - To save the changes and close the page, click **Save and Close**.
 - To close the page without saving the changes, click **Close**.

Deleting an Invitation

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **Invitations To** tab and click the **Delete** link to the right of the email address of the person whose invitation you want to delete. The invitation is removed immediately (no confirmation is required.)
Note: If the invitation does not appear in the list, it may have already been accepted and can therefore be found in the list on the Shared To tab. See *"Viewing the "Shared To" list" on page 159*.

Managing Who Can View Your Repositories (Shared To)

Viewing the "Shared To" list

The Shared To list includes the individuals (identified by their email addresses) who have accepted invitations to share your selected definitions.

To view the list, click the **Repositories** tab on the main tab bar and then click the **Shared To** tab.

Deleting Accounts from the “Shared To” List (Revoke Access)

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **Shared To** tab and click the **Delete** link to the right of the email address of the person whose account you want to delete. The entry is removed immediately (no confirmation check is required).

Managing Invitations From Other Users (Invitation From)

Accepting or Declining an Invitation

The total number of invitations appears beside the Invitations From tab label.

- 1 Click the **Repositories** tab on the main tab bar. The Repositories and Sharing page opens.
- 2 Click the **Invitations From** tab.
- 3 Do one of the following:
 - To accept an invitation to have (read-only) access, click the **Accept** link to the right of the email address of the person who issued the invitation. The item is moved to the list on the Shared From tab.
 - To decline an invitation, click the **Decline** link to the right of the email address of the person who issued the invitation

Managing Repositories Shared From Other Users (Shared From)

Viewing the “Shared From” list

The Shared From list includes the users (identified by their email addresses) who are sharing models with you.

To view the list, click the **Repositories** tab on the main tab bar and then click the **Shared From** tab.

Note: All new accounts have access to a set of Sample Models from iRISK@foodrisk.org that will appear in the “Shared From” list.

You can do the following on this page:

- Select the **Show In List** check box for those shared repositories that you want included in the **Select Repository** for drop-down list on the Risk Models page.
- Click the **View Models** link to view the model definitions to which you have (read-only) access.

Editing the Display Name and Show in List from the “Shared From” List

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **Shared From** tab and click the **Edit** link to the right of the email address of the person whose display name you want to edit.
- 3 On the **Edit models shared with me** page, do one of the following:
 - To edit the display name, enter a new name in the **Display Name** input field.
 - To include the model in the Select model for drop-down list on the Risk Models page, select the **Show In List** check box.

4 Do one of the following:

- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

The new display name appears in the list of “Shared From” accounts. If you have selected the Show in List check box, the new display name also appears in the “Select Repository” drop-down list on the Risk Models page:

Deleting Accounts from the “Shared From” List (Reject Access)

- 1 Click the **Repositories** tab on the main tab bar.
- 2 Click the **Shared From** tab and click the **Delete** link to the right of the email address of the person whose account you no longer want to access. Your access is revoked immediately (there is no confirmation check required).