FDA-iRISK® 4.2
Food Safety Modeling Tool

User Guide

March 2021

Disclaimer

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March 2021

CONTENTS

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.

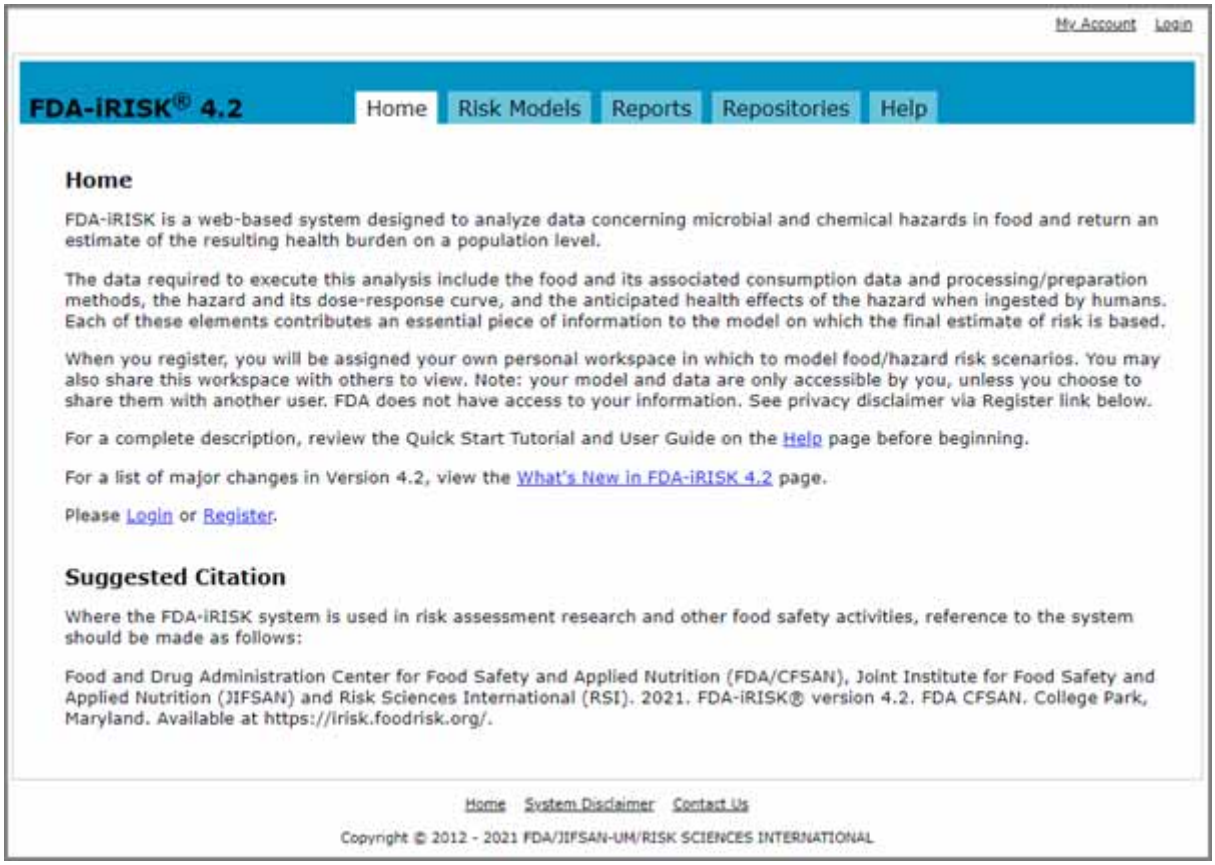
Each of these elements contributes an essential piece of information to the model on which the final estimate of risk is based.

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.

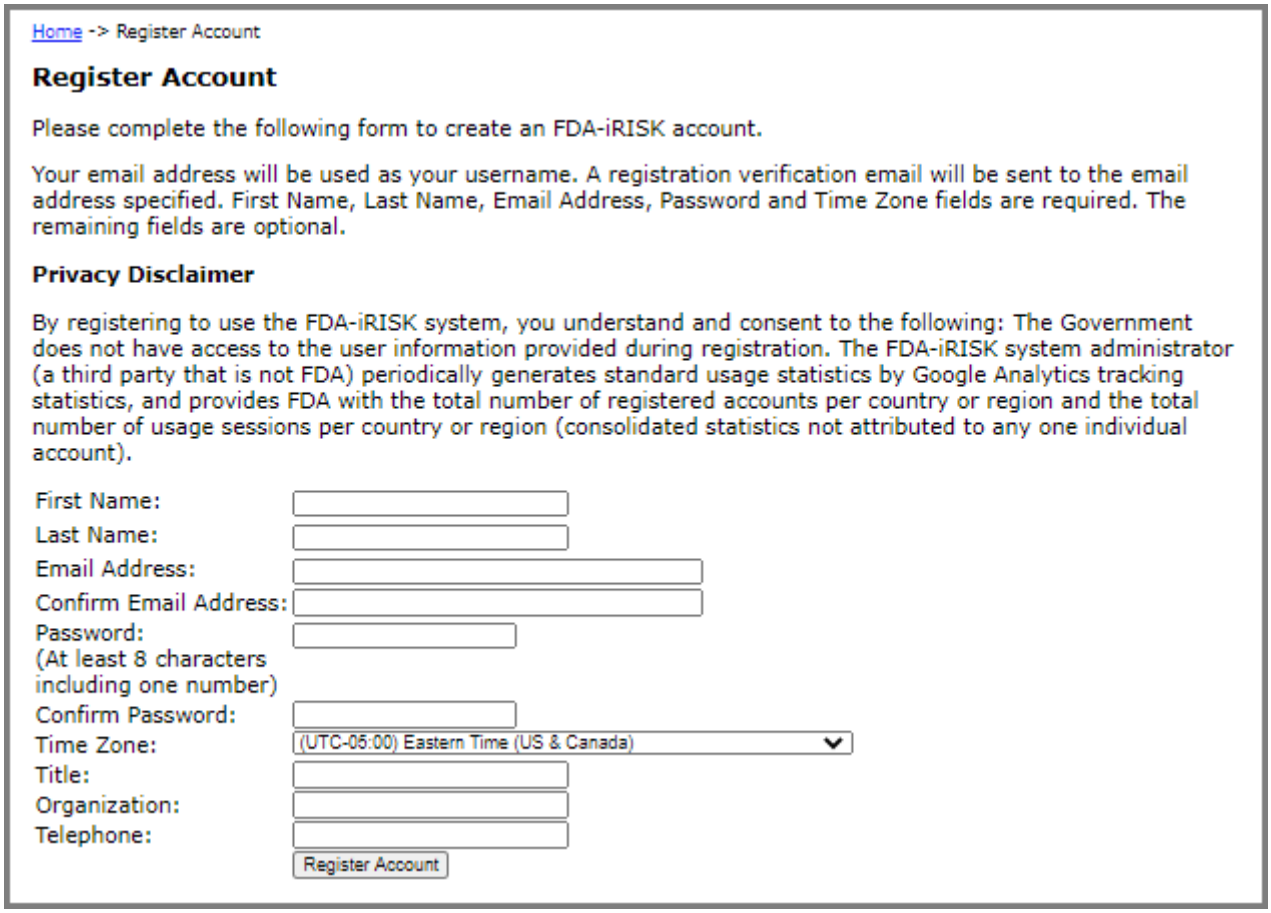


The main FDA-iRISK page consists of the following tabs:

- **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.


Home -> Register Account

Register Account

Please complete the following form to create an FDA-iRISK account.

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.

Privacy Disclaimer

By registering to use the FDA-iRISK system, you understand and consent to the following: The Government does not have access to the user information provided during registration. The FDA-iRISK system administrator (a third party that is not FDA) periodically generates standard usage statistics by Google Analytics tracking statistics, and provides FDA with the total number of registered accounts per country or region and the total number of usage sessions per country or region (consolidated statistics not attributed to any one individual account).

First Name:
Last Name:
Email Address:
Confirm Email Address:
Password:
(At least 8 characters including one number)
Confirm Password:
Time Zone: (UTC-05:00) Eastern Time (US & Canada)
Title:
Organization:
Telephone:
Register Account

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.

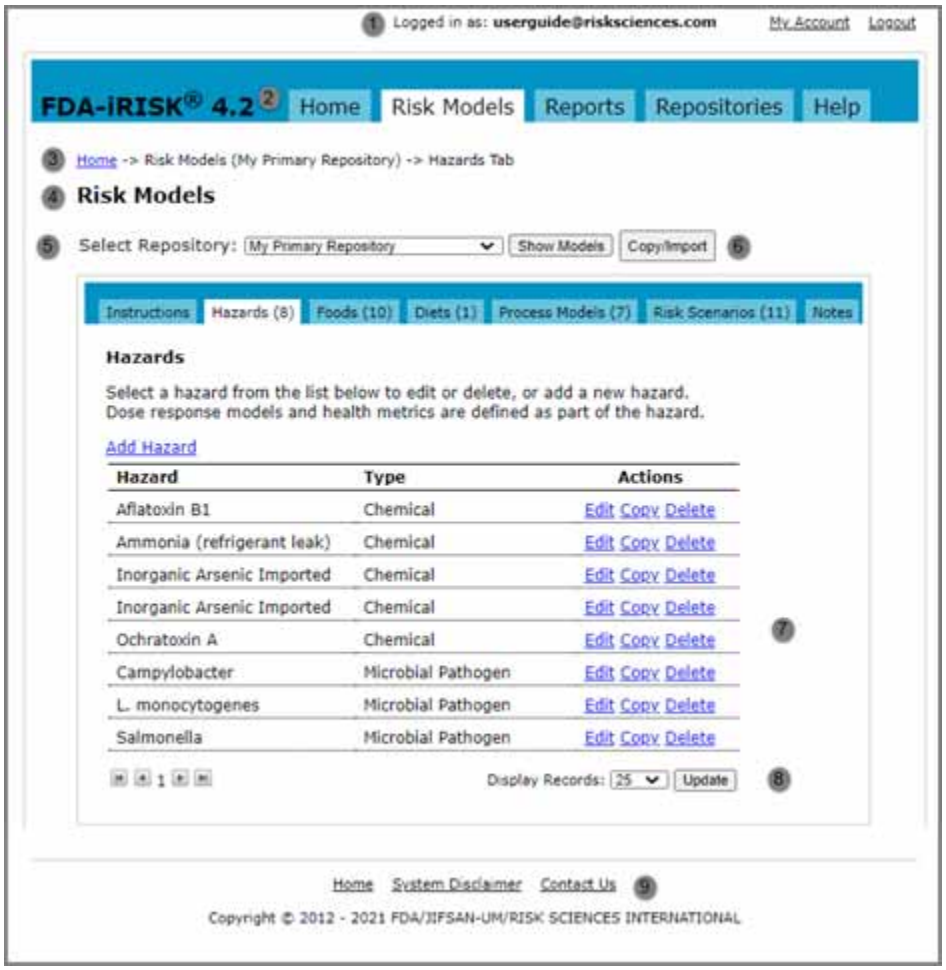
3 Click **Login**. The Risk Models page opens.

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 Titl**e 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.

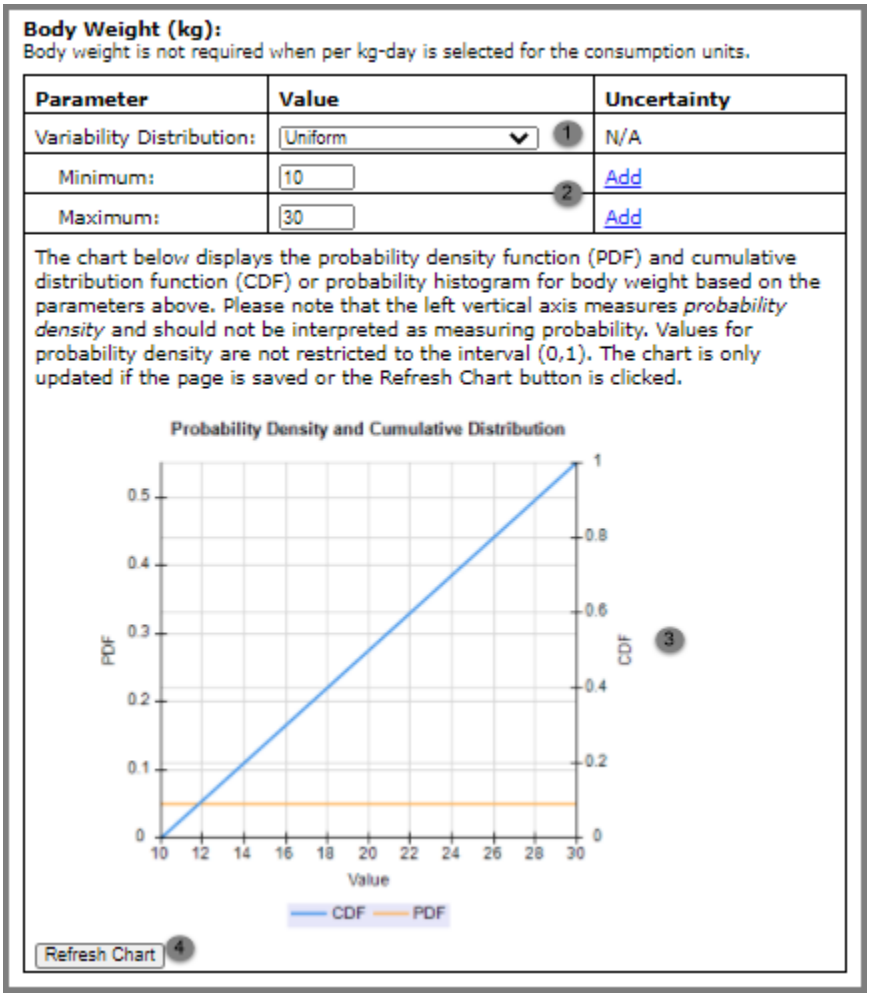
You may enter the value in standard notation:

You may also enter the value in scientific notation:

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.

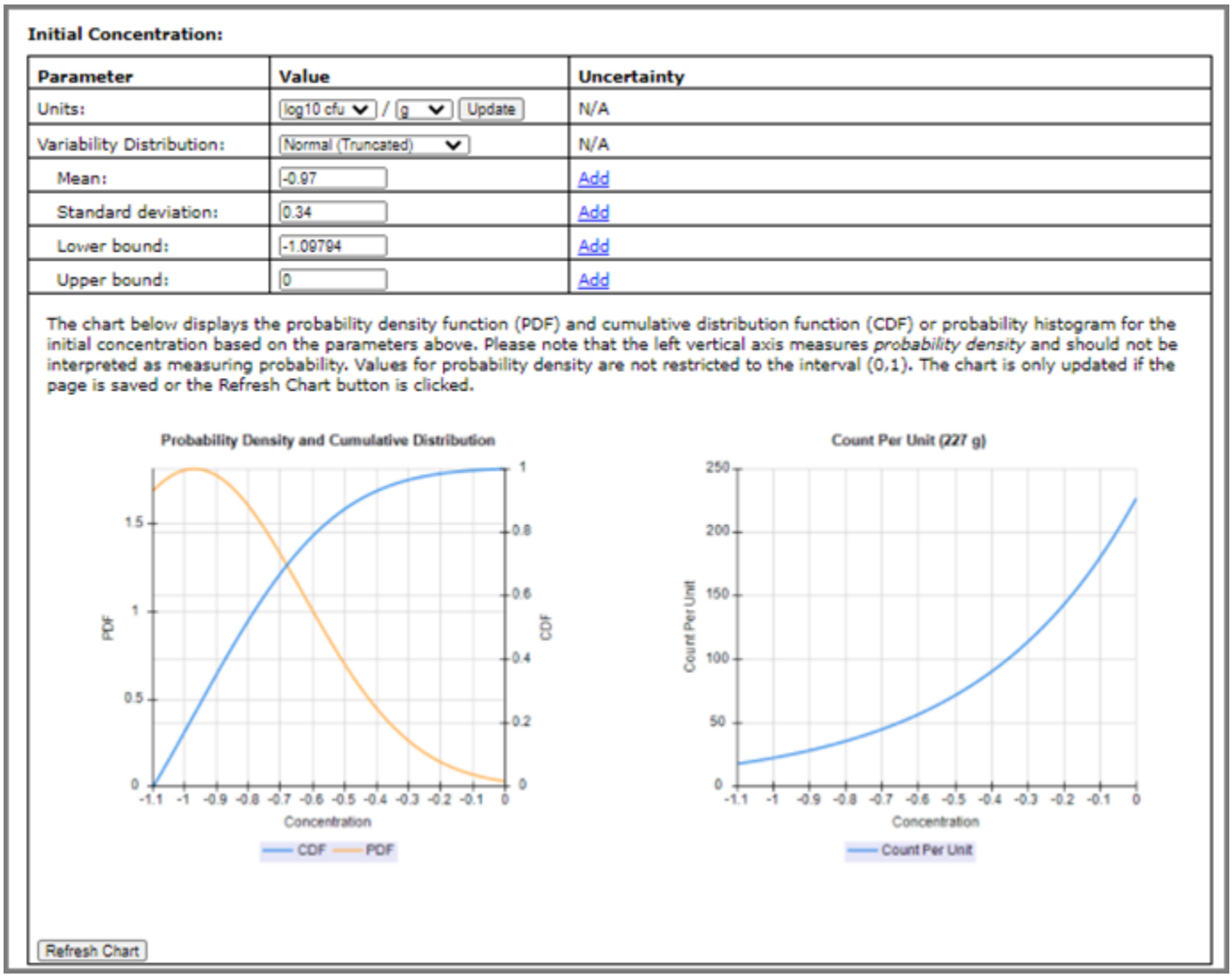


To achieve this, you would first select Uniform from the list of available distribution options 1. The page reloads and displays the Minimum and Maximum parameters 2. (The parameters that display depend on the distribution option that you select.)

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

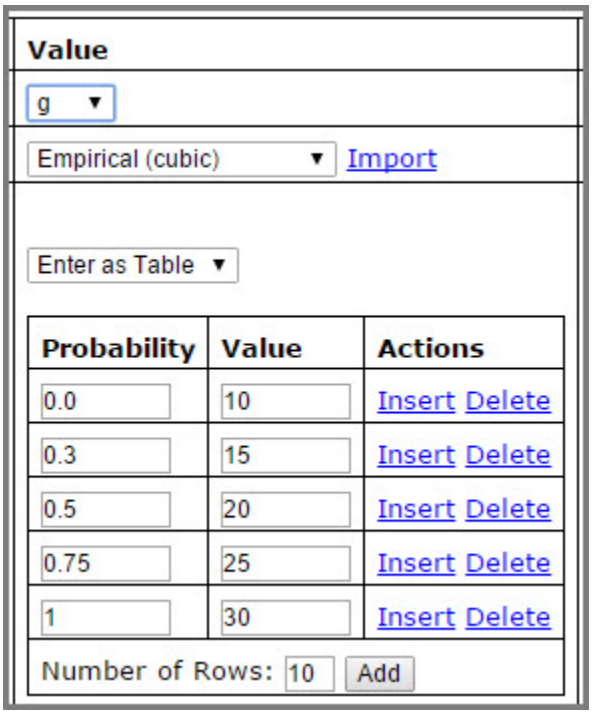
Consider the following:

- 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).

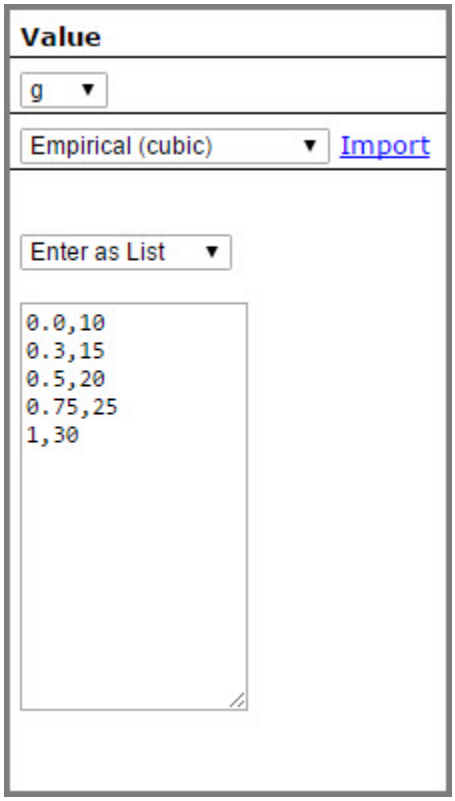
- Cumulative probabilities must be increasing and unique. Values must also be increasing but duplicates values are allowed.
- For each cumulative probability, the probability is given an outcome that is less than or equal to the corresponding value.
- Parameters for the cumulative empirical distributions (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:



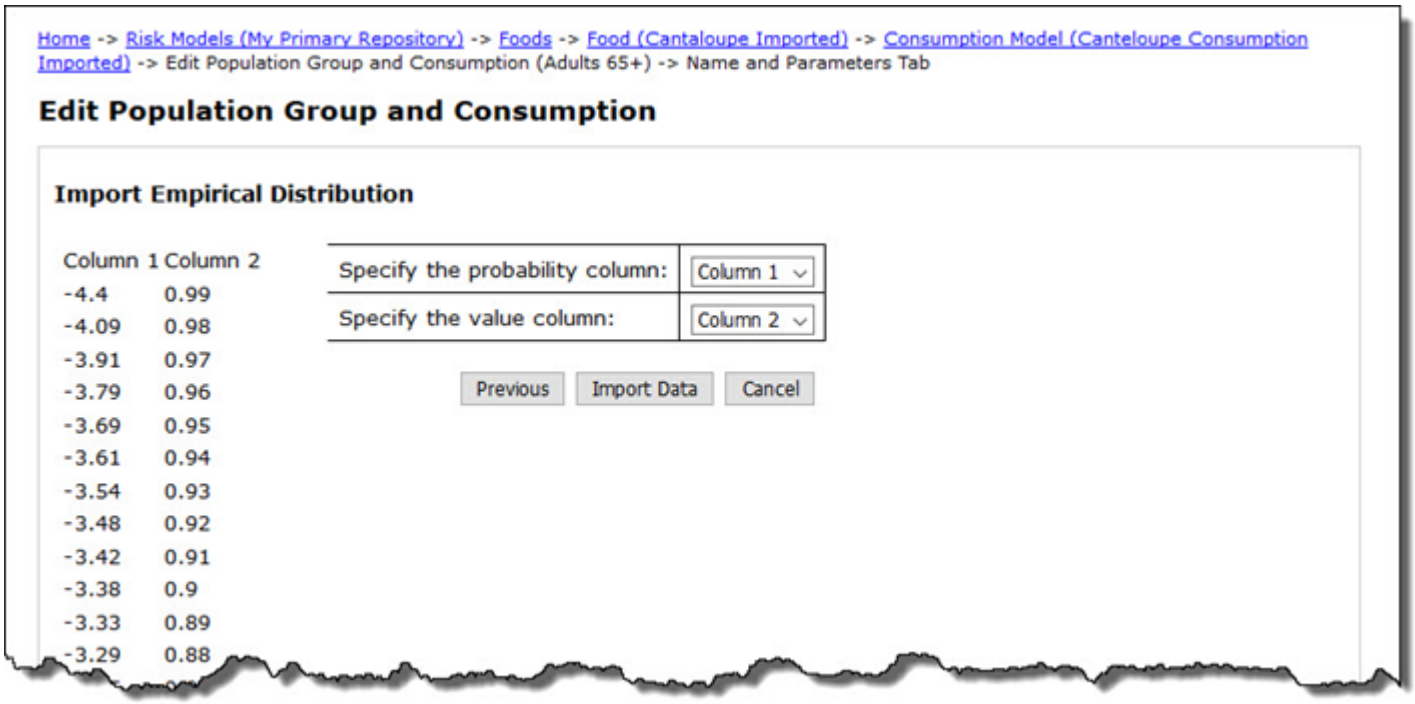
Example entering the same data in an input field:



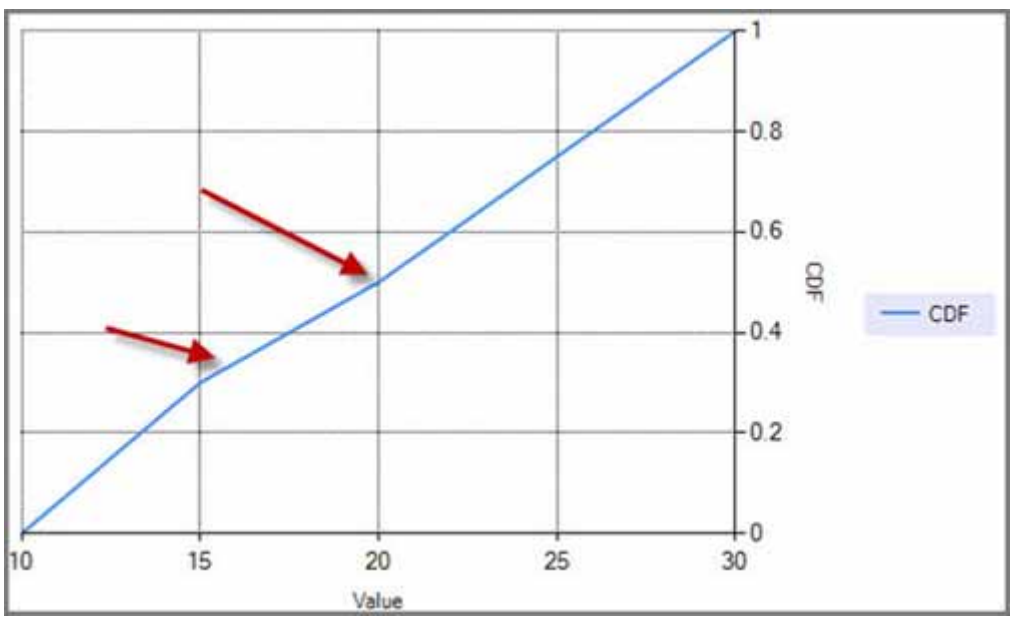
Alternatively, you can click the Import link to import empirical distributions from text, CSV, or Microsoft Excel files.

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).

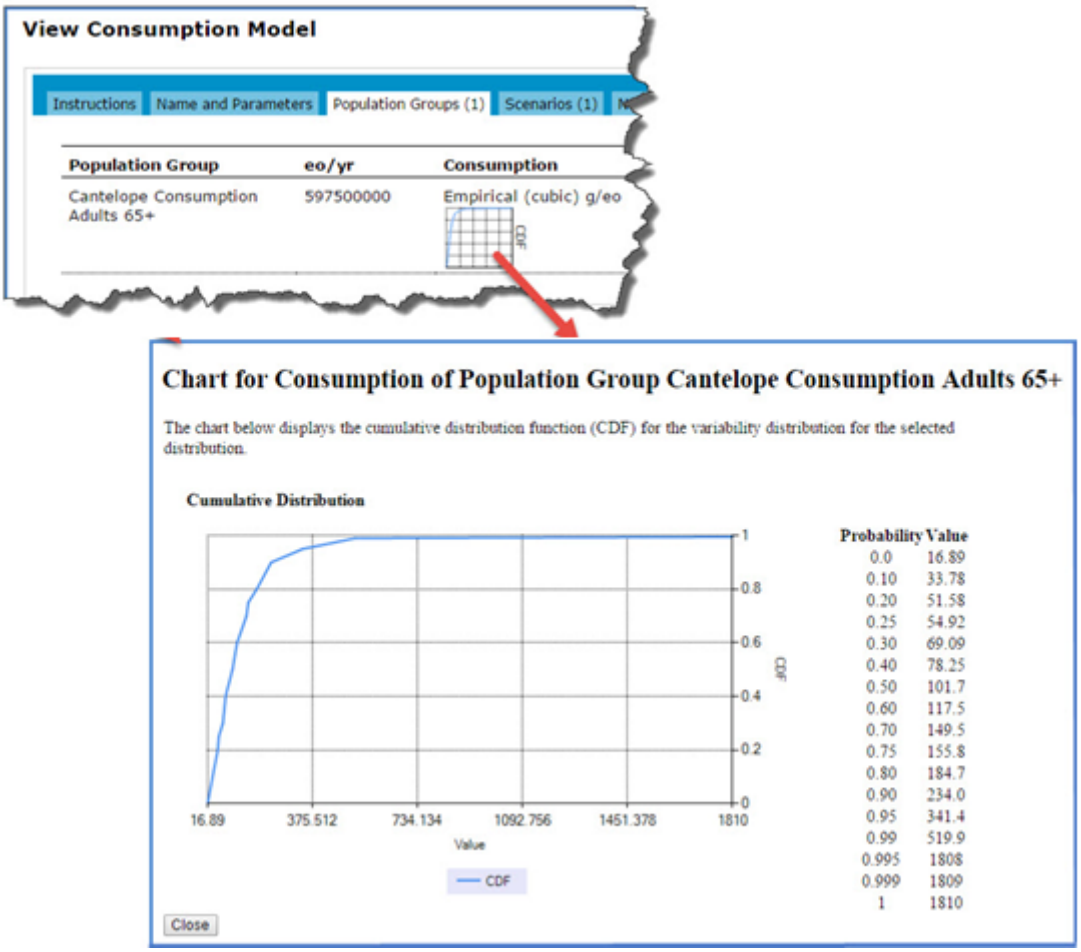


Note that the chart of the defined distribution uses linear interpolation between data points for both Empirical (cubic) and Empirical (linear):



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 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 of 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:

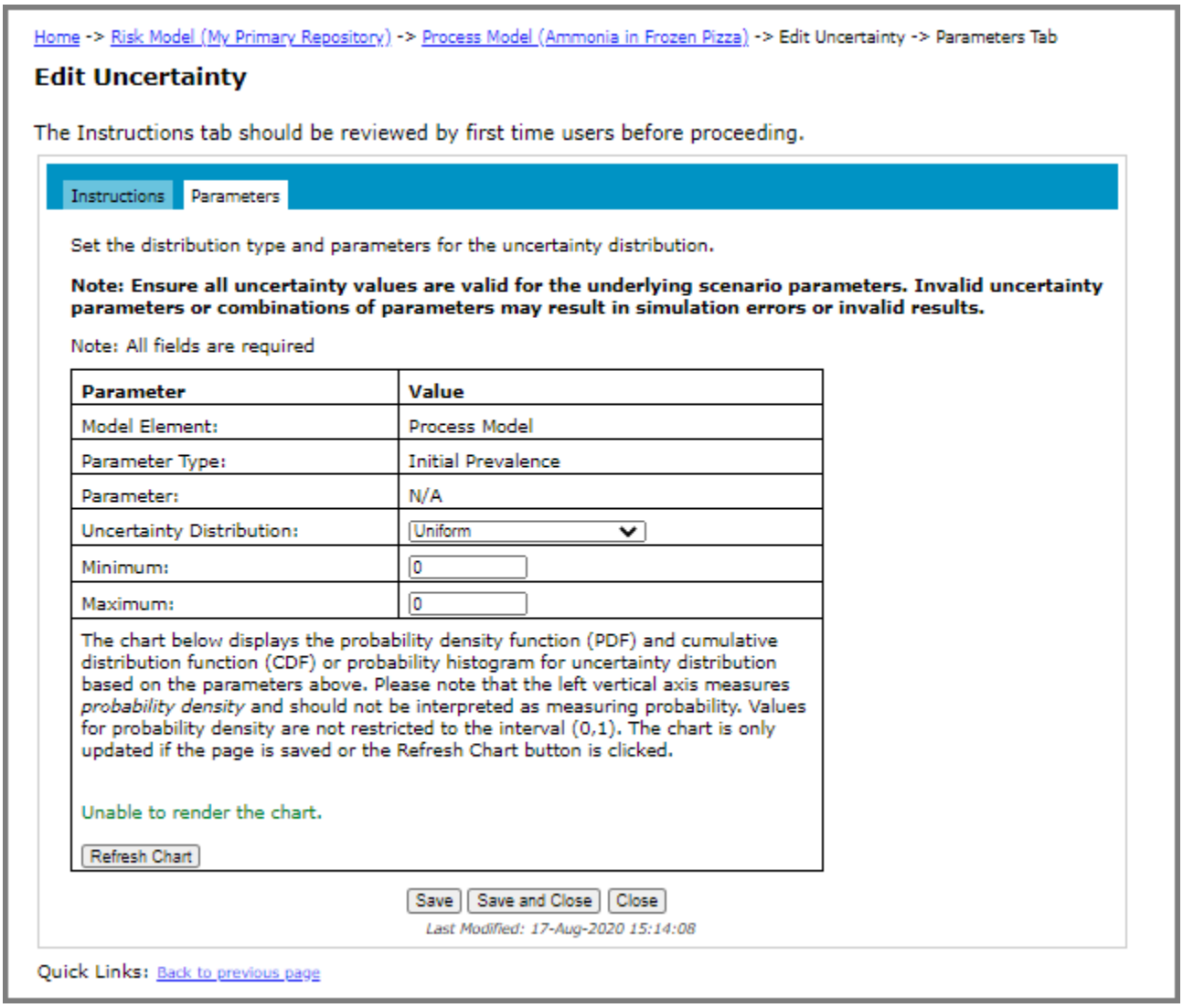
Initial Contamination, Unit Size and Prevalence:

Parameter	Value	Uncertainty
Hazard:	Ammonia	N/A
Food:	Frozen Pizza	N/A
Initial Units are Contaminated:	☑	N/A
Initial Prevalence:	1E-6	Add
Select Mass Units:	g	N/A

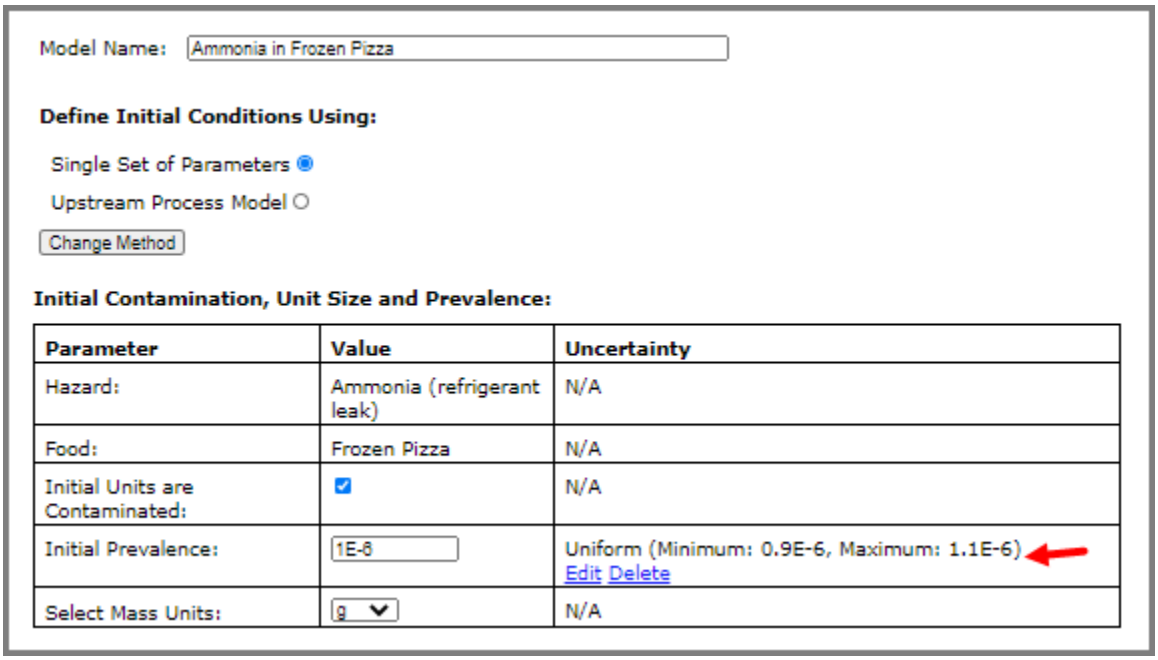
All model parameters support single parameter uncertainty. Some model parameters also support linked uncertainty parameters. See the following sections for more information on these uncertainty types.

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



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.



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:	☑	N/A
Initial Prevalence:	5.5E-6	Linked uncertainty, edit to view details. Edit Delete
Select Mass Units:	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(5th Percentile, Mode, 95th 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(5th Percentile, 95th Percentile)	UniformPercentiles(2,8)

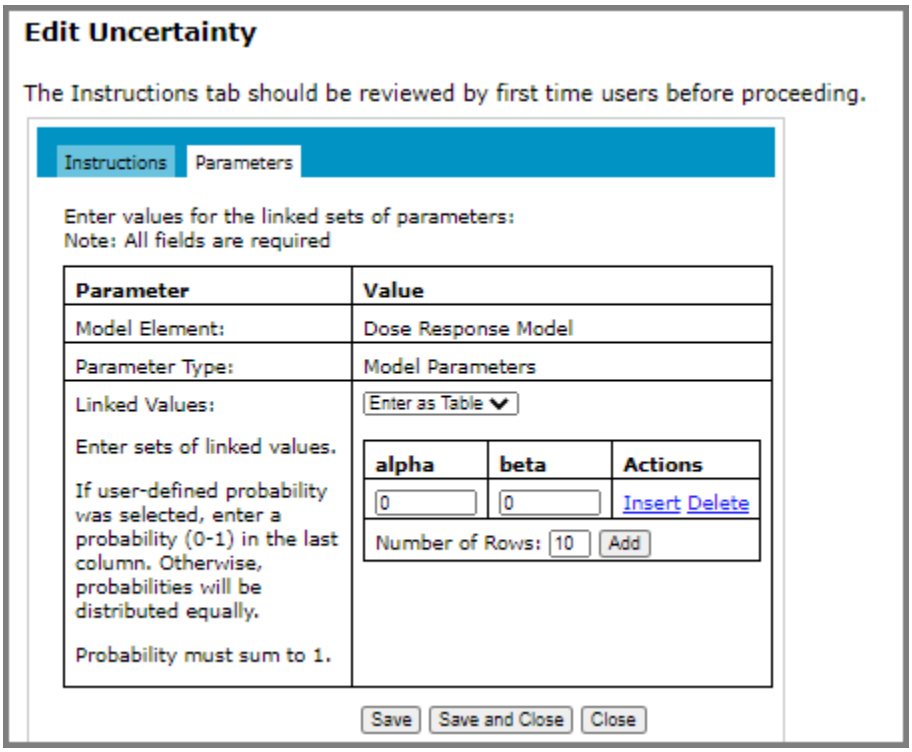
Uncertainty for Dose Response Models

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 individuals probabilities for each set. The Edit Uncertainty page opens where you can enter sets of linked values.



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

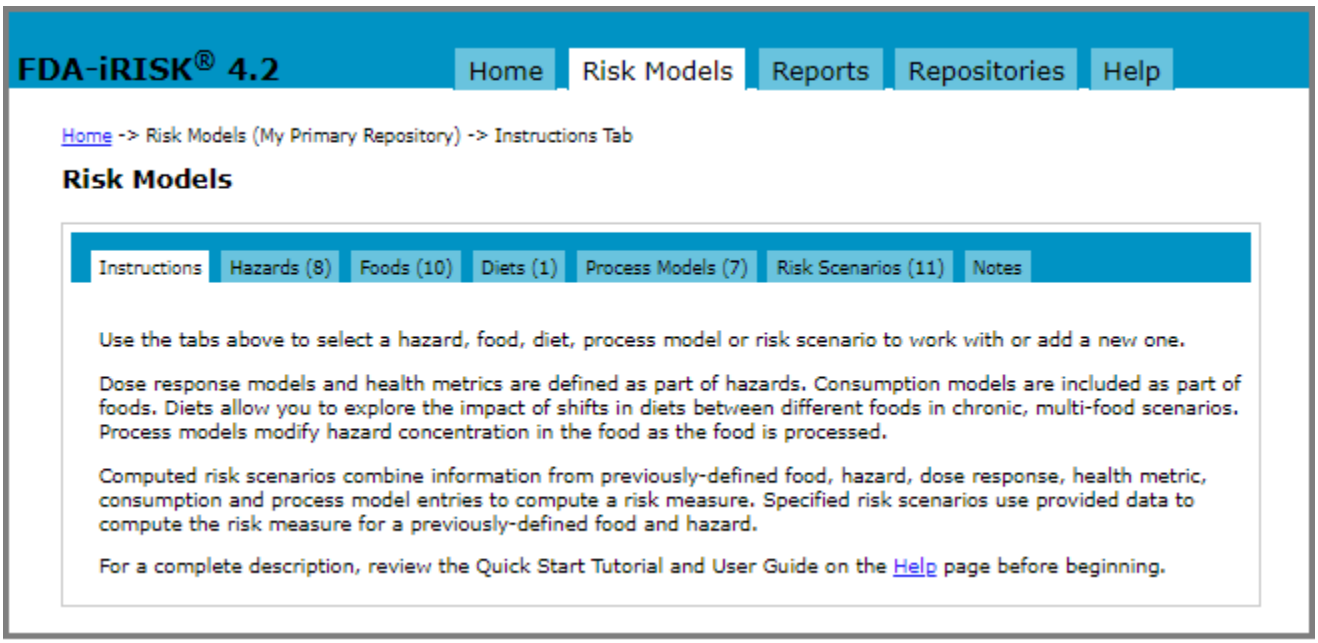
Hazards

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**.

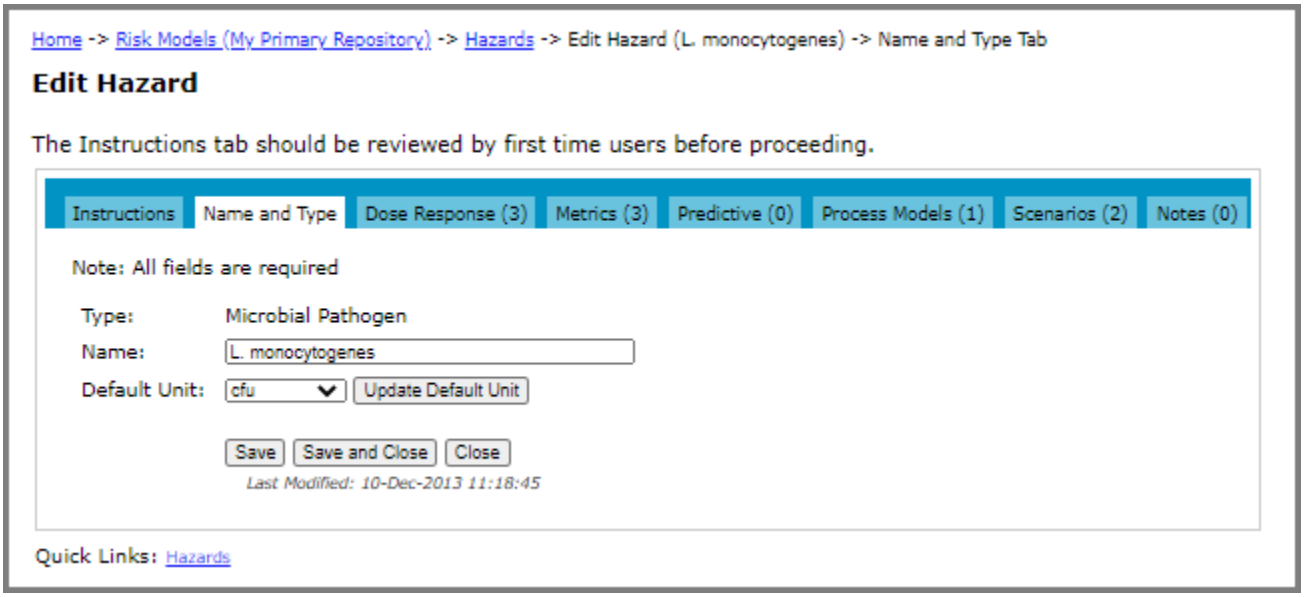
3 Click the **Hazards** tab, and then click the **Add Hazard** link. The Add Hazard page opens.



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.



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**.

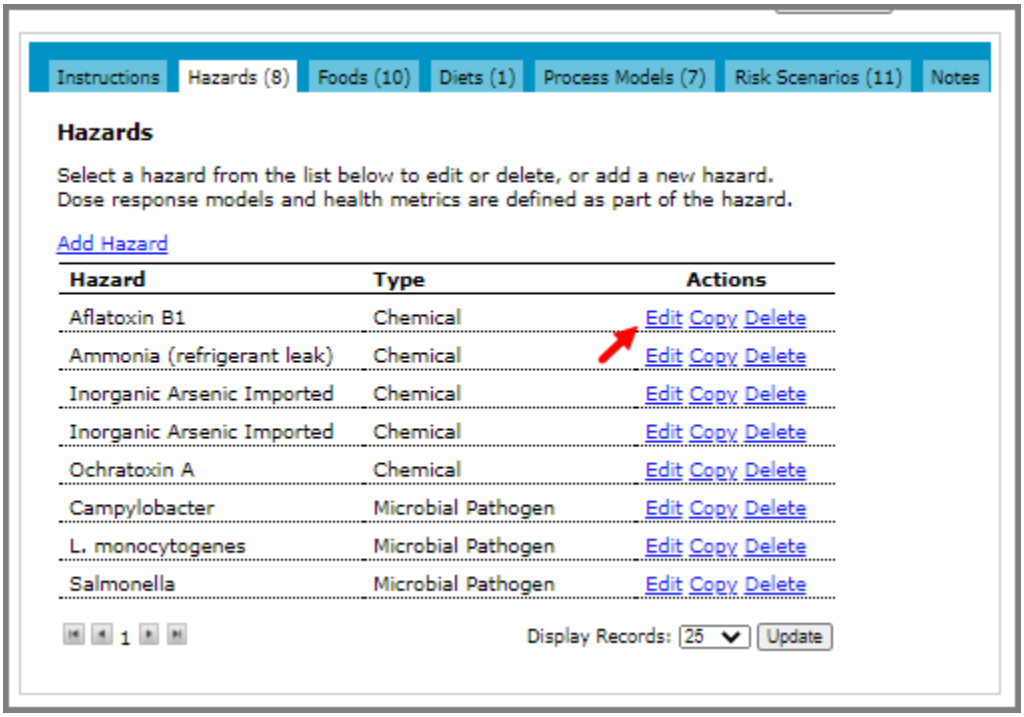
Editing a Hazard

You can edit the hazard name and default unit.

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

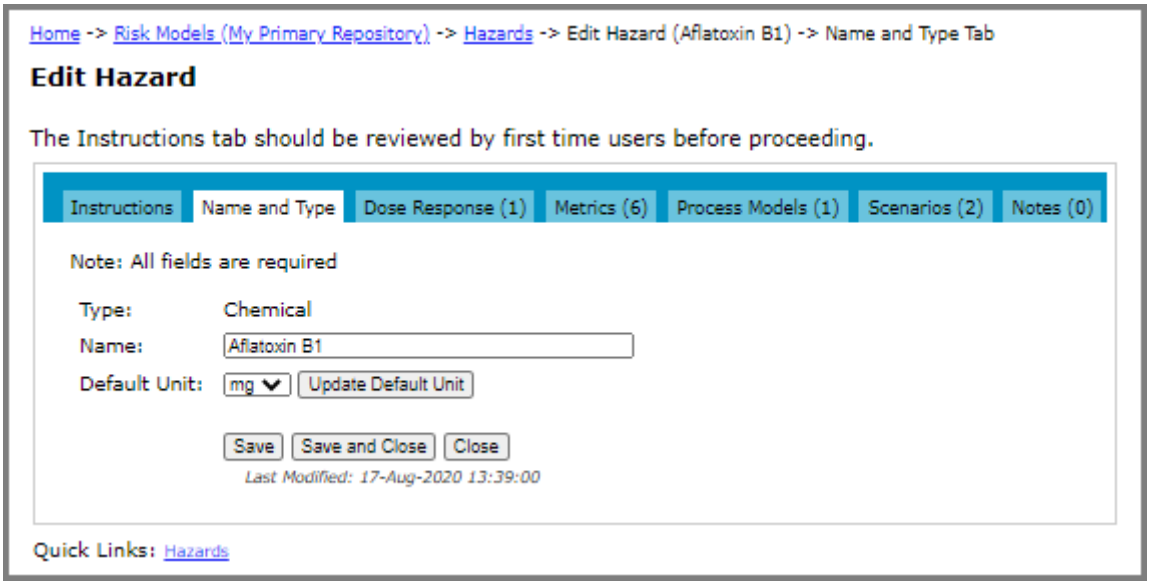
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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



4 On the **Edit Hazard** page, make one or more of the following changes:

- The hazard name.
- The default units for the hazard.



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.

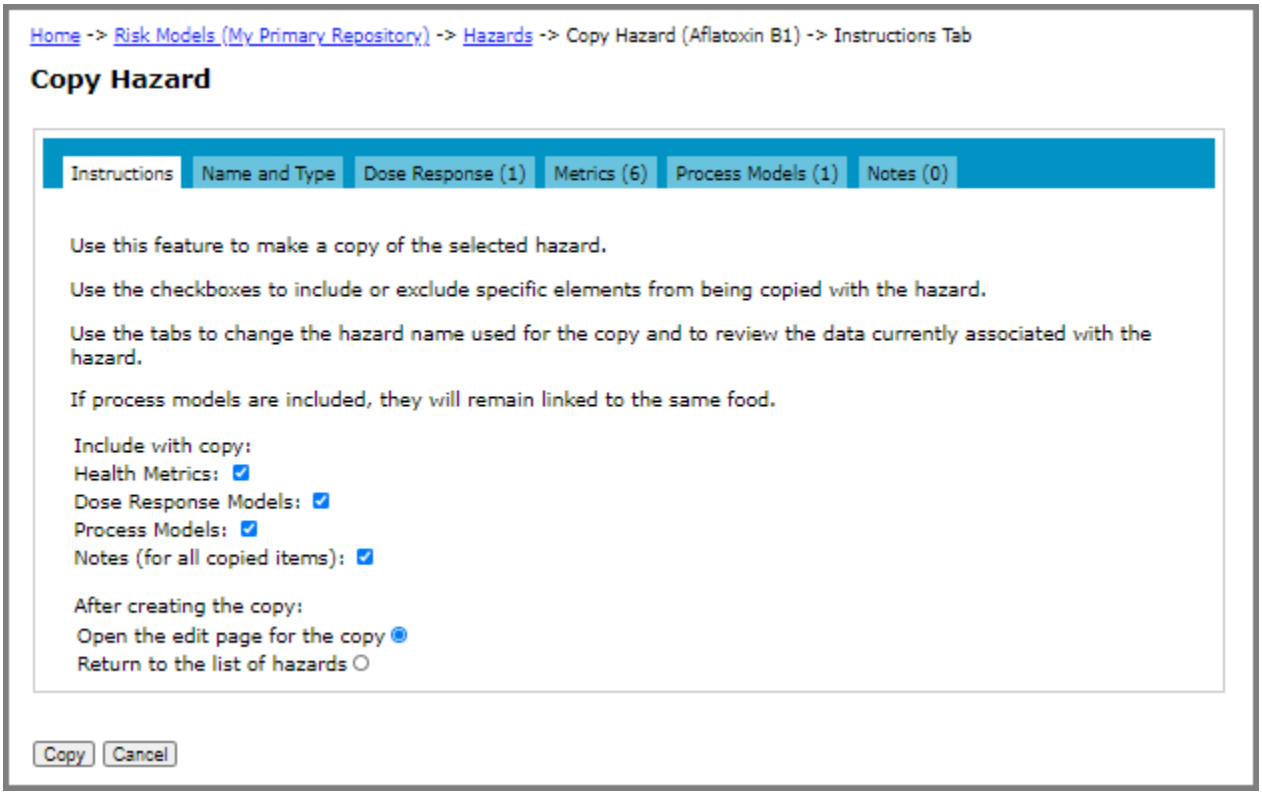
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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*.

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 Hazard

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

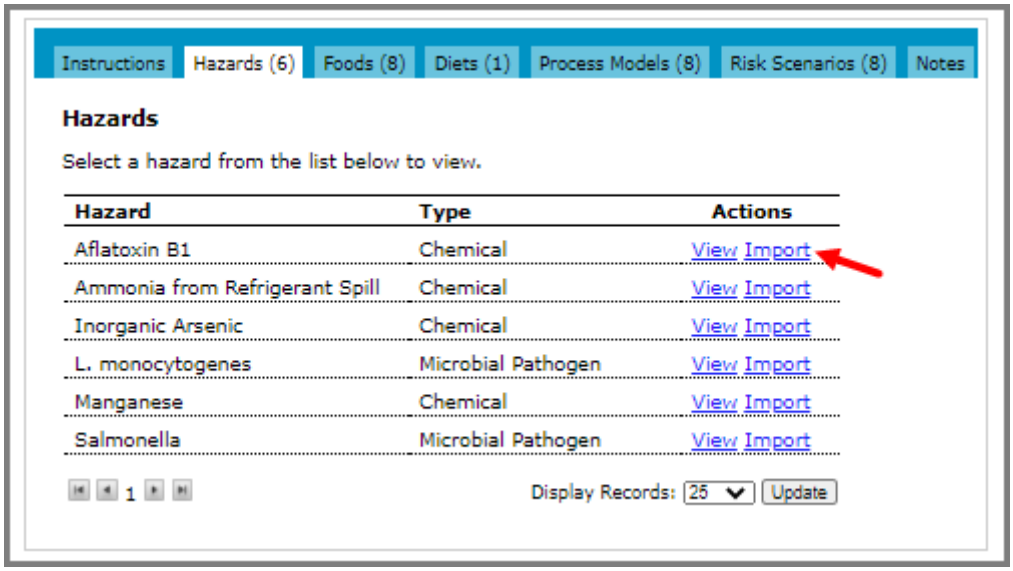
When you import a hazard, all associated elements are also imported, including dose response models, health metrics, and notes. However, the process model is not imported. For information about how to import a complete process model, see *"Importing a Process Model" on page 93*.

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

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 **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.

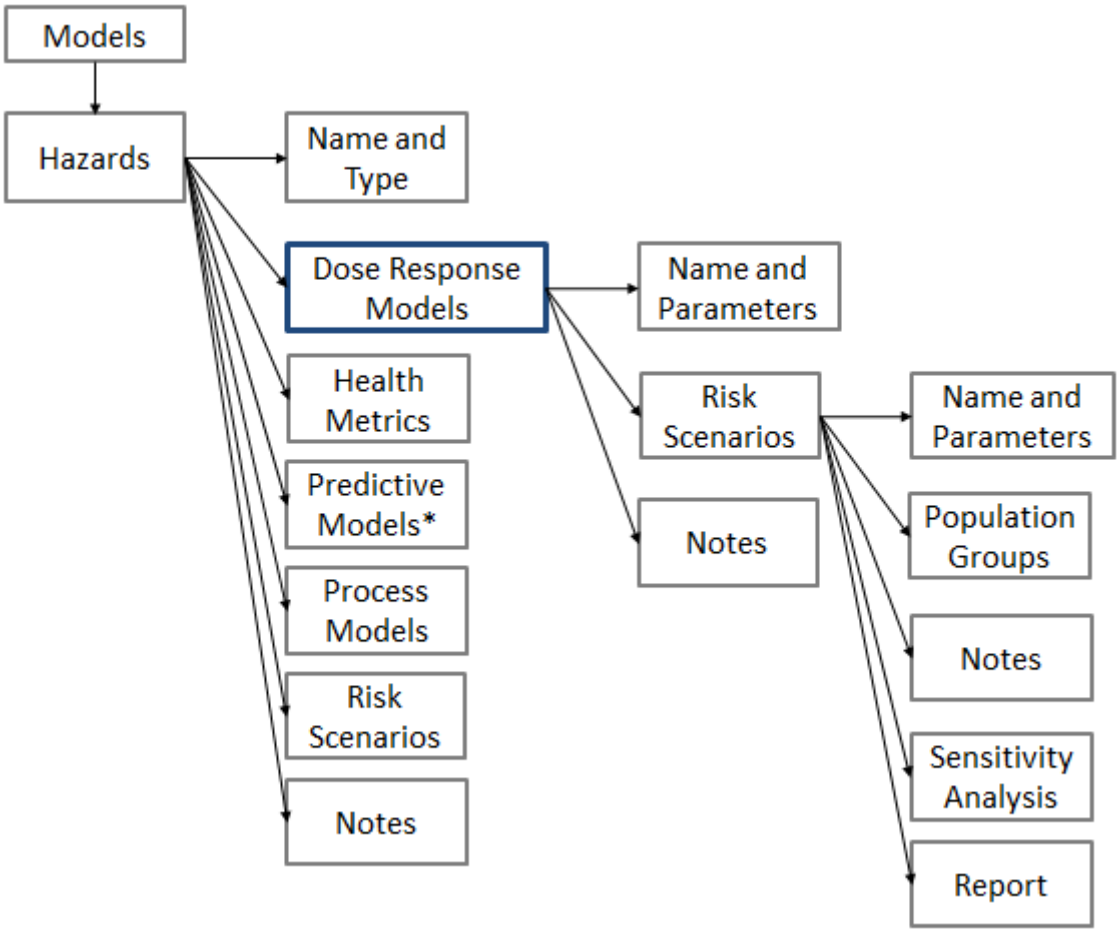
7 Click **Import**.

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: Acute

Next Cancel

Available models:

for Acute Exposure

- 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)

for Chronic Exposure

- 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.	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.	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**.

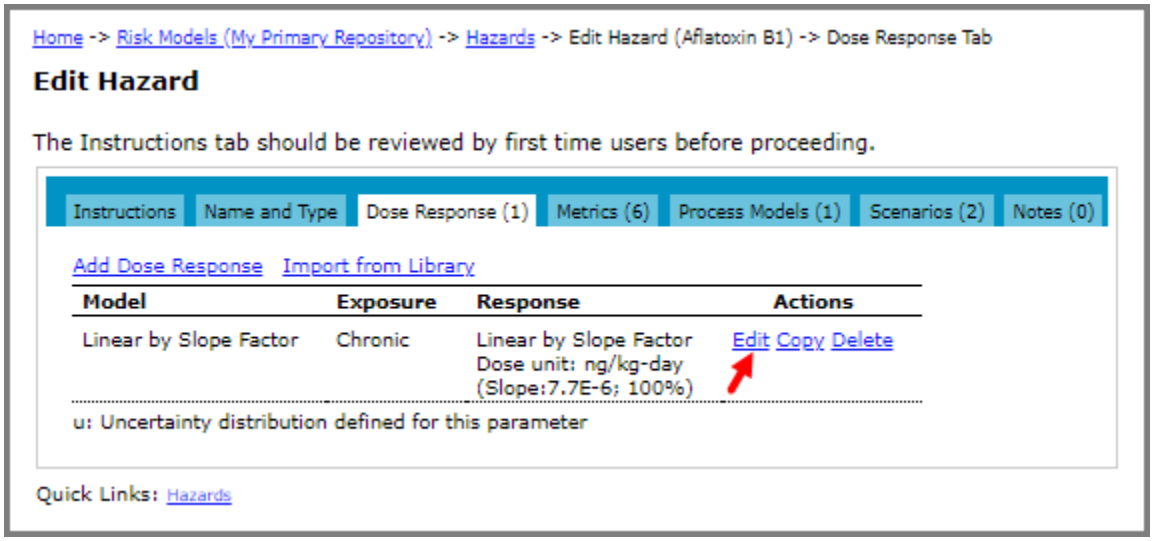
Editing a Dose Response Model

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

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 dose response model.

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

5 Click the **Delete** link to the right of the dose response model that you want to delete.

6 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.

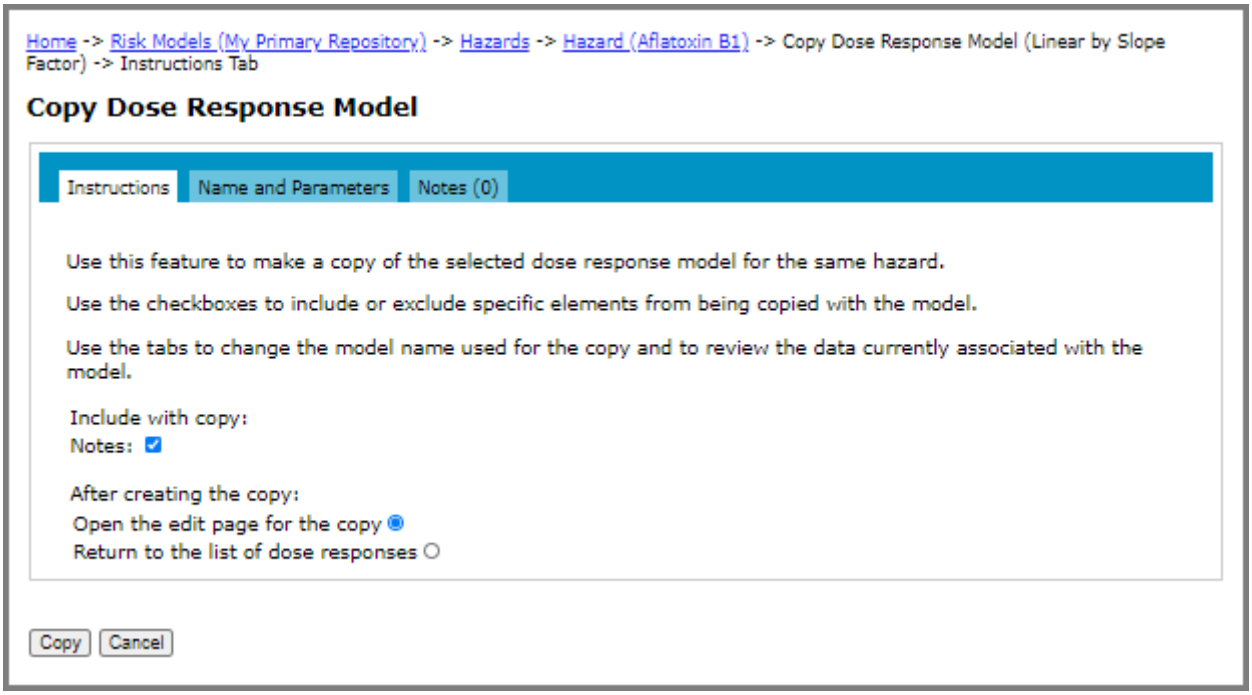
4 On the Edit Hazard page, click the **Dose Response** tab.

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.



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

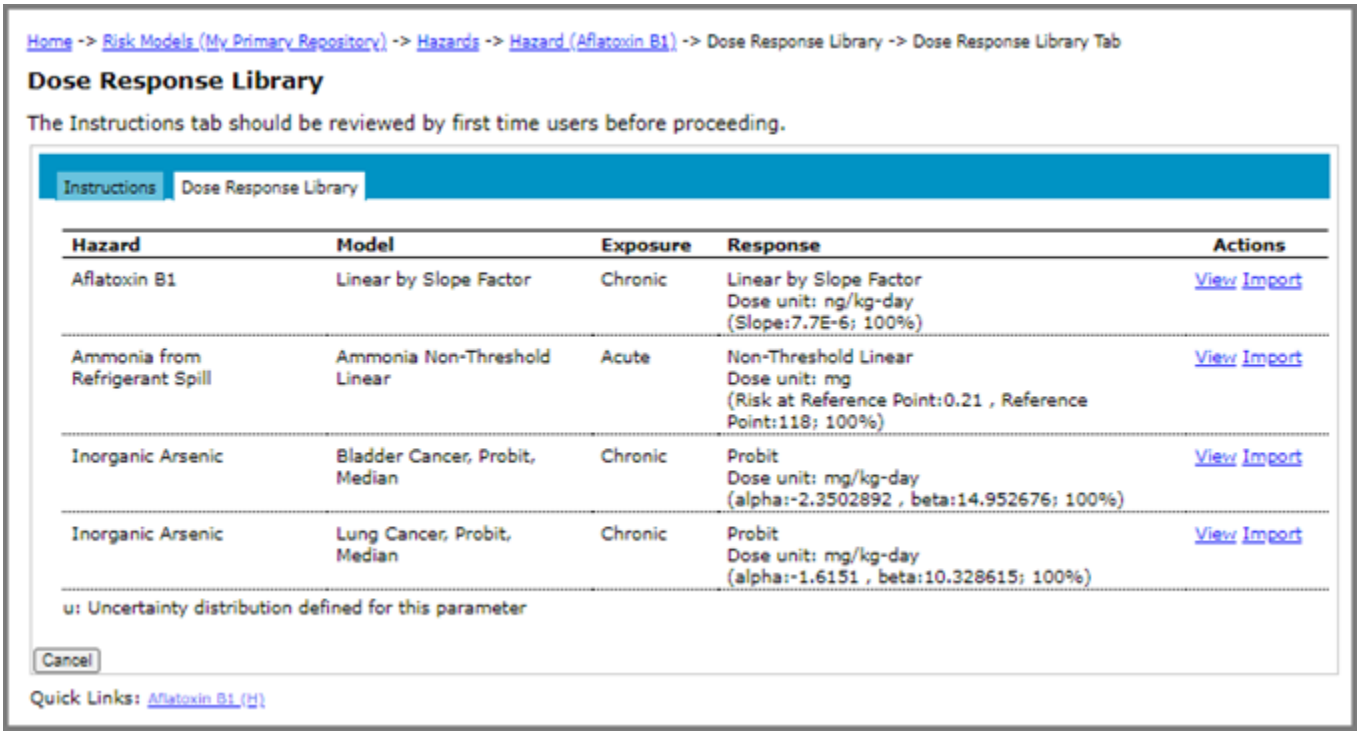
1 Click the **Risk Models** tab on the main tab bar.

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).



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*.

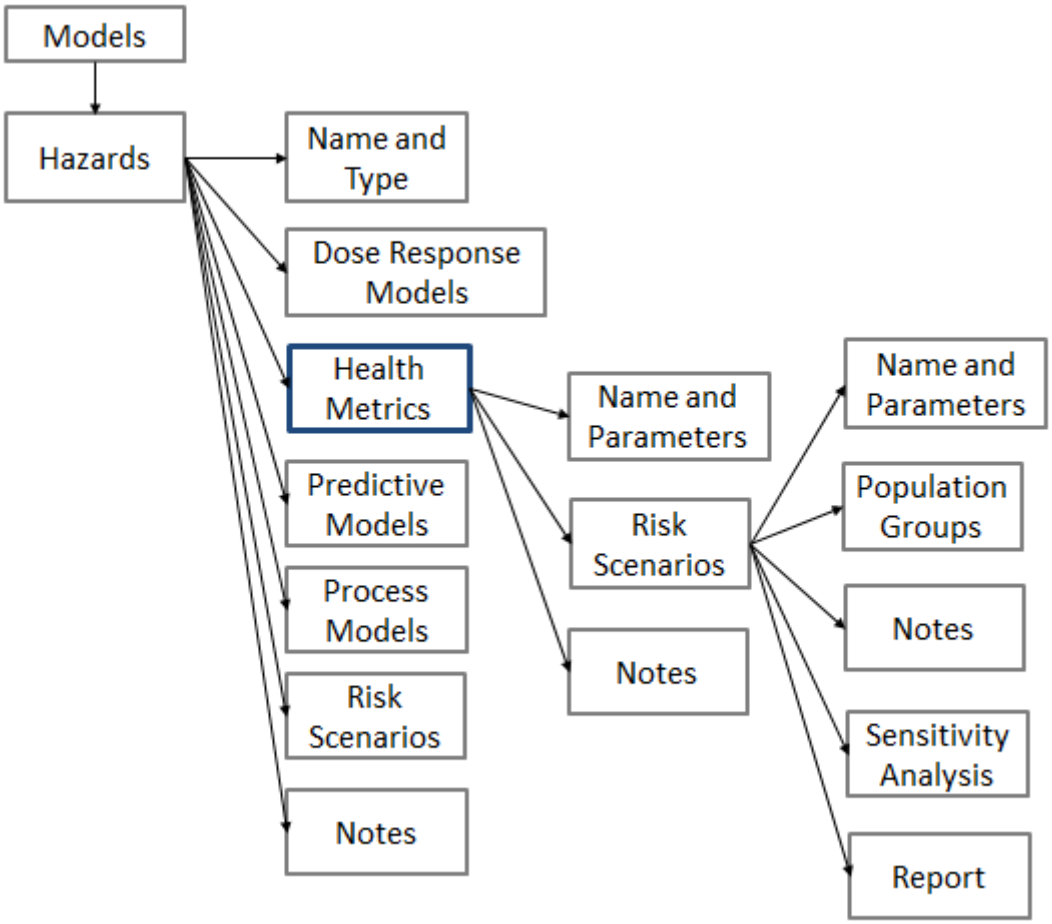
10 Click **Import**. The page reloads and a View Imported Dose Response link displays.

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.

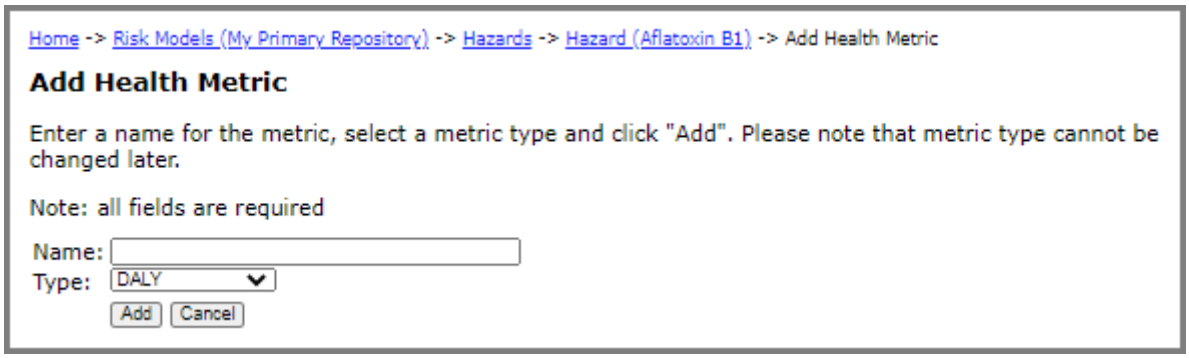
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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.



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.

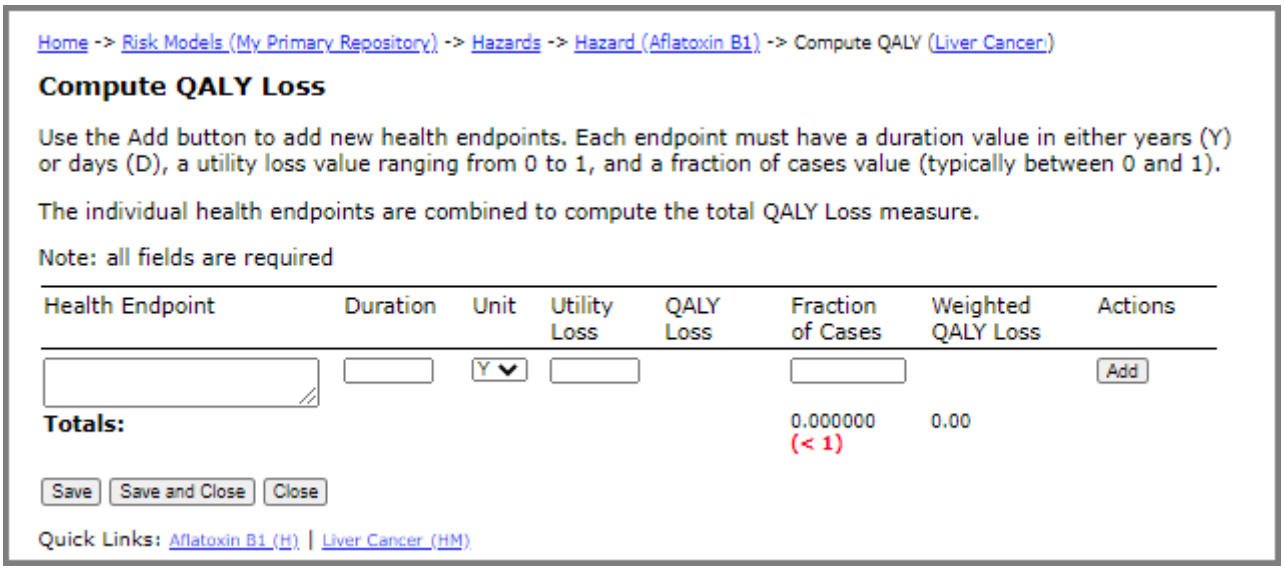
5 Click the **Add Health Metric** link.

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.



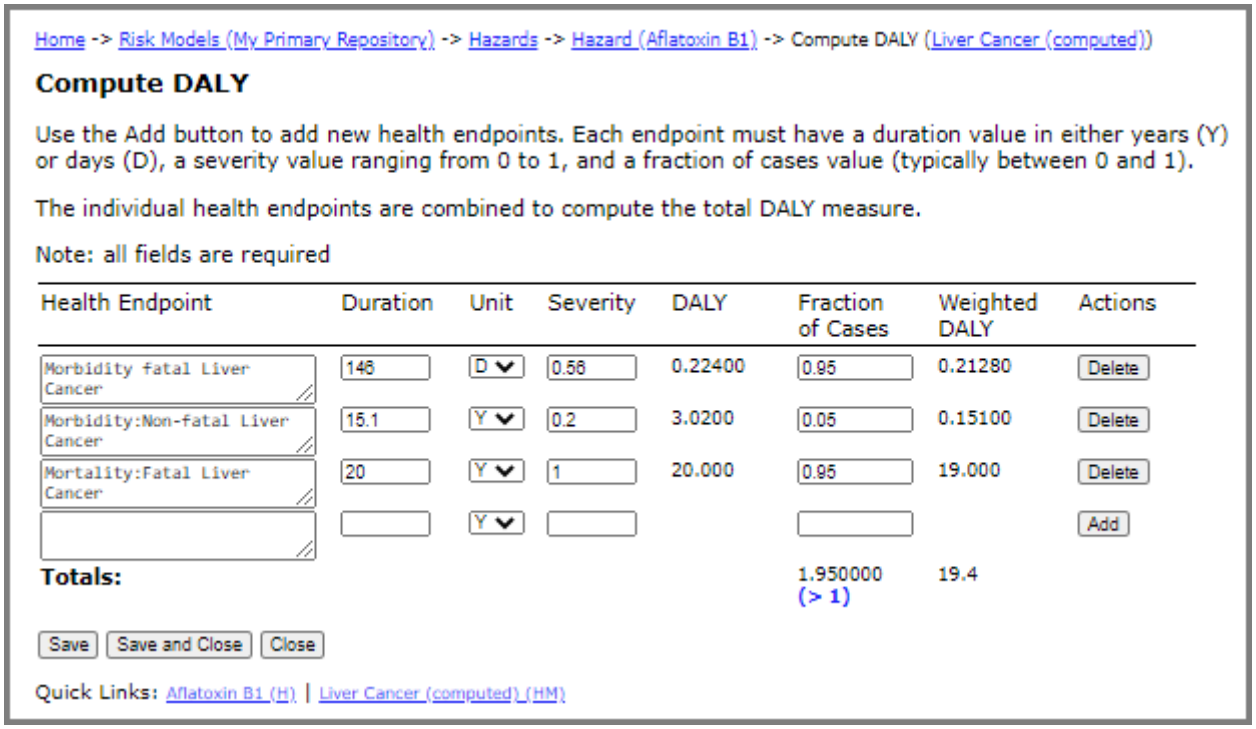
10 Under **Health Endpoint**, type the name of one of the relevant health endpoints resulting from exposure to the hazard in question in the empty input field.

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.



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

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.

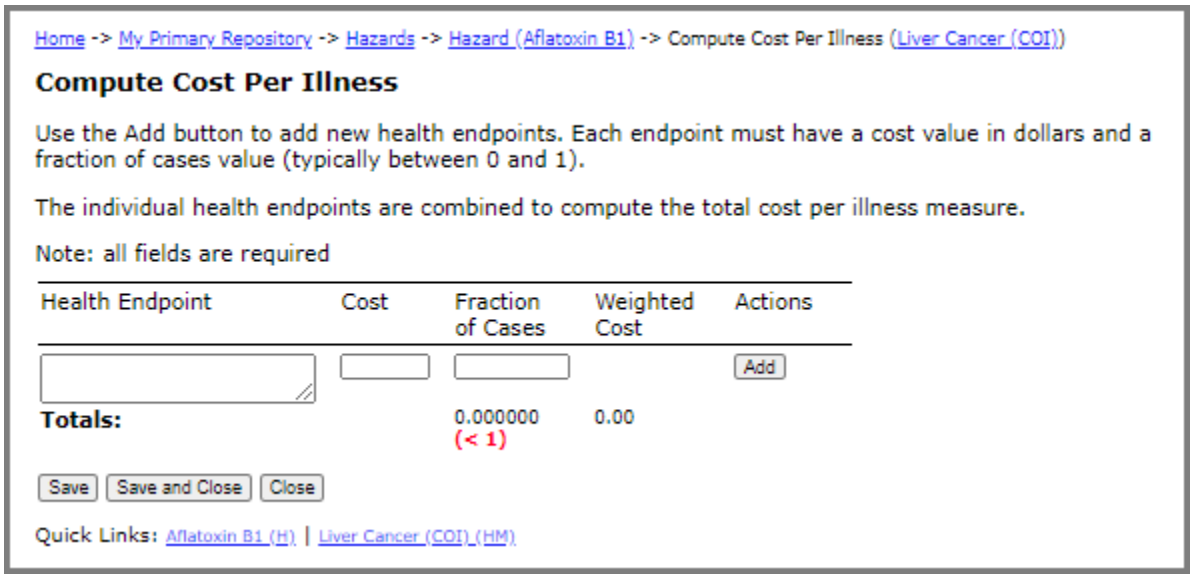
5 Click the **Add Health Metric** link.

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 **Cost per Illness**.

8 Click **Add**.

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



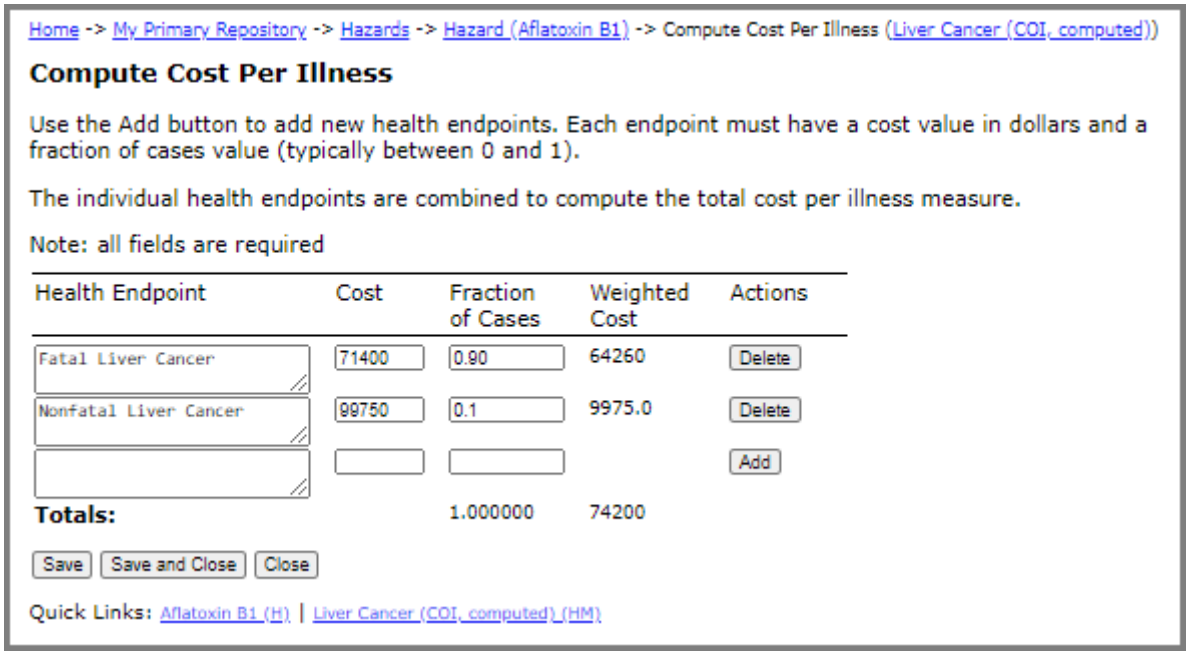
10 Under **Health Endpoint**, type the name of one of the relevant health endpoints resulting from exposure to the Hazard in question in the empty input field.

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.



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

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.

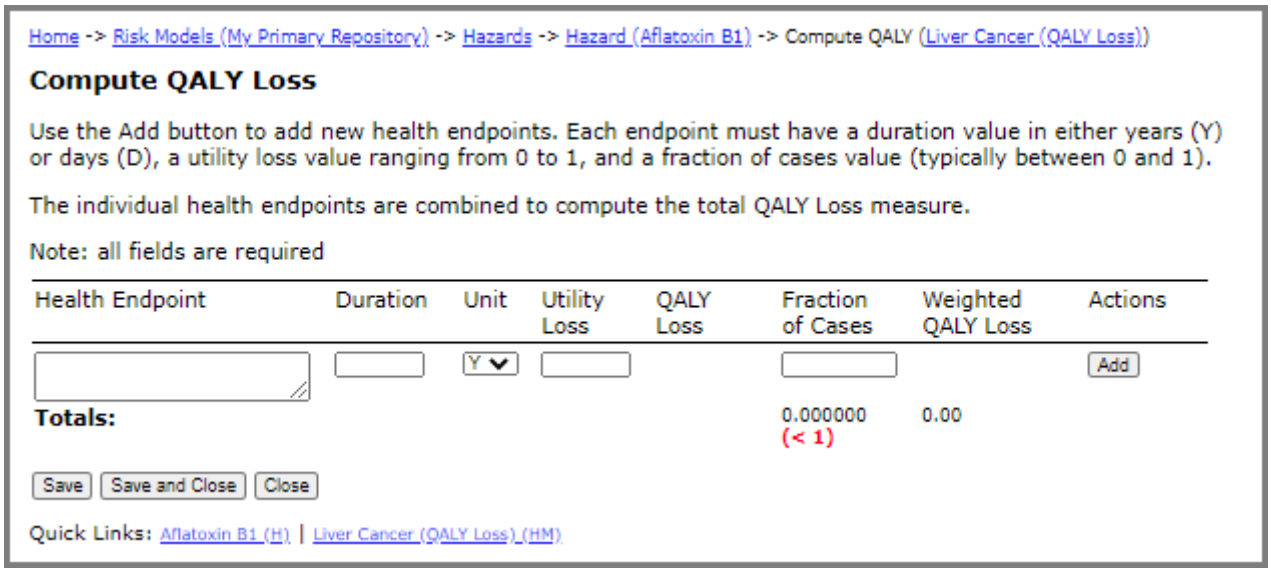
5 Click the **Add Health Metric** link.

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 **QALY Loss**.

8 Click **Add**.

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



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

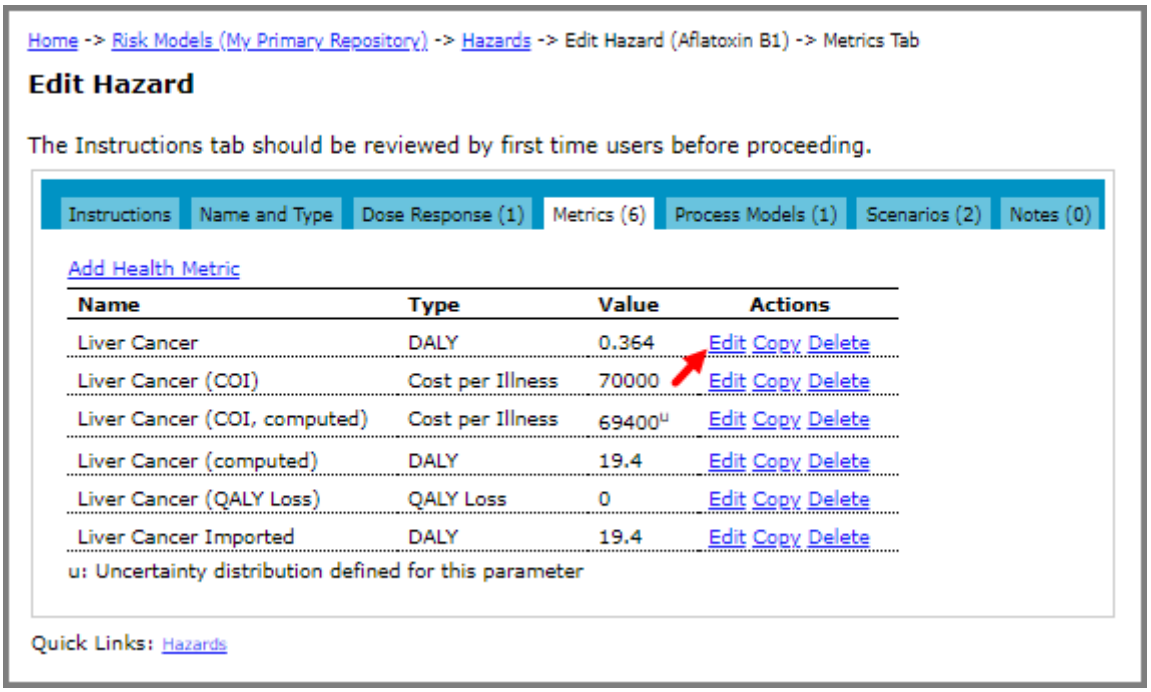
1 Click the **Risk Models** tab on the main tab bar.

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 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.



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**.

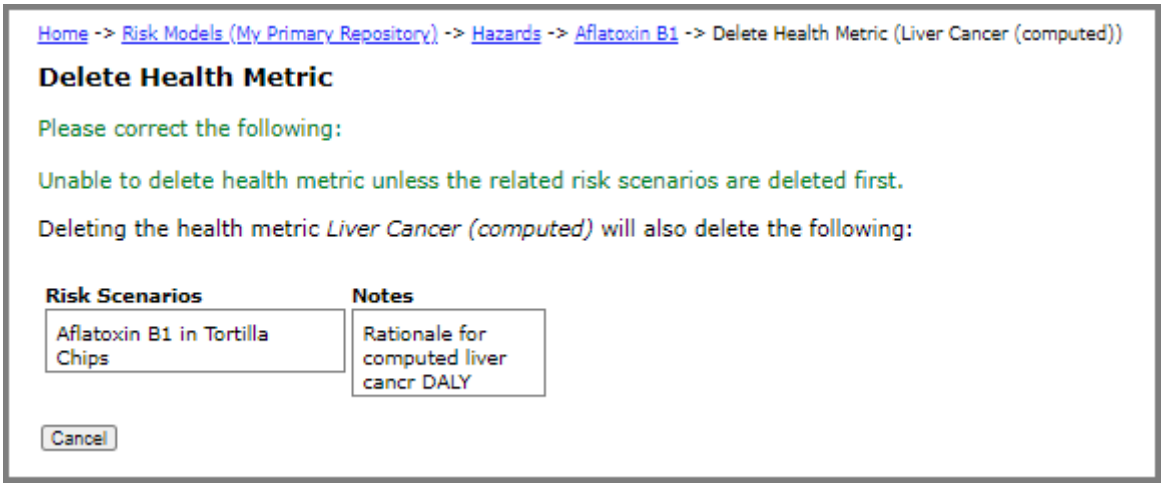
3 Click the **Hazards** tab, and then click the **Edit** link to the right of the hazard from which you want to delete a health metric.

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**.



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.

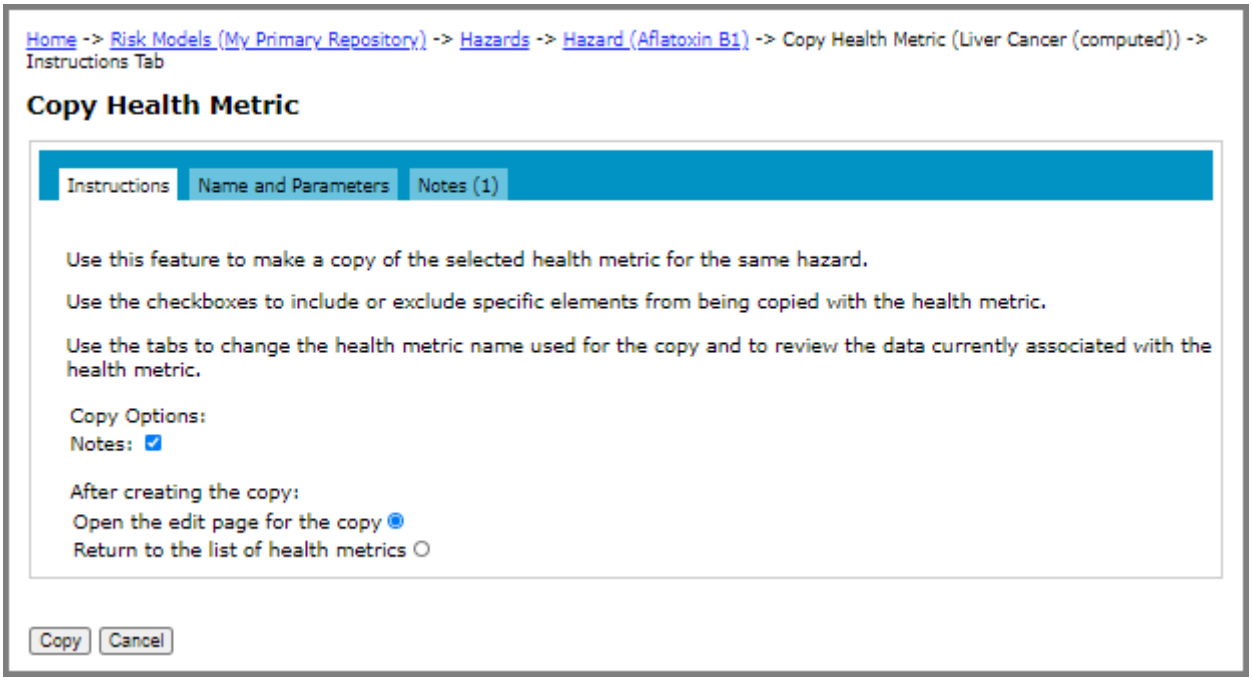
4 On the Edit Hazard page, click the **Metrics** tab.

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.



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 heath 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:

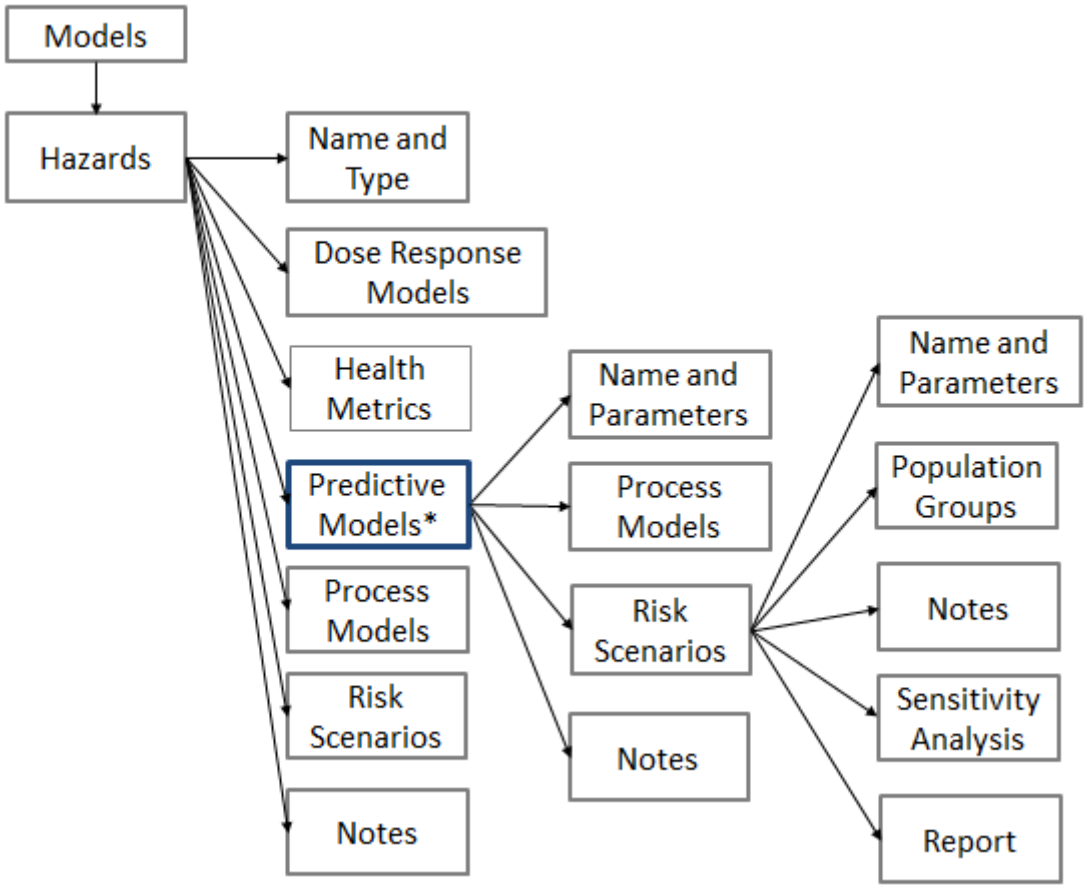
- To edit the imported health metric, click the **View Imported Dose Response** link.
- To return to the list of shared health metrics, click **Close**.

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.

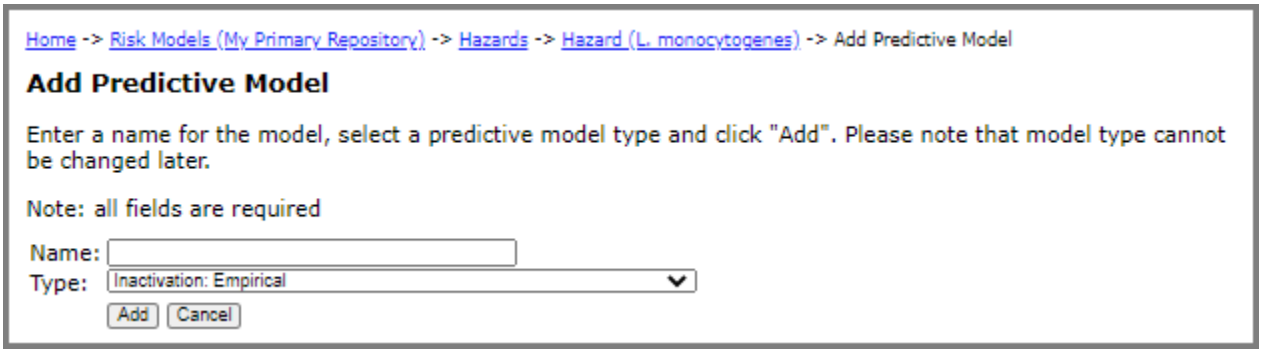
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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.



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

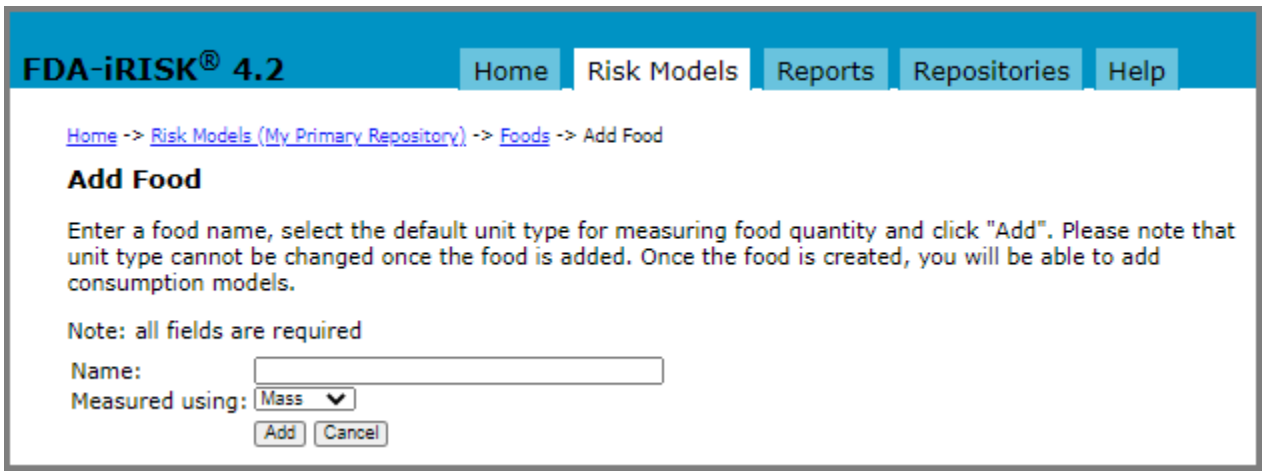
Foods

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.

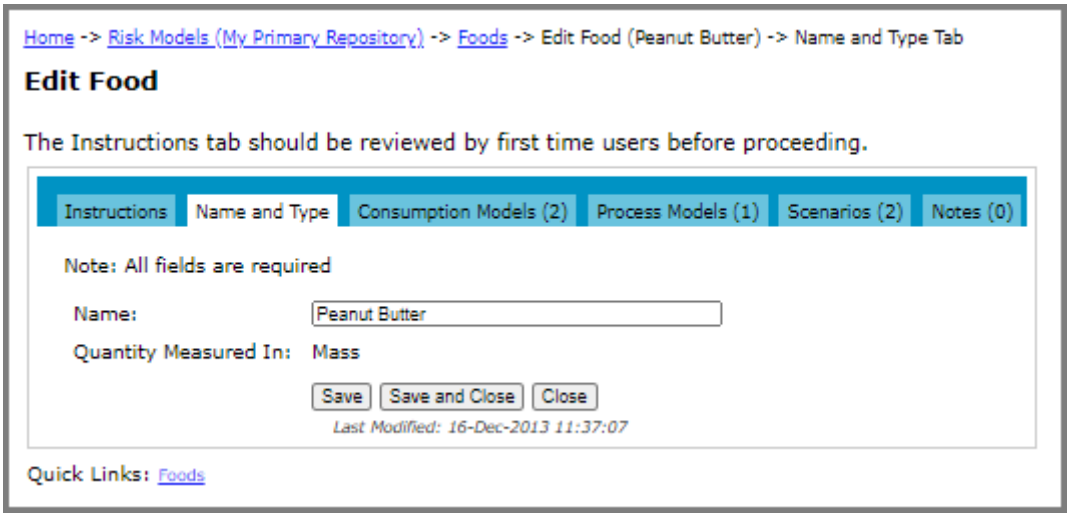


4 In the **Name** input field, enter a name for the food.

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.



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

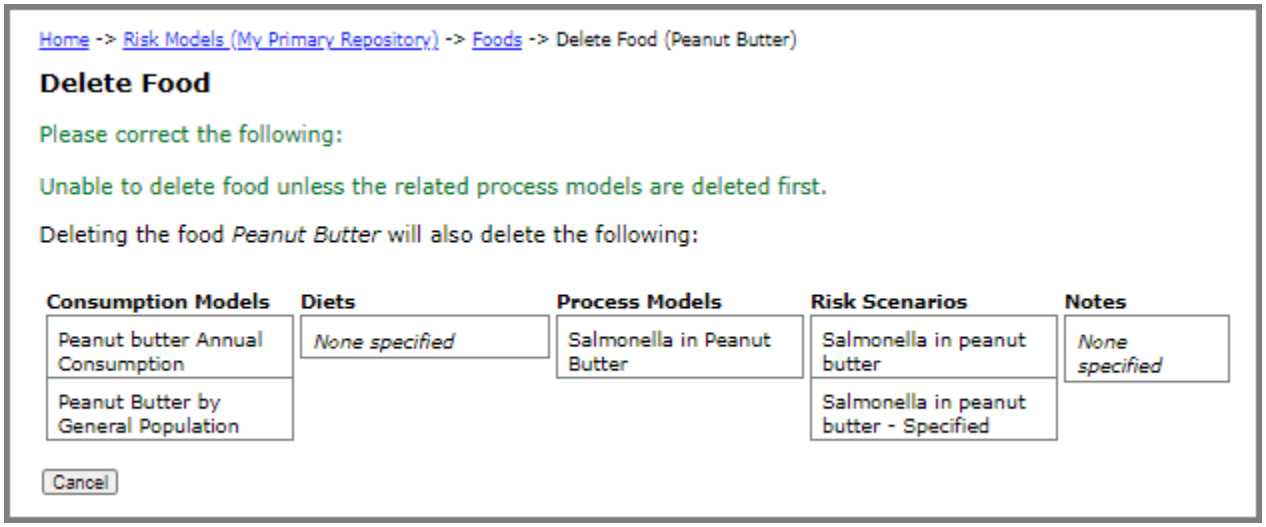
1 Click the **Risk Models** tab on the main tab bar.

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**.



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.

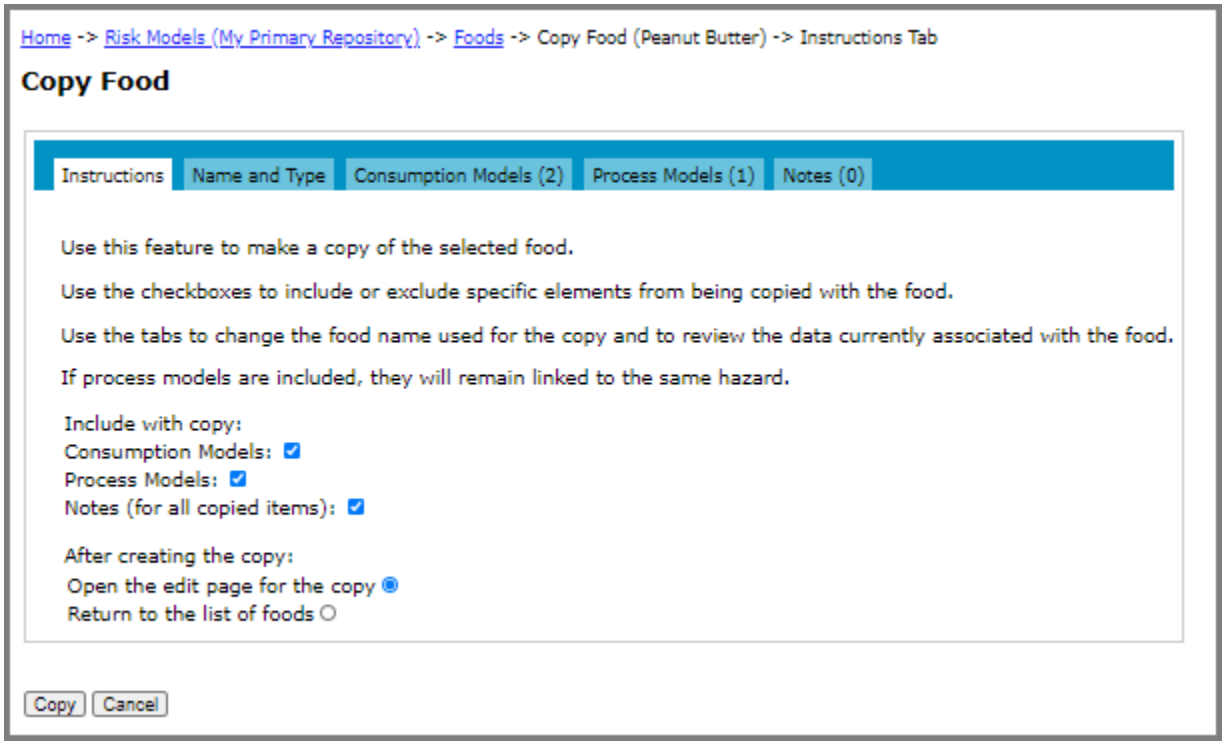
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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**.

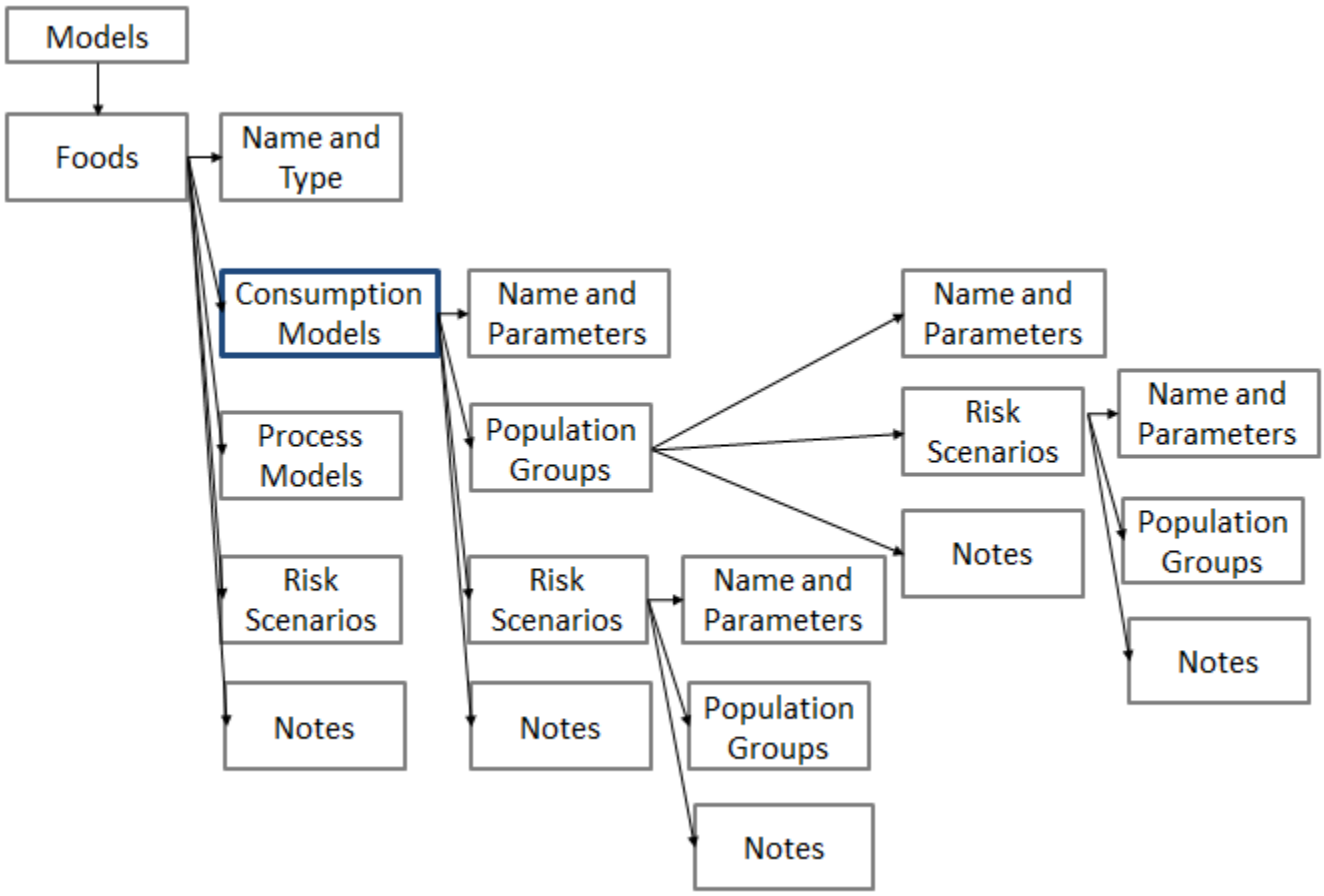
8 Do one of the following:

- 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

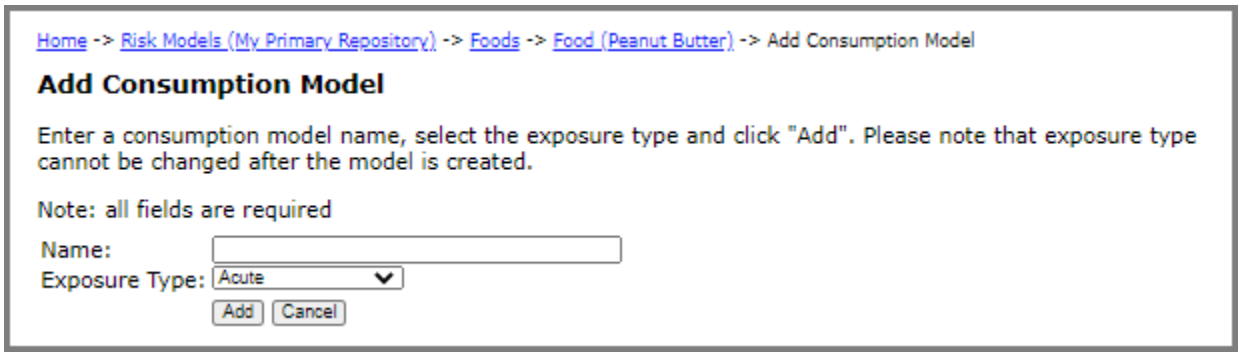
1 Click the **Risk Models** tab on the main tab bar.

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.



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.

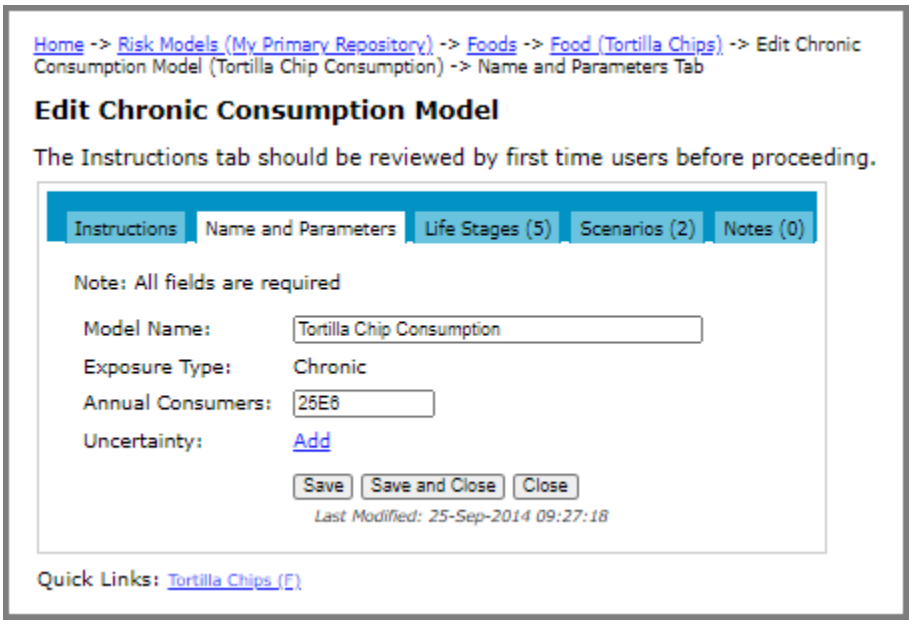
4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.

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.



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.

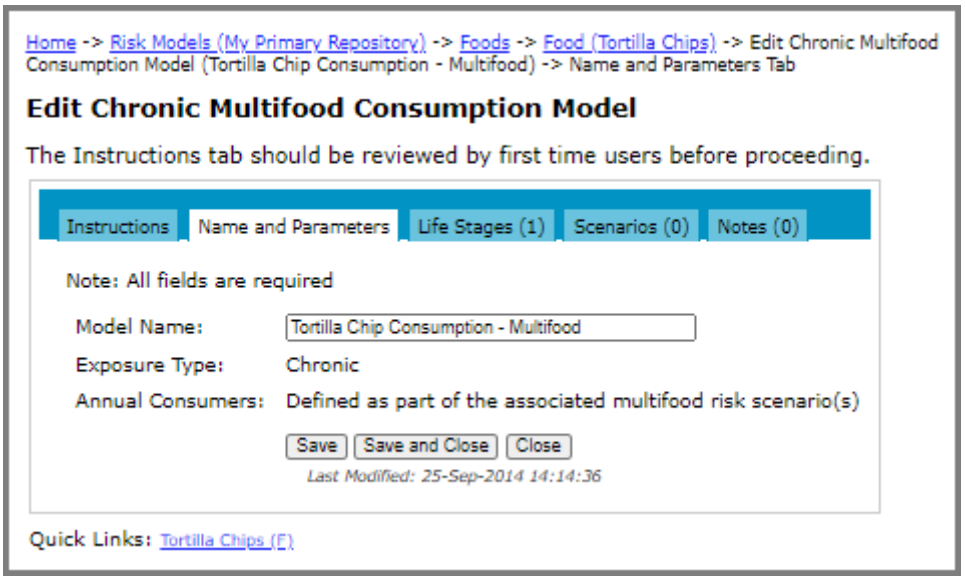
4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.

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

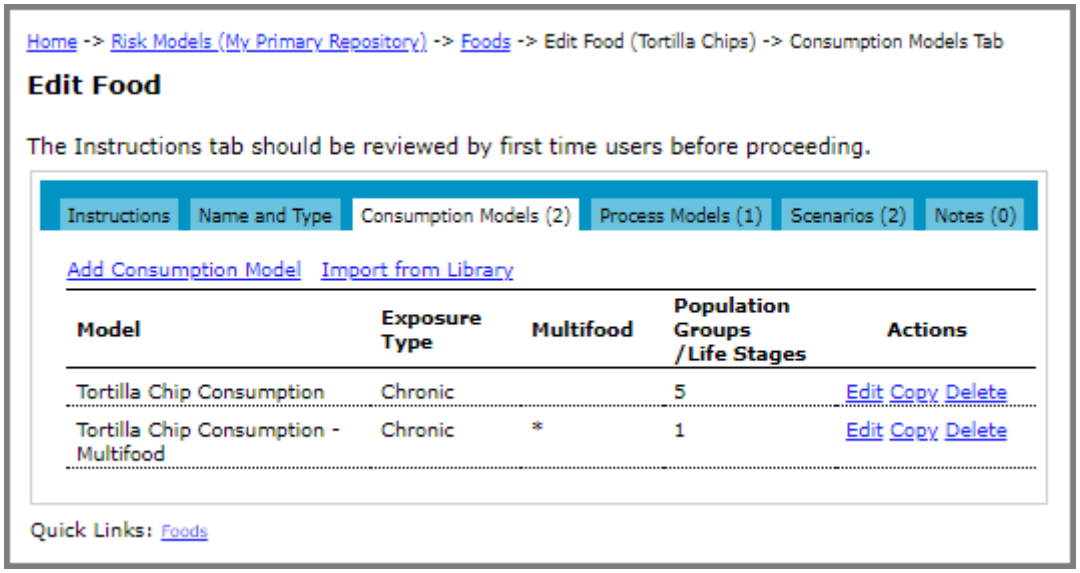
1 Click the **Risk Models** tab on the main tab bar.

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.



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.

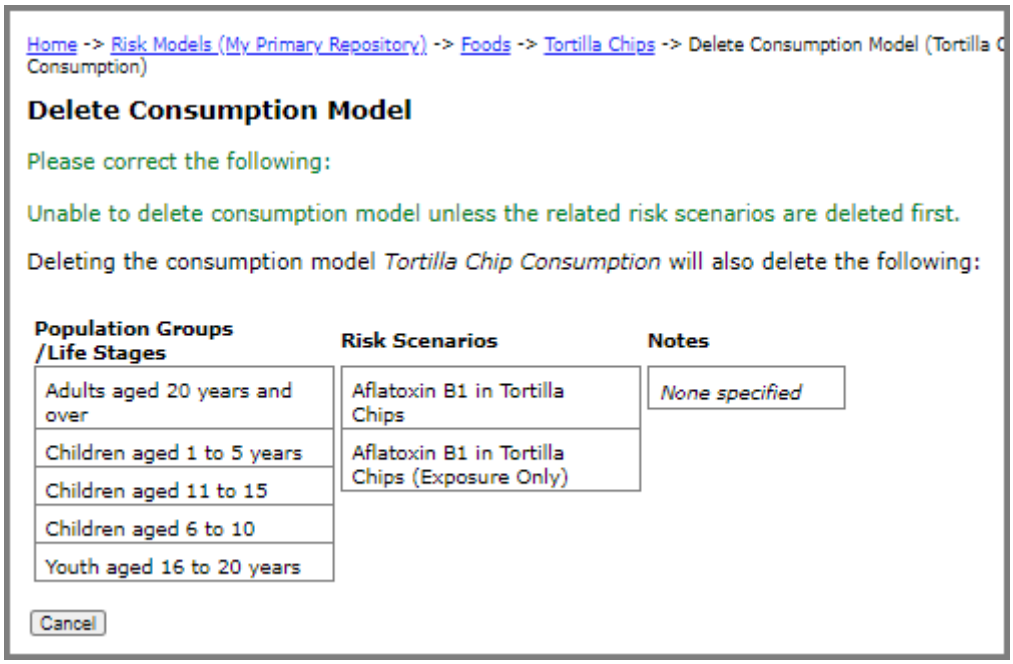
4 On the Edit Food page, click the **Consumption Models** tab.

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**.

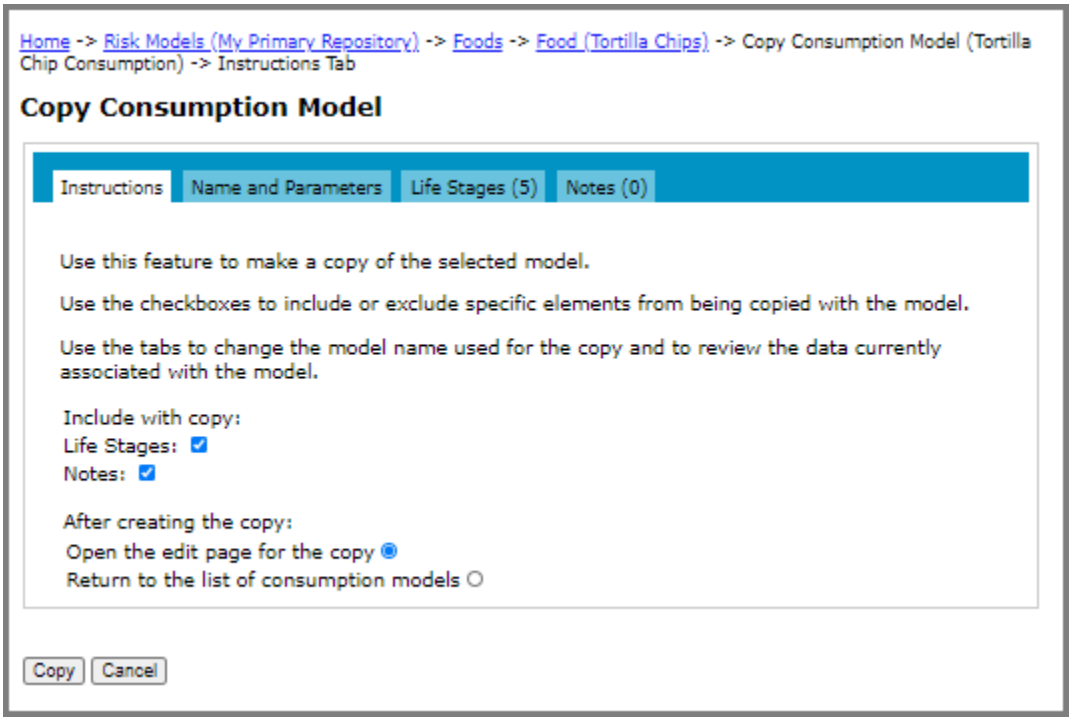


Copying a Consumption Model

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.



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.

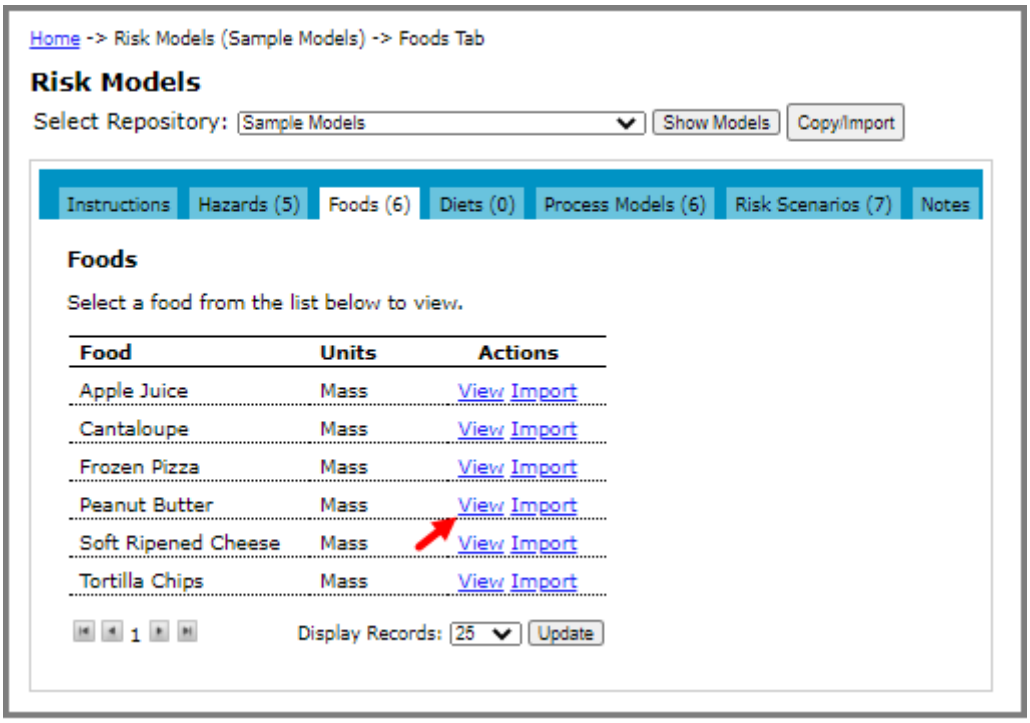
When you import a consumption model, its consumption population groups and notes are also imported.

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

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 **View** link to the right of the food.



4 On the Food page, click the **Consumption Models** tab.

5 Click the **Import** link to the right of the consumption model that you want to import.

6 On the Import Consumption Model page, switch between the tabs and review all element definitions associated with the consumption model.

7 Click the **Instructions** tab.

8 In the **Select Repository** drop-down list, select a repository in which to import the consumption model.

9 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.

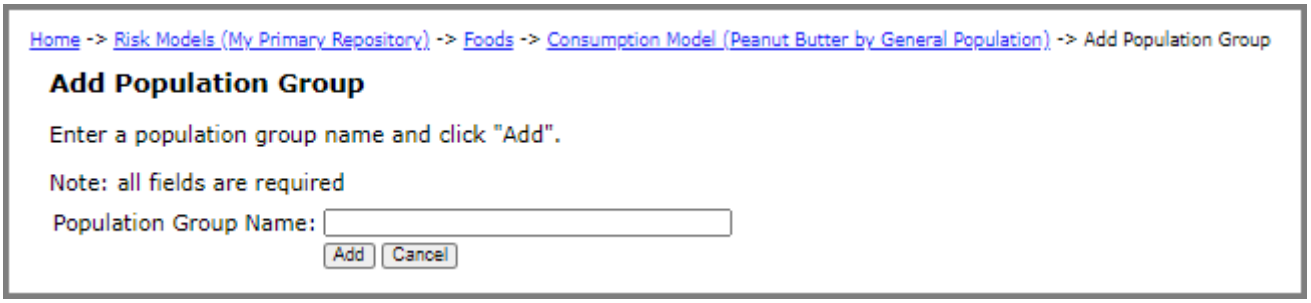
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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.

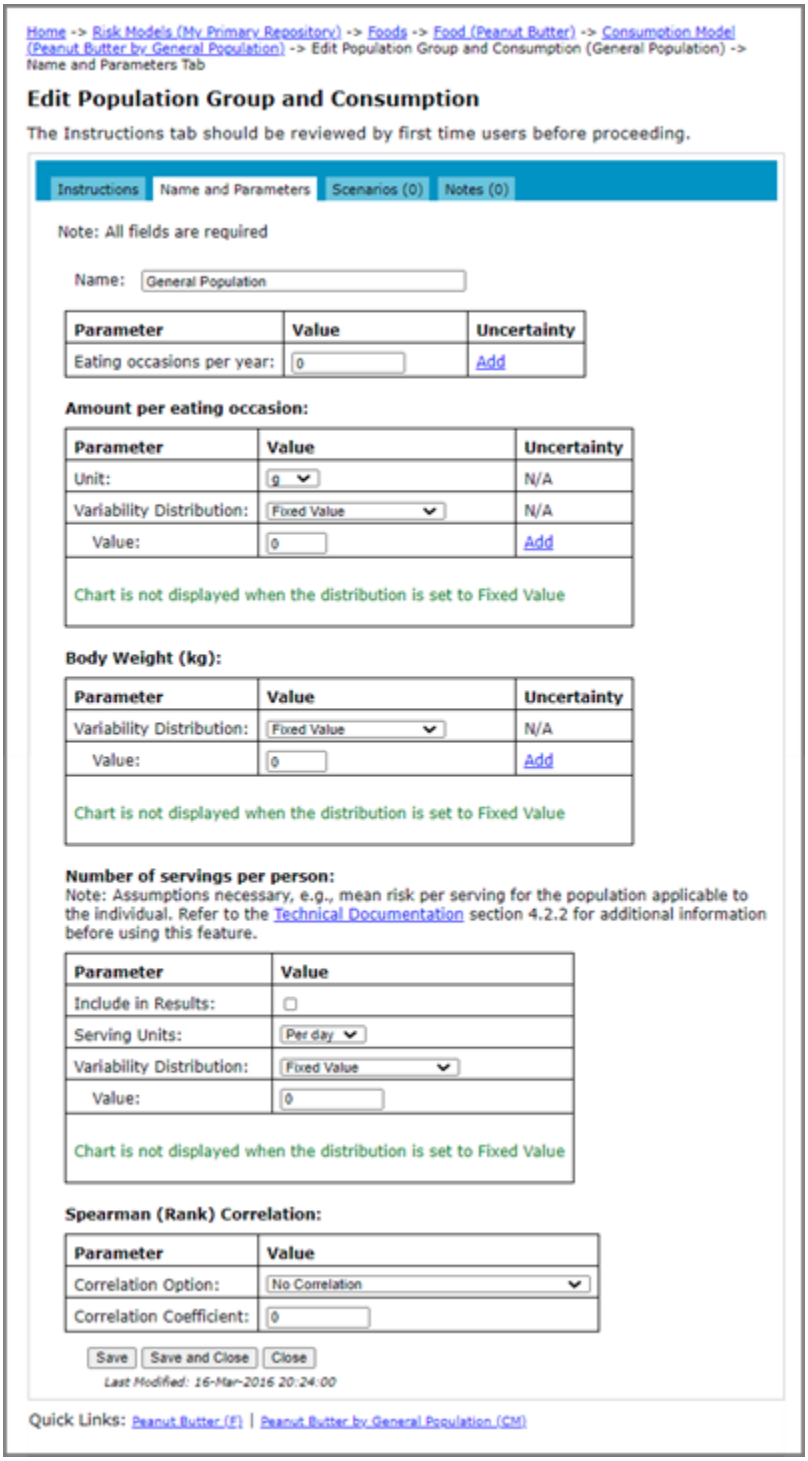
5 Click the **Edit** link to the right of the consumption model to which you want to add a population group.

6 Click the **Population Groups** tab, and then click the **Add Population Group** link. The Add Population Group page opens.



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

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



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.

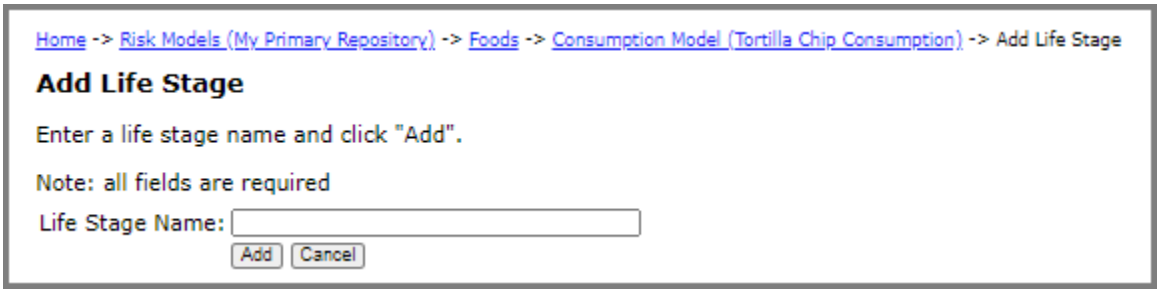
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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.

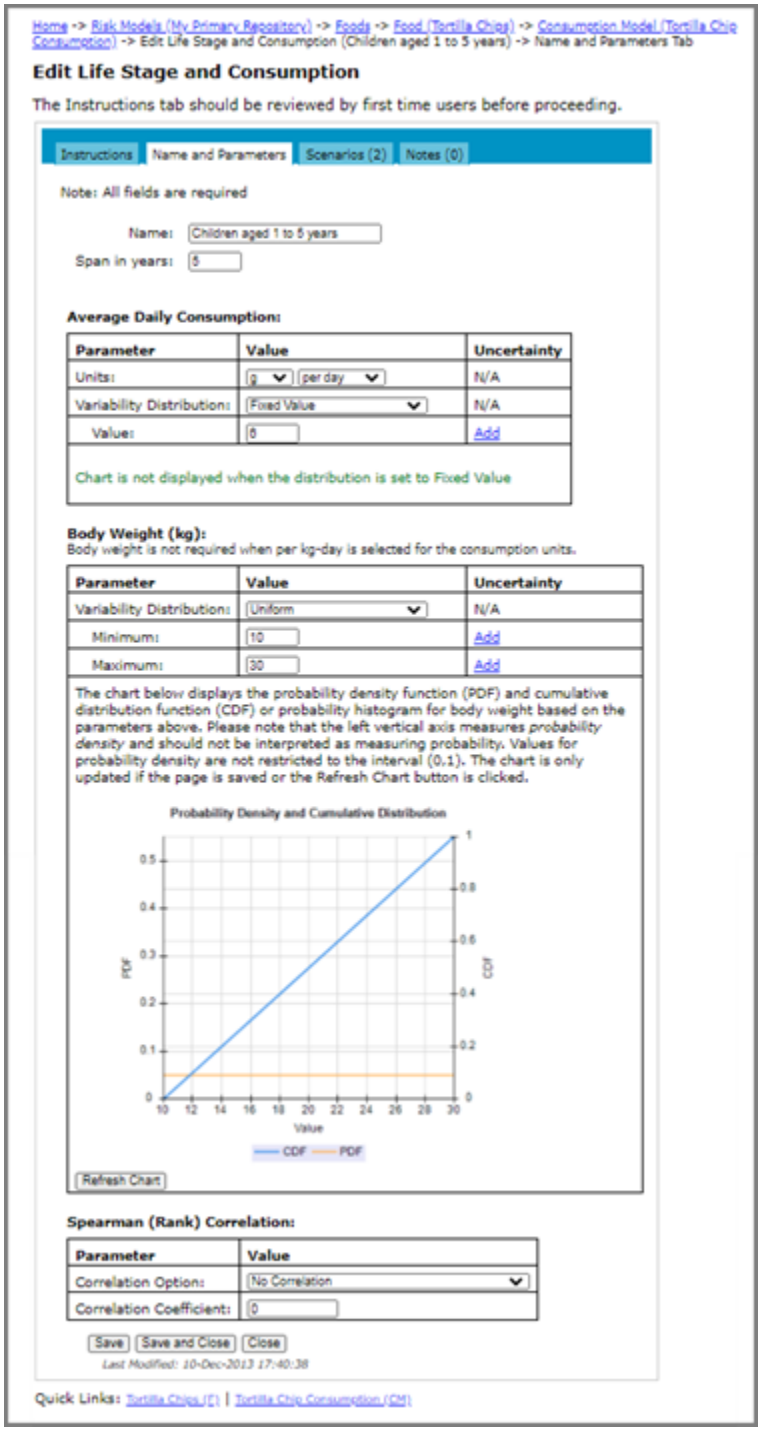
5 Click the **Edit** link to the right of the consumption model to which you want to add a life stage.

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



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

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



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**.

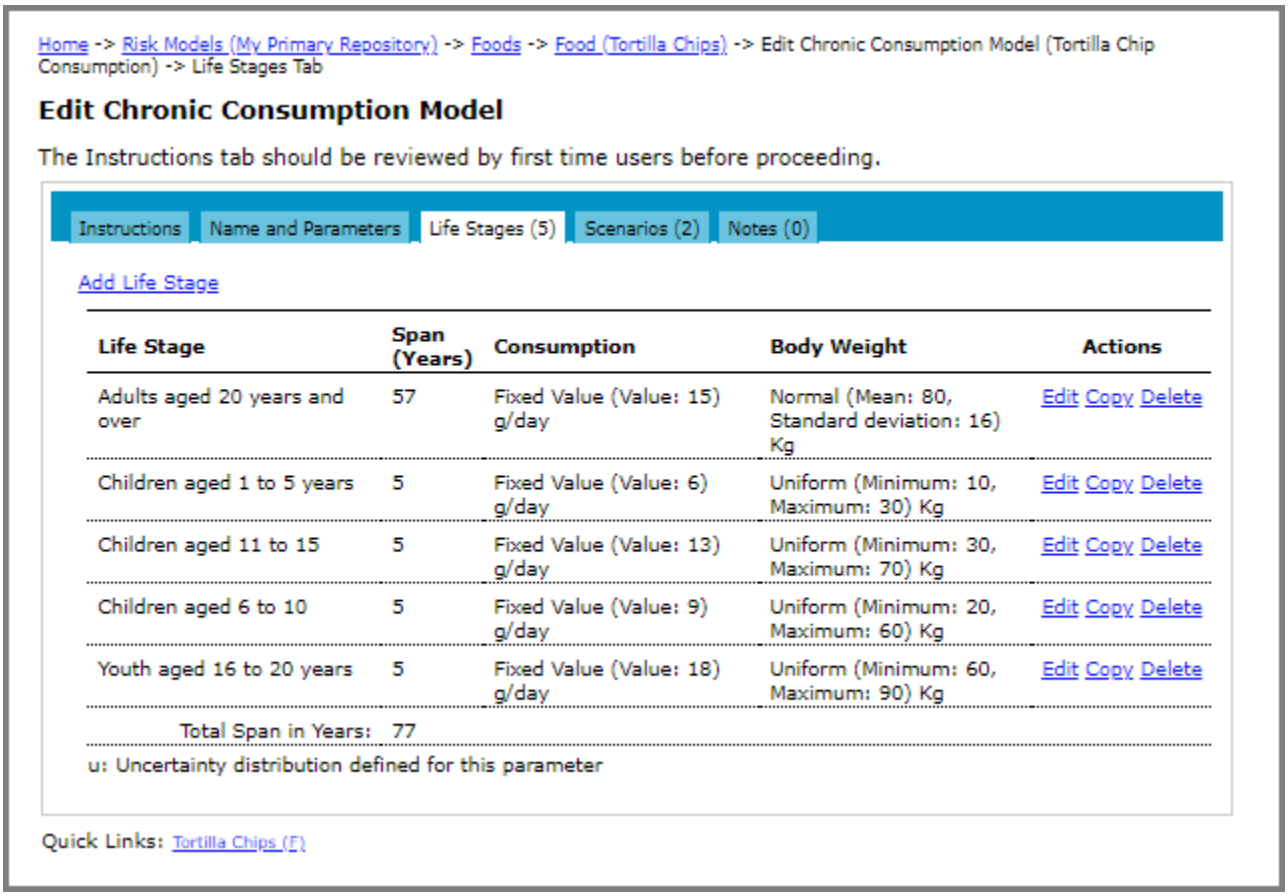
Note: When using consumption data that are expressed in terms of "grams of food per kg body weight", the body weight of the associated life stage should be entered as "1 kg" to recognize that this division by body weight has already been considered.

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.

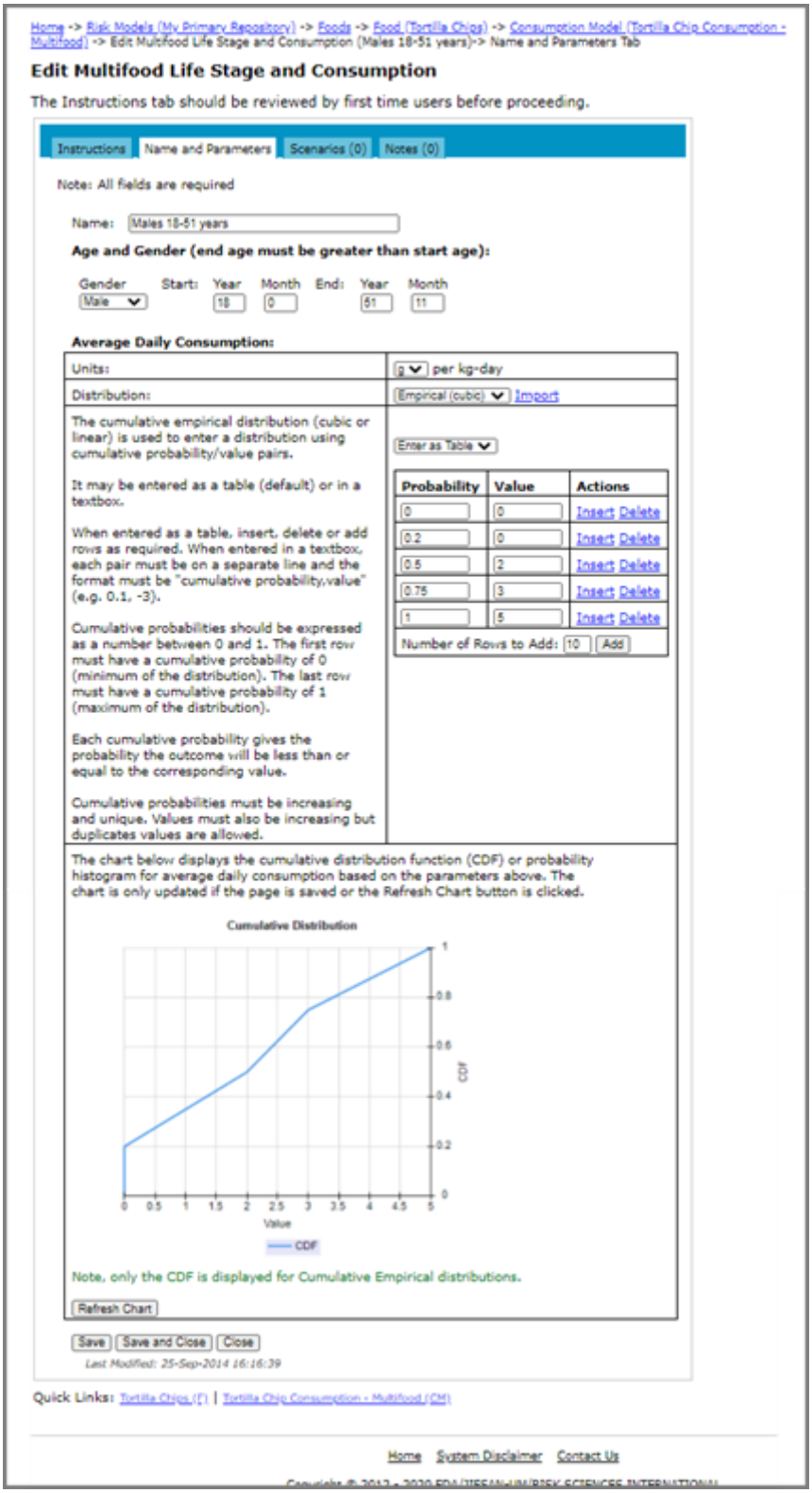
4 On the Edit Food page, click the **Consumption Models** tab. The list of consumption models for the food displays.

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.



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 gender and age range. Gender 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 Gender** enter values for Gender, 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.

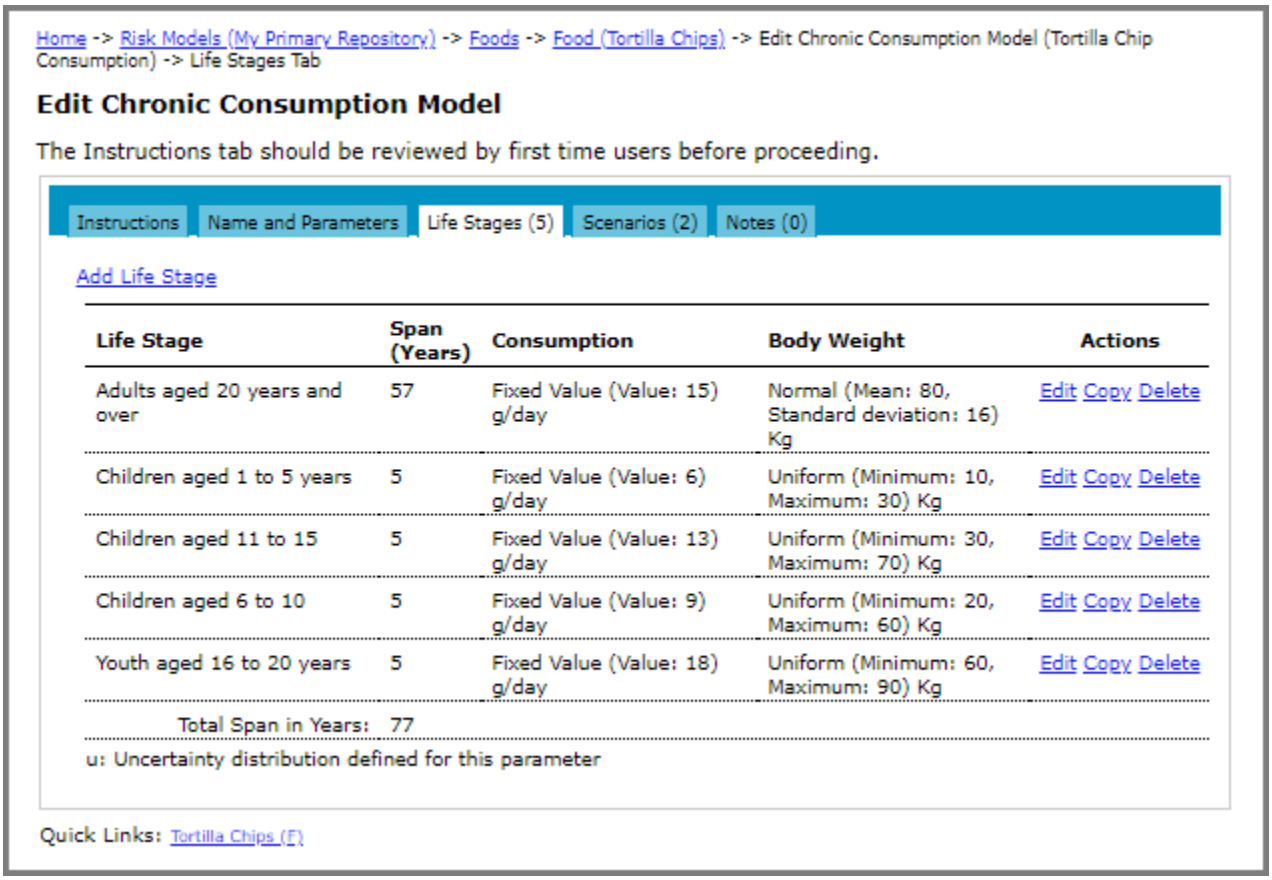
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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.



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 multifood exposure, you can edit the name of the life stage, gender, 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.

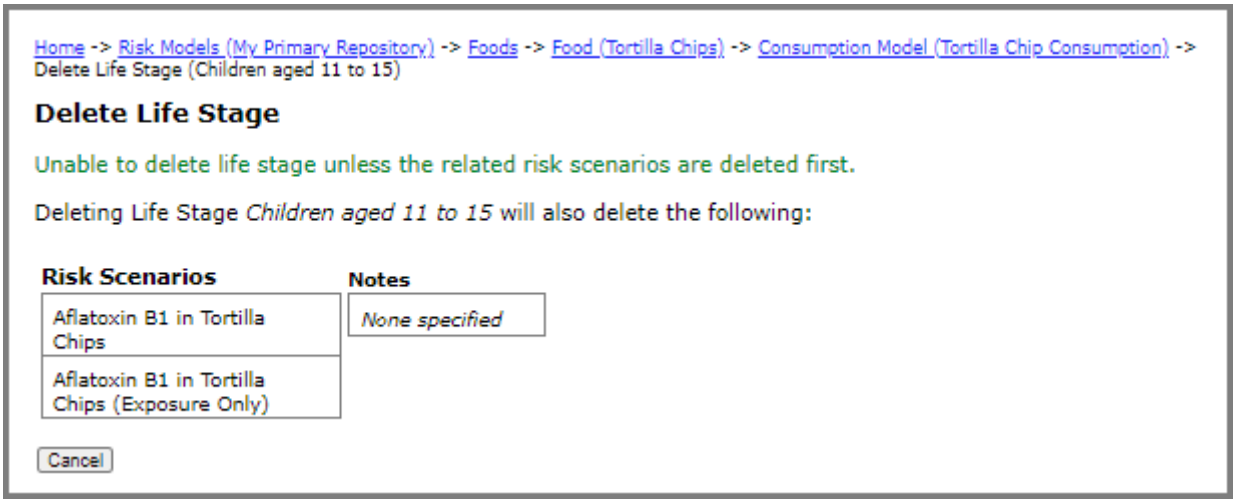
4 On the Edit Food page, click the **Consumption Models** tab.

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**.



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.

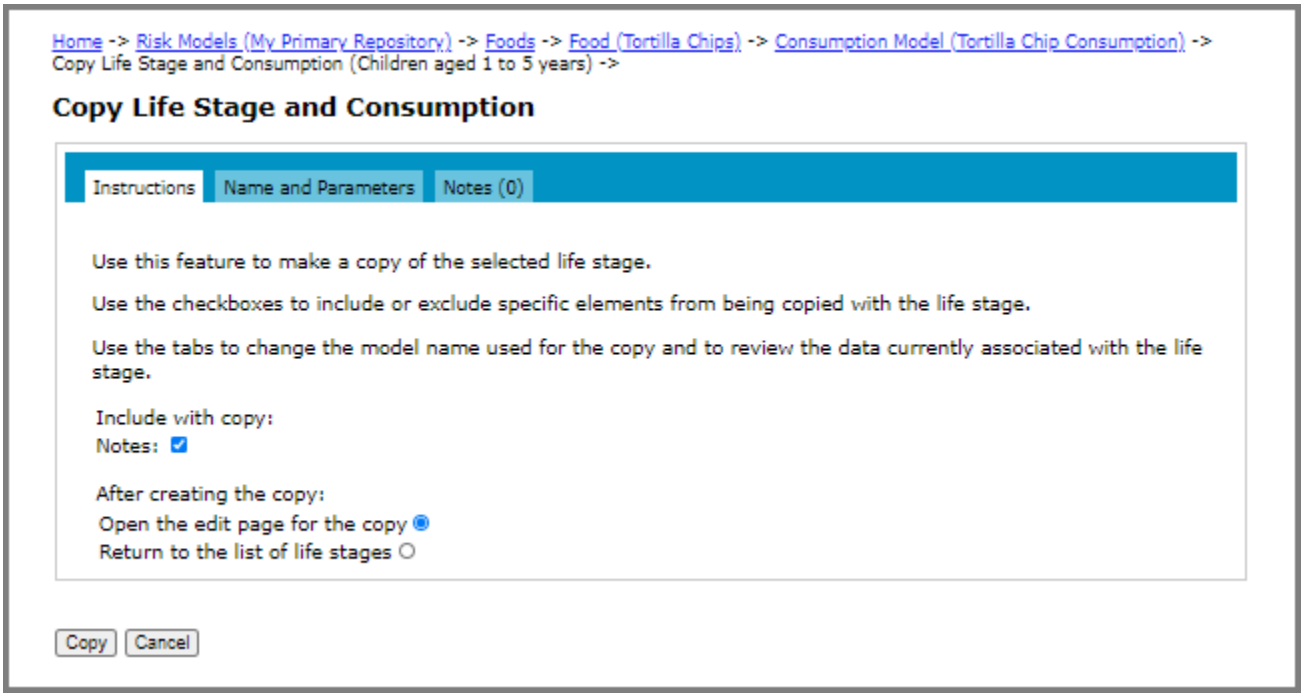
5 Click the **Edit** link to the right of the consumption model for which you want to copy a population group / life stage.

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.



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.

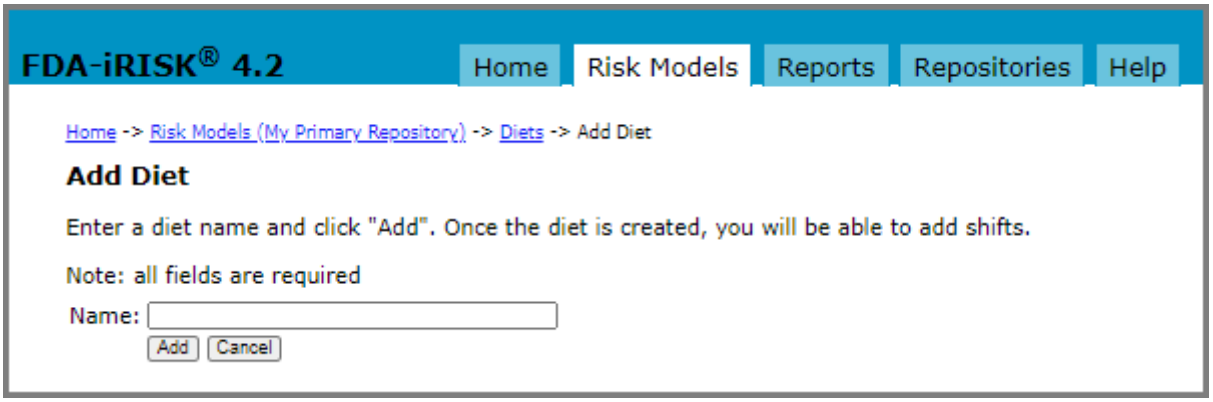
The diets are linked to select foods for maximum flexibility so that you can apply them to any consumption model. This allows you to define alternative baseline consumption models but still apply the same overall diet shifts in different scenarios to explore the impact of different initial estimates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

Adding a Diet

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

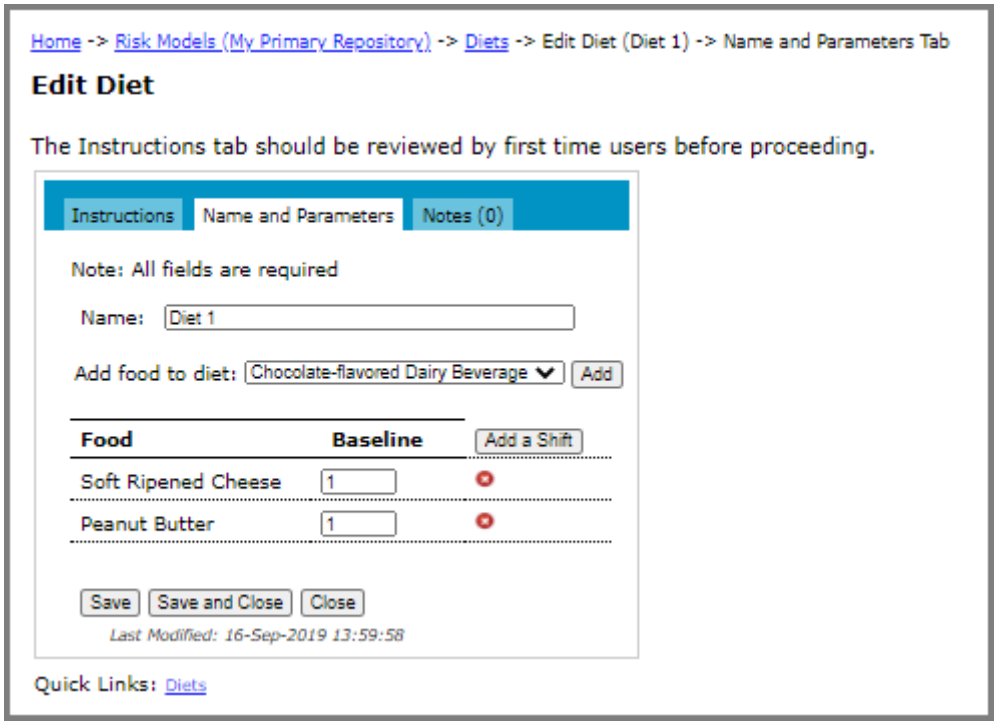
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

3 Click the **Diets** tab, and then click the **Add Diet** link. The Add Diet page opens.



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

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

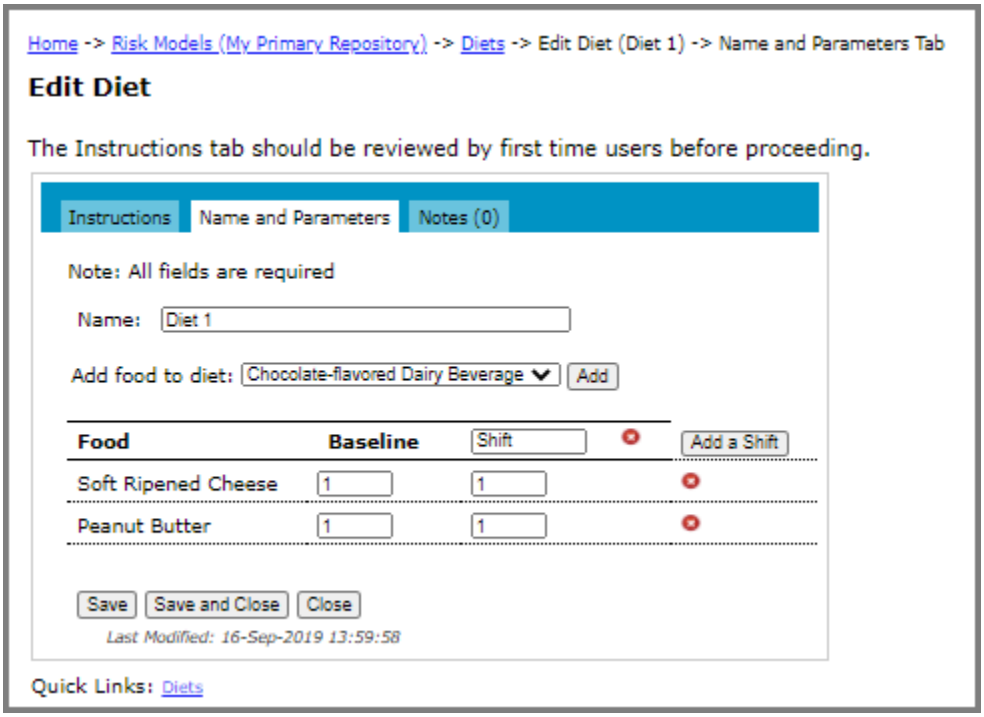


6 In the **Add food to diet** drop-down list, select a food and click **Add**. Repeat this step until you have added all of the required foods to the diet.

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.



9 Do one of the following:

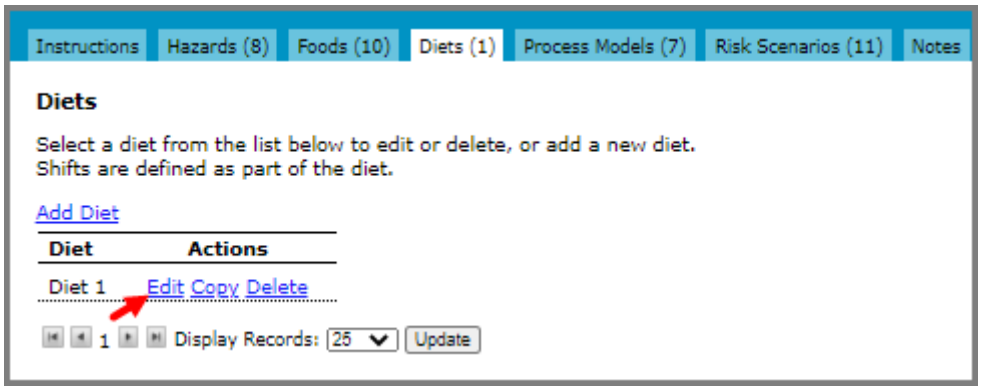
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

Editing a Diet

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 **Edit** link to the right of the diet that you want to edit.



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**.

Copying a Diet

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

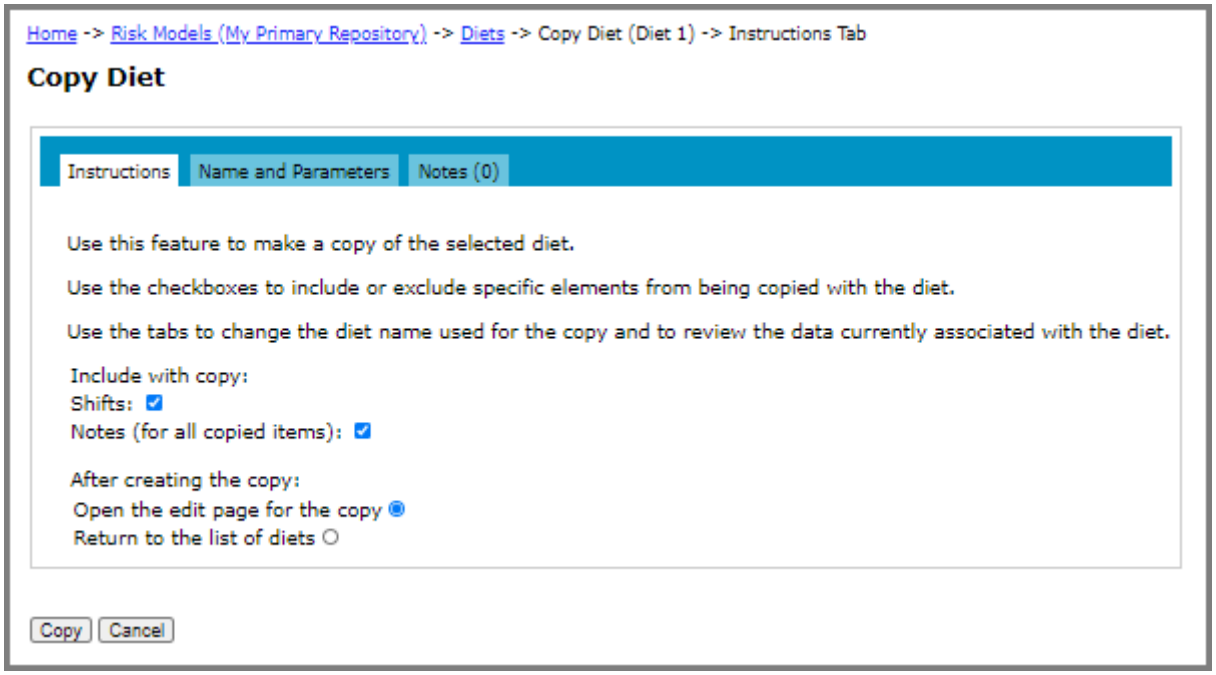
2 In the **Select Repository** drop-down list, select a repository and click **Show Models**.

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.



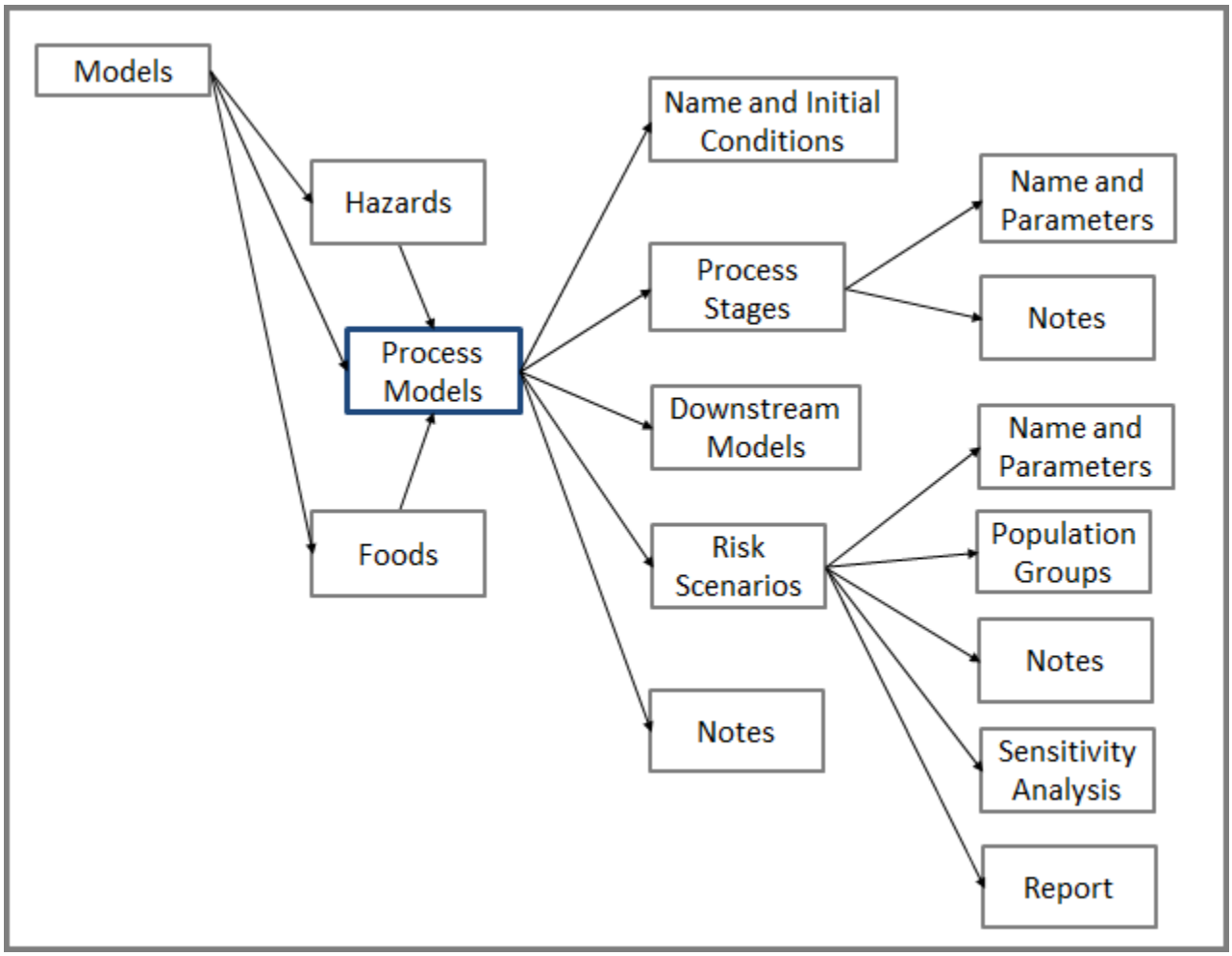
7 Select the check boxes for the elements that you want to include with the copy and the action that you want taken after the copy completes.

8 Click **Copy**.

CHAPTER 5

Process Models and Process Stages

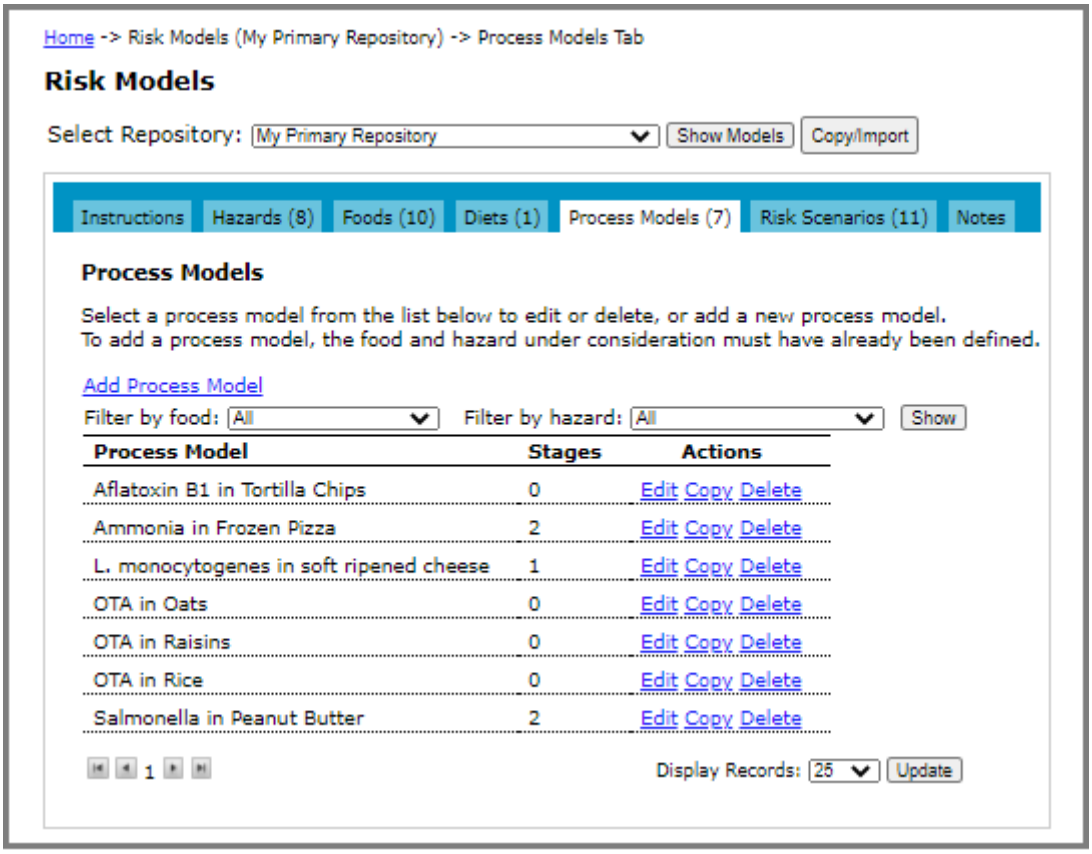
The following illustration shows the edit pathways for process models in FDA-iRISK. Each arrow represents a potential one-to-many relationship; however, a process model can only be associated with one food hazard combination:



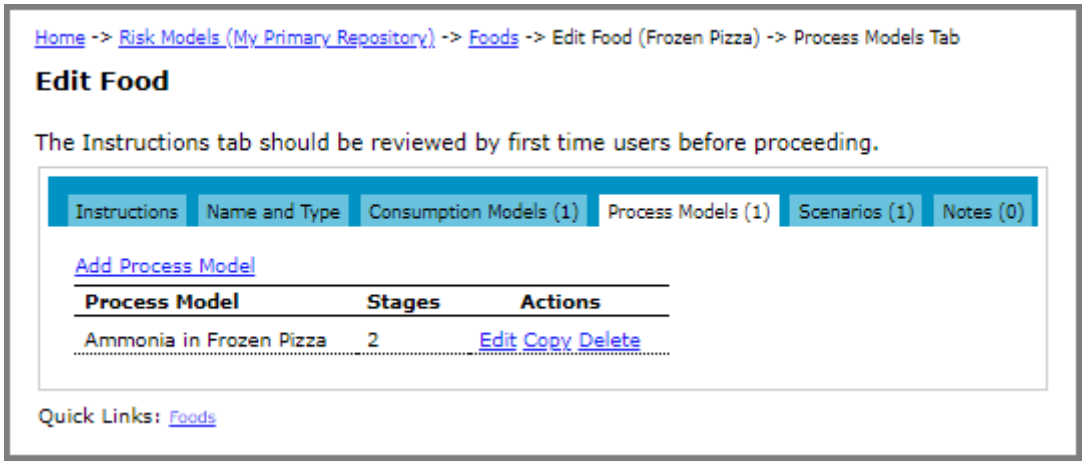
Navigating to Process Models

You navigate to the process models in the following ways:

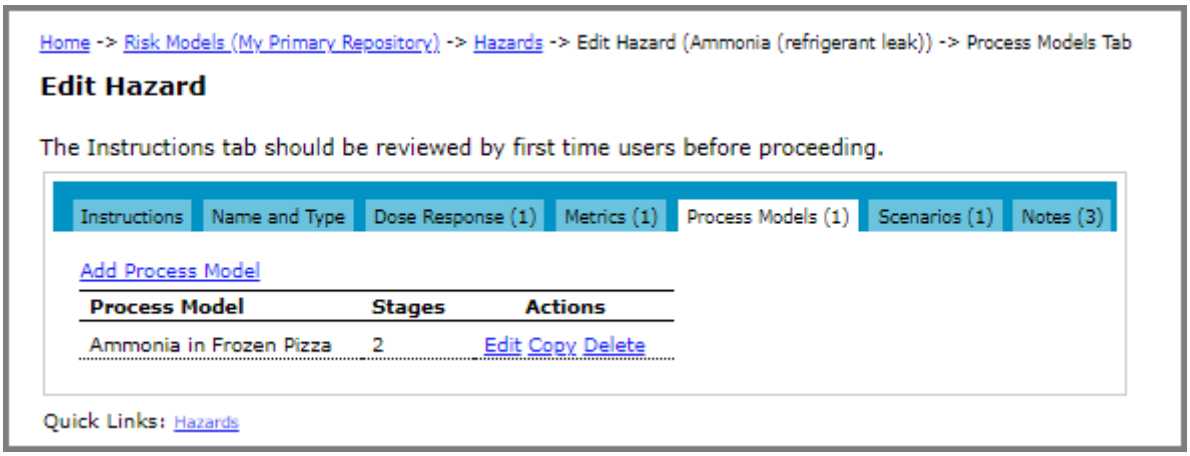
- Click the **Process Models** tab on the Risk Models page. A complete list of process models displays; however, you can filter the list by food or hazard.



- To navigate to the process models 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 process models. On the Edit Food page, click the **Process Models** tab.



- 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*)

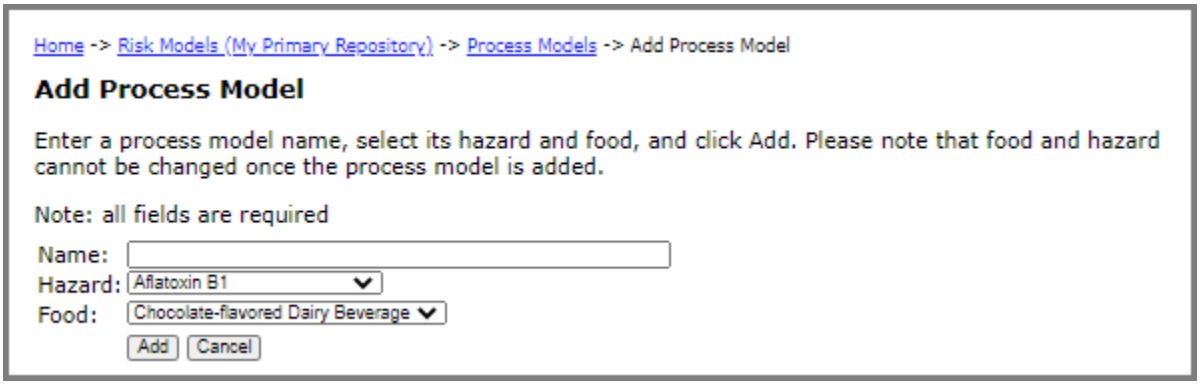
For process models with a microbial hazard, you can define multiple parameter sets for the same process model that reflect differences in a single process model between for example, geographic regions, or seasons. In this case, each parameter set is optionally assigned a proportion of the total number 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*.

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**, (if is not already selected) select **Single Set of Parameters** and then click **Change Method**.

9 In the **Select Mass Units** drop-down list under **Initial Contamination, Unit Size and Prevalence**, select the mass unit.

10 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.

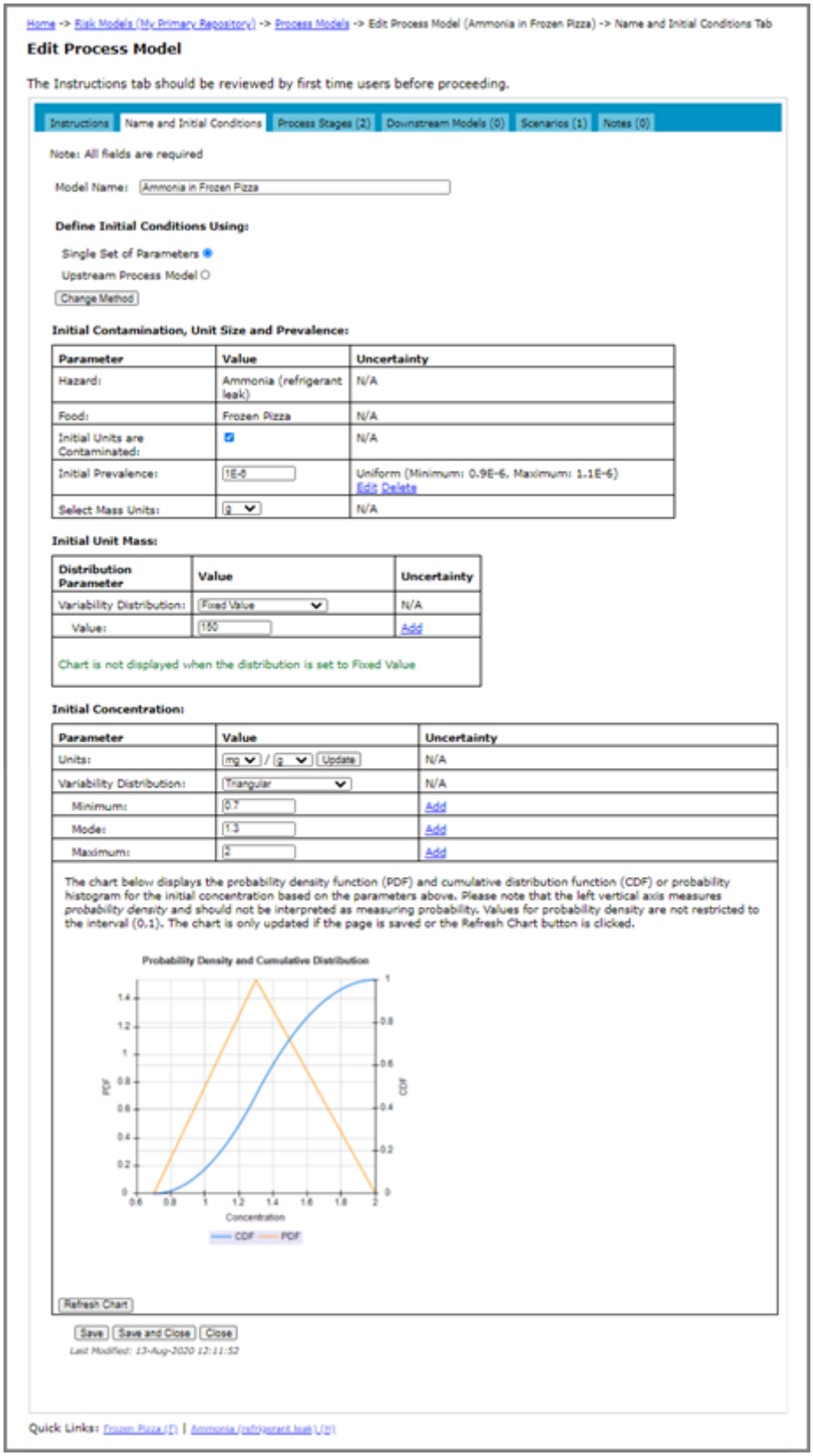
11 Do one of the following:

- 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.



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**.

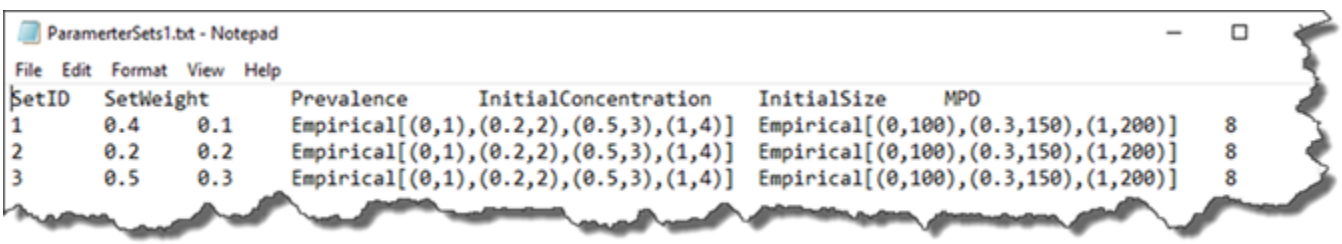
4 To the right of the **Parameter Set Name** input field, click **Delete Parameter Set**.

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:



ParameterSets1.txt - Notepad

File Edit Format View Help

```
SetID   SetWeight       Prevalence      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
```

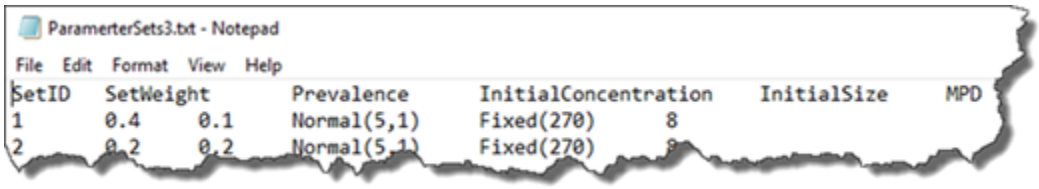
Size units and concentration units are copied from the existing primary set. Any existing process stages are also copied from the existing primary set.

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(5th Percentile, Mode, 95th 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(5th Percentile, 95th Percentile)	UniformPercentiles(2,8)

For example,


ParamerterSets3.txt - Notepad

File Edit Format View Help

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.

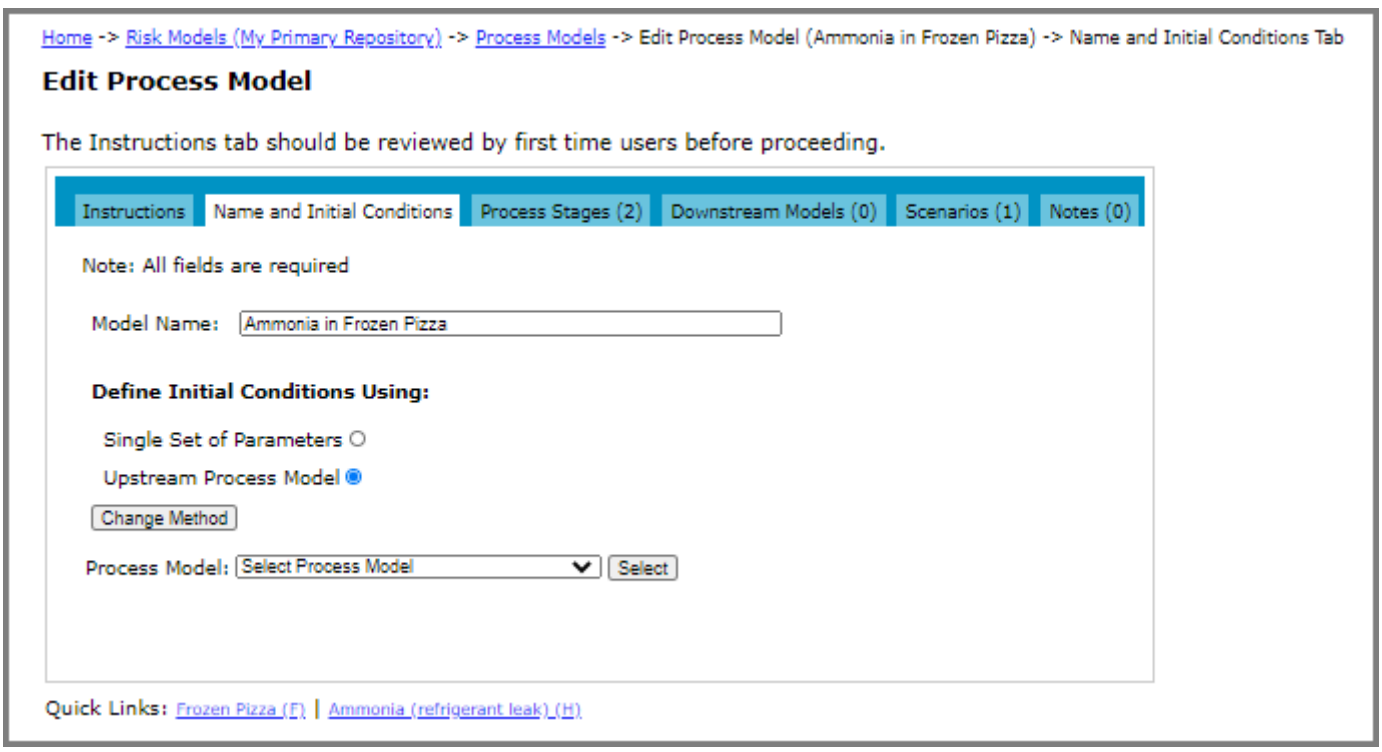
5 In the **Food** drop-down list, select the food.

Note: The food and hazard cannot be changed once the process model is added.

6 Click **Add**. The Edit Process Model page opens.

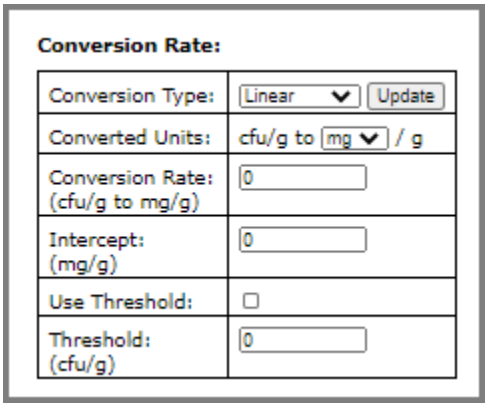
7 In the **Model Name** input field, edit the process model name, if required.

8 Under **Initial Conditions**, select **Upstream Process Model** and then click **Change Method.**



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.



11 Do one of the following:

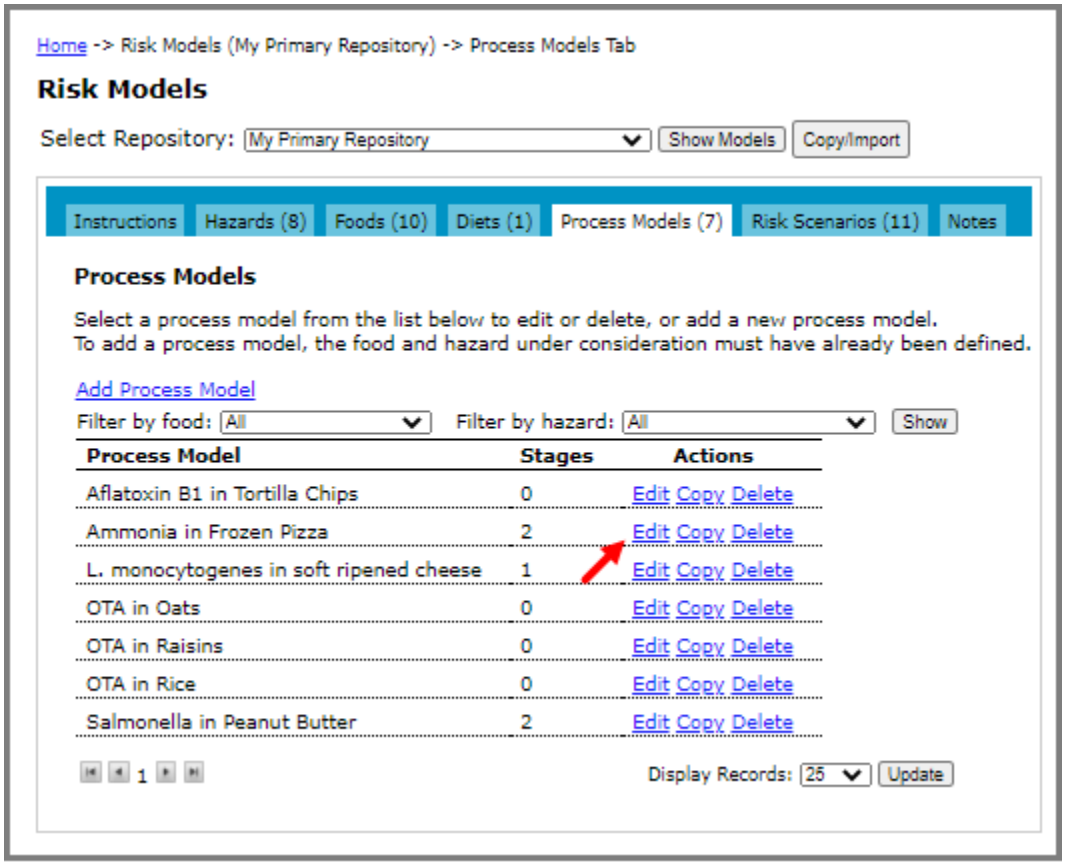
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

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*.

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



3 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.)

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**.

Deleting a Process Model

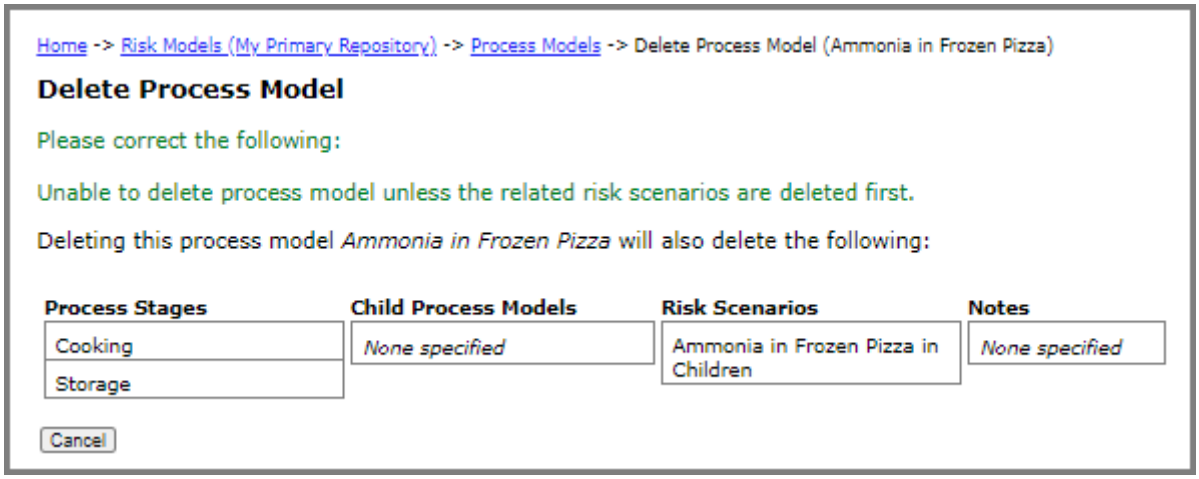
1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.

2 On the **Process Models** tab, click the **Delete** link to the right of the process model that you want to delete.

3 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**.



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.

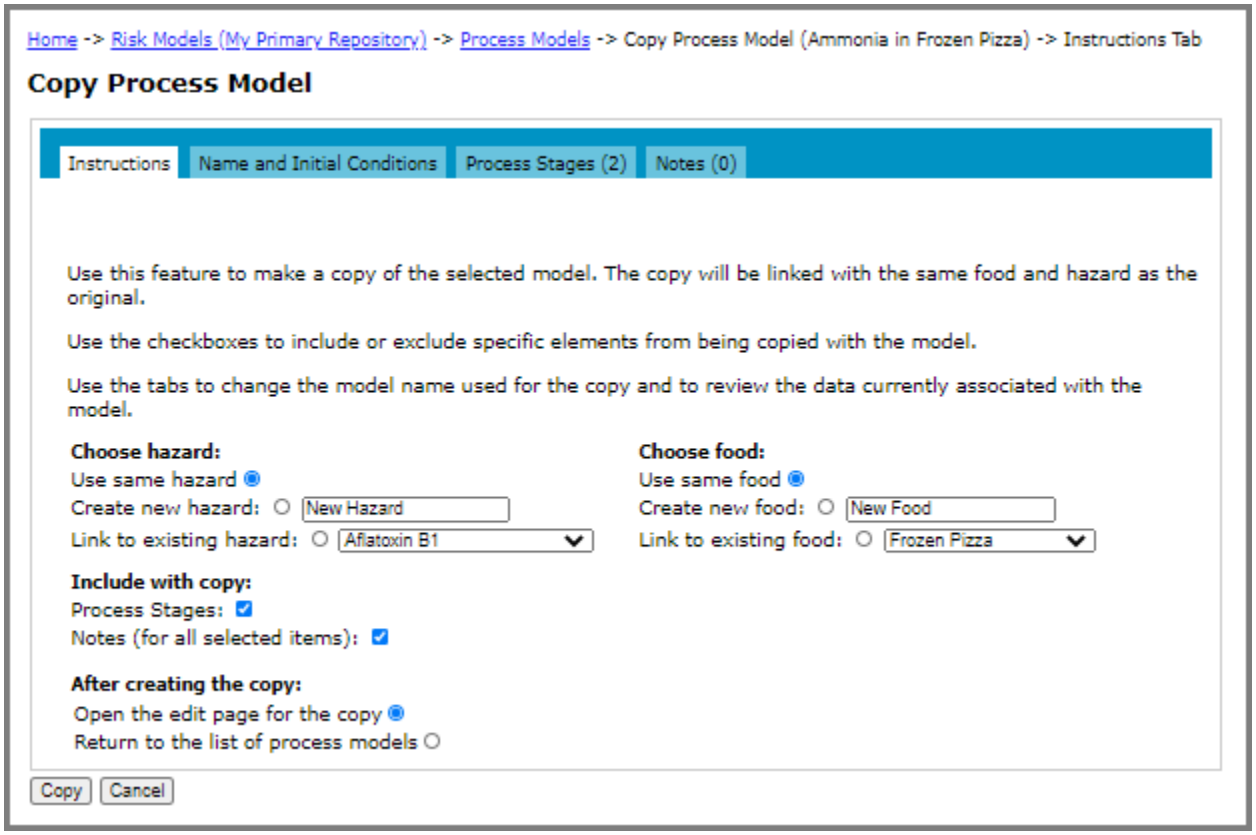
1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.

2 On the **Process Models** tab, click the **Copy** link to the right of the process model that you want to copy.

3 On the Copy Process Model page, switch between the tabs and review all element definitions associated with the process model.

4 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*.

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**.

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*.

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

4 Click the **Import** link to the right of the process model that you want to import.

5 On the Import Process Model page, switch between the tabs and review all element definitions associated with the process model.

6 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*.

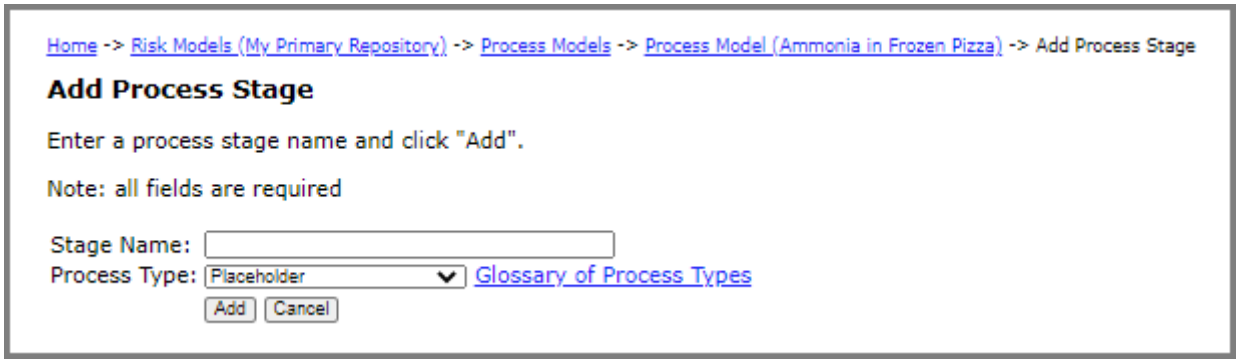
Before you begin: When adding a process stage for the Decrease by Inactivation Model or Increase by Growth Model process types, the predictive model(s) that you want to select must be available. For more information, see the section, *"Predictive Models" on page 44*

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.

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



5 In the **Stage Name** input field, enter a name for the process stage.

6 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:

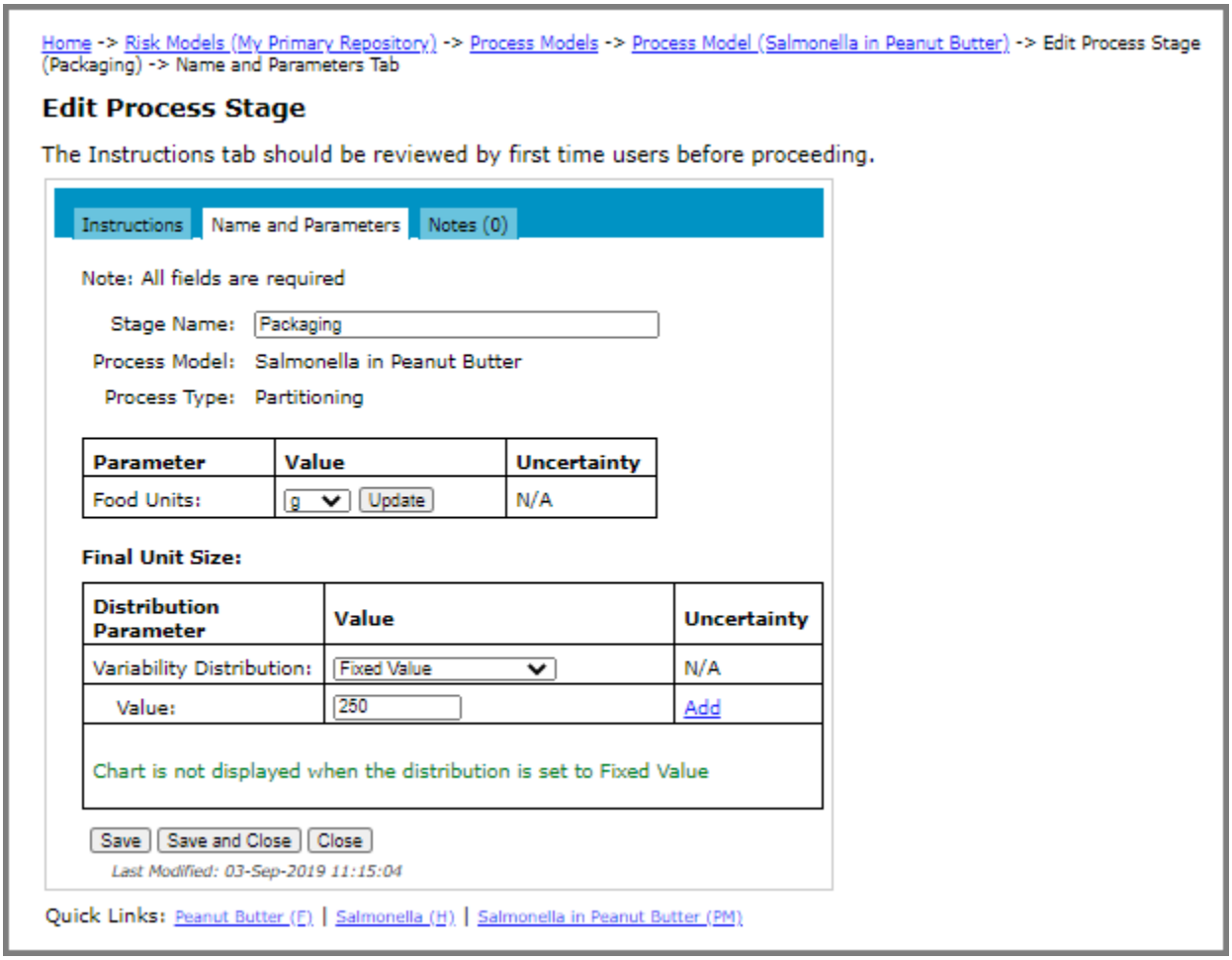
- To include a process step that has no impact on these values, select **No Change** from the **Process Type** drop-down list.
- If you are building a process model framework prior to data collection, select **Placeholder** from the **Process Type** drop-down list. You can change it to any other type by editing later, as required.

7 Click **Add**. The Edit Process Stage page opens.

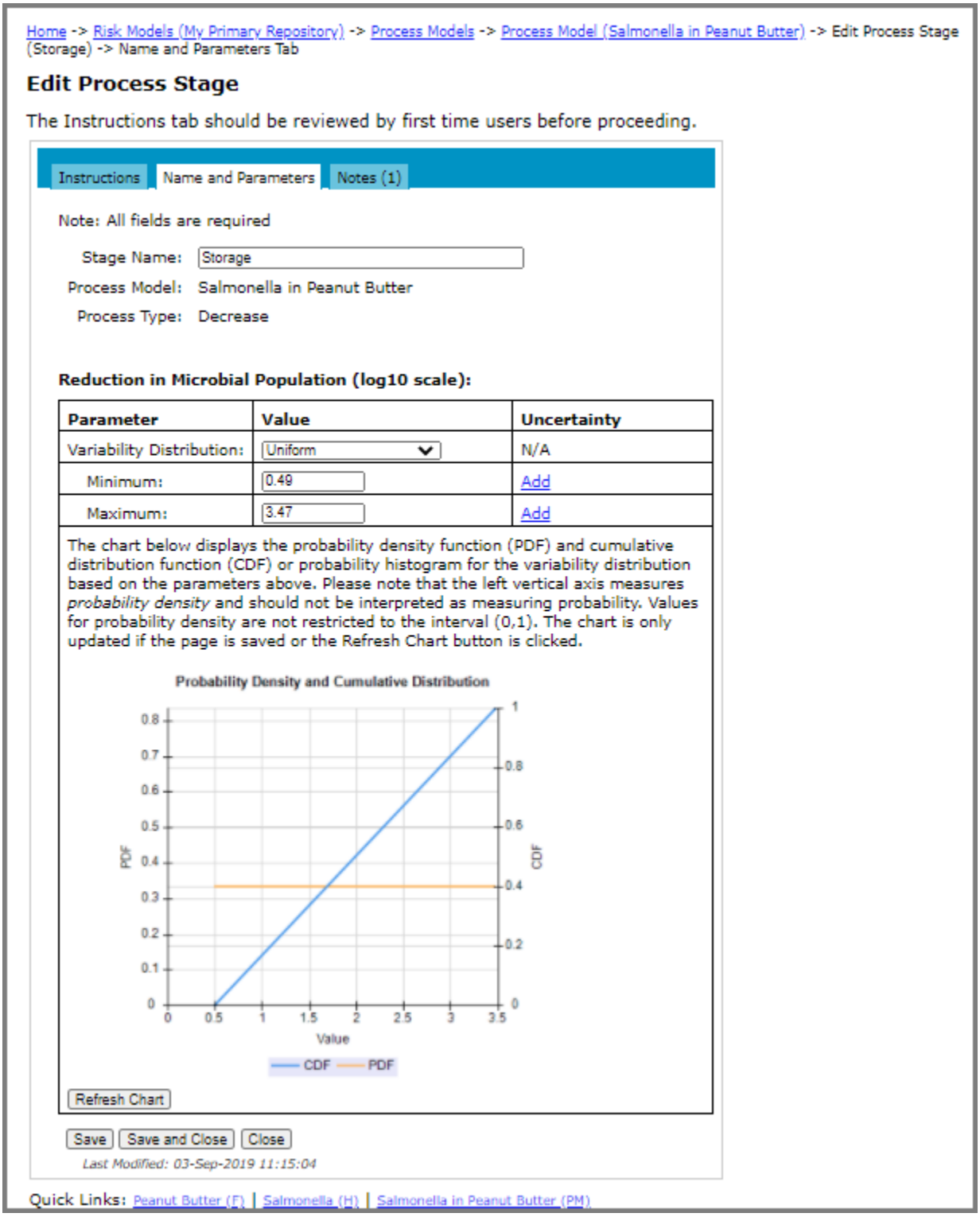
(The input fields that display on this page are determined by the process type that you selected on the previous page.)

8 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.



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



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

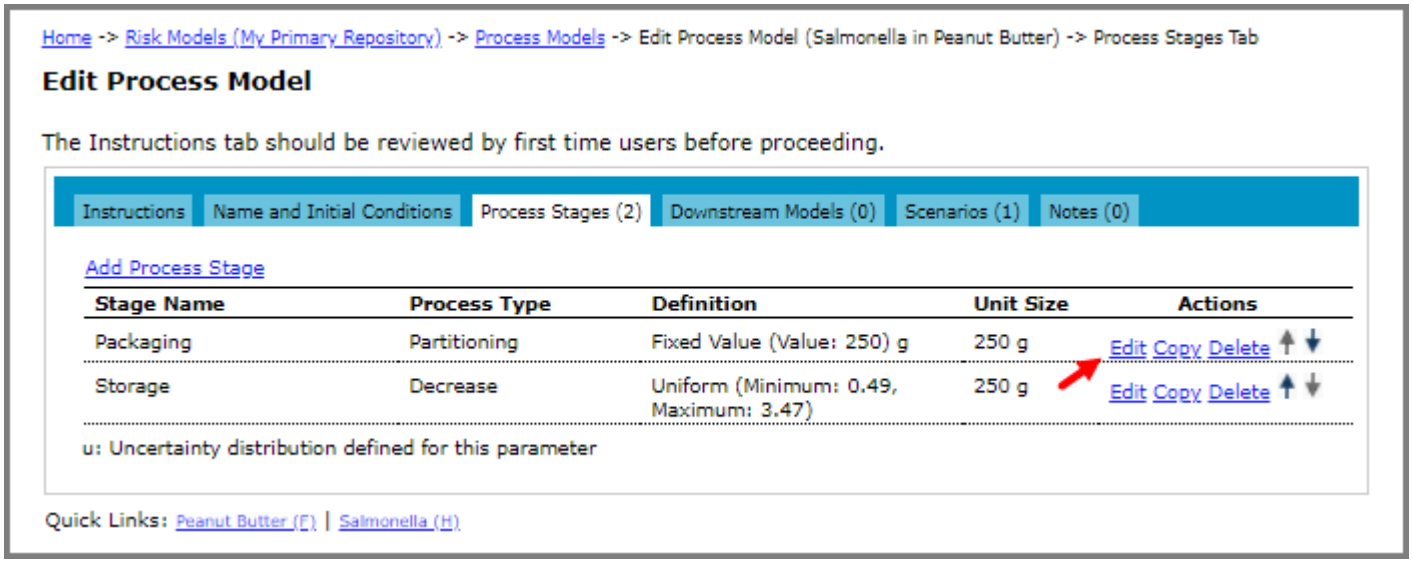
1 Navigate to the Process Models page. See *"Navigating to Process Models" on page 80*.

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.



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.

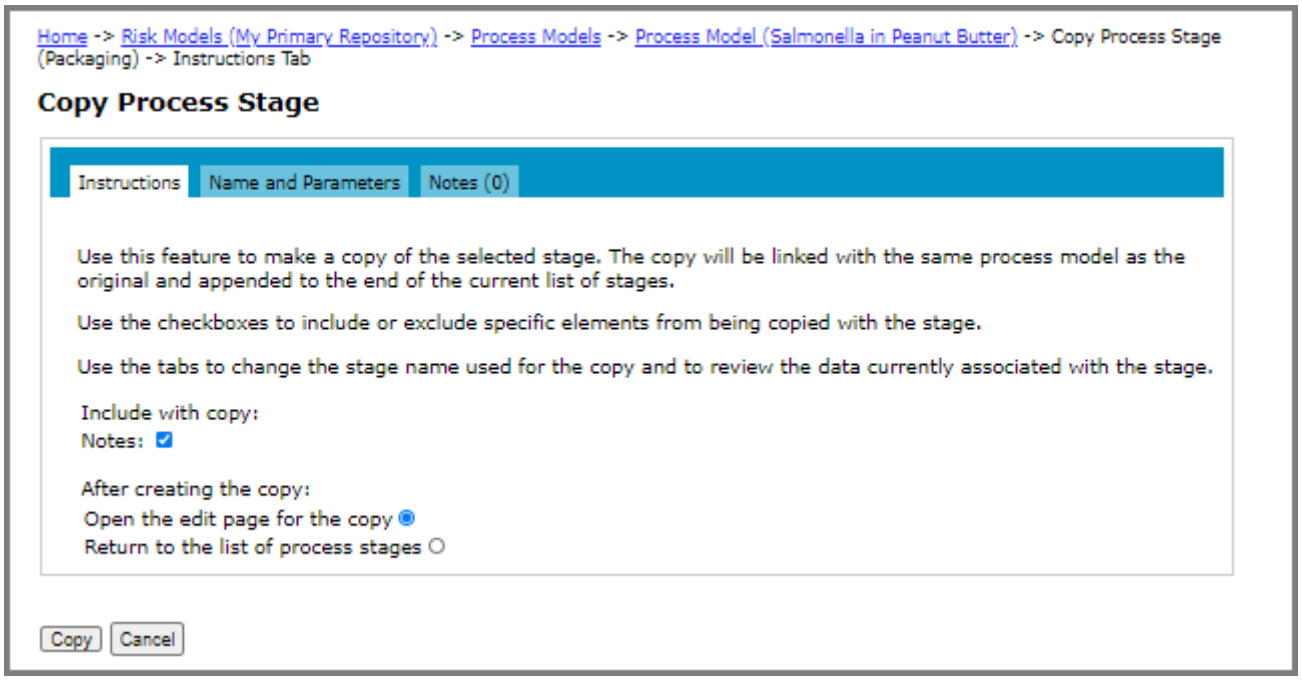
3 On the Edit Process Model page, click the **Process Stages** tab.

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.



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**.

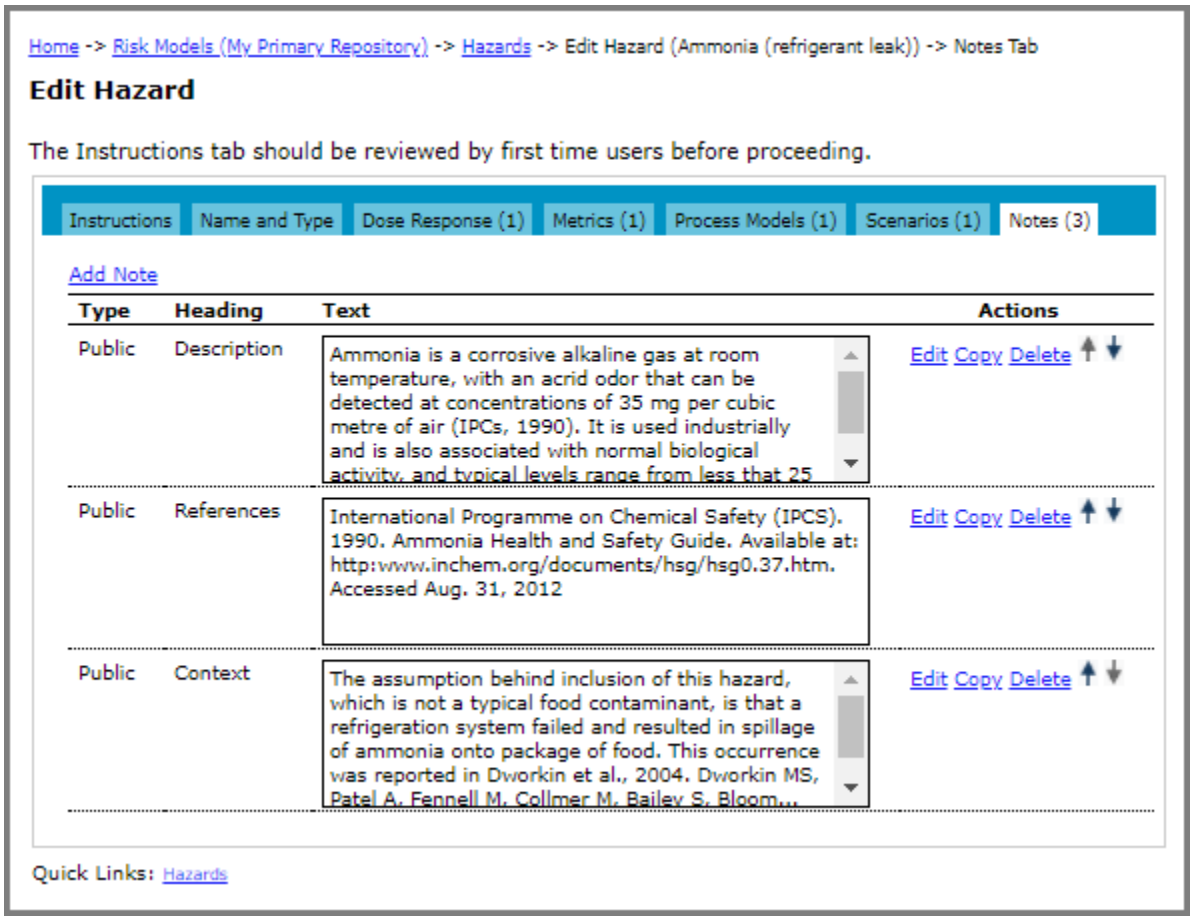
Importing a Process Stage

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

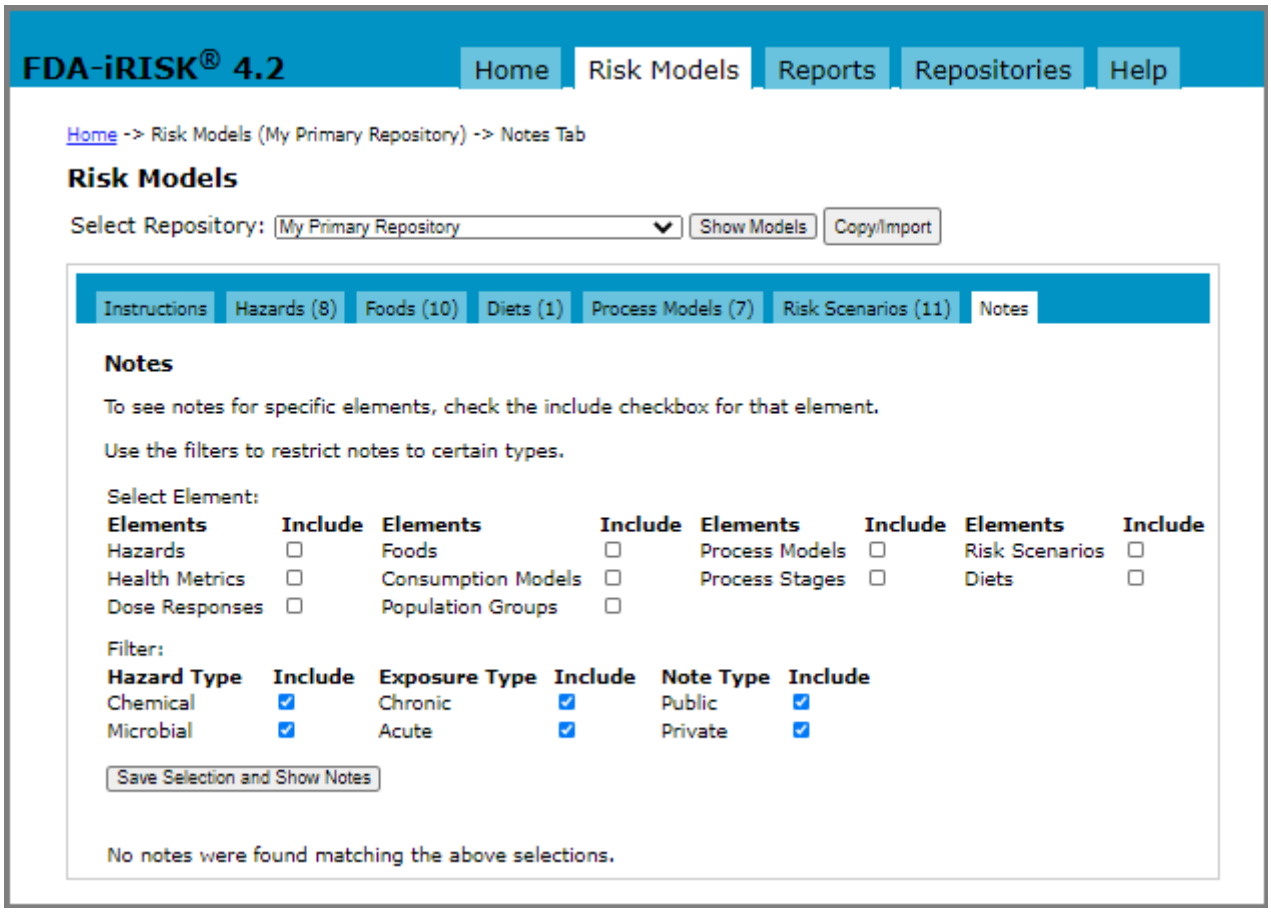
CHAPTER 6

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:



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.



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.

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.

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

3 On the Edit Note page, make the required changes.

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**.

Deleting 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 delete.
- Navigate to the **Notes** tab for the element where you want to delete the note.

2 Click the **Delete** link to the right of the note that you want to delete.

3 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**.

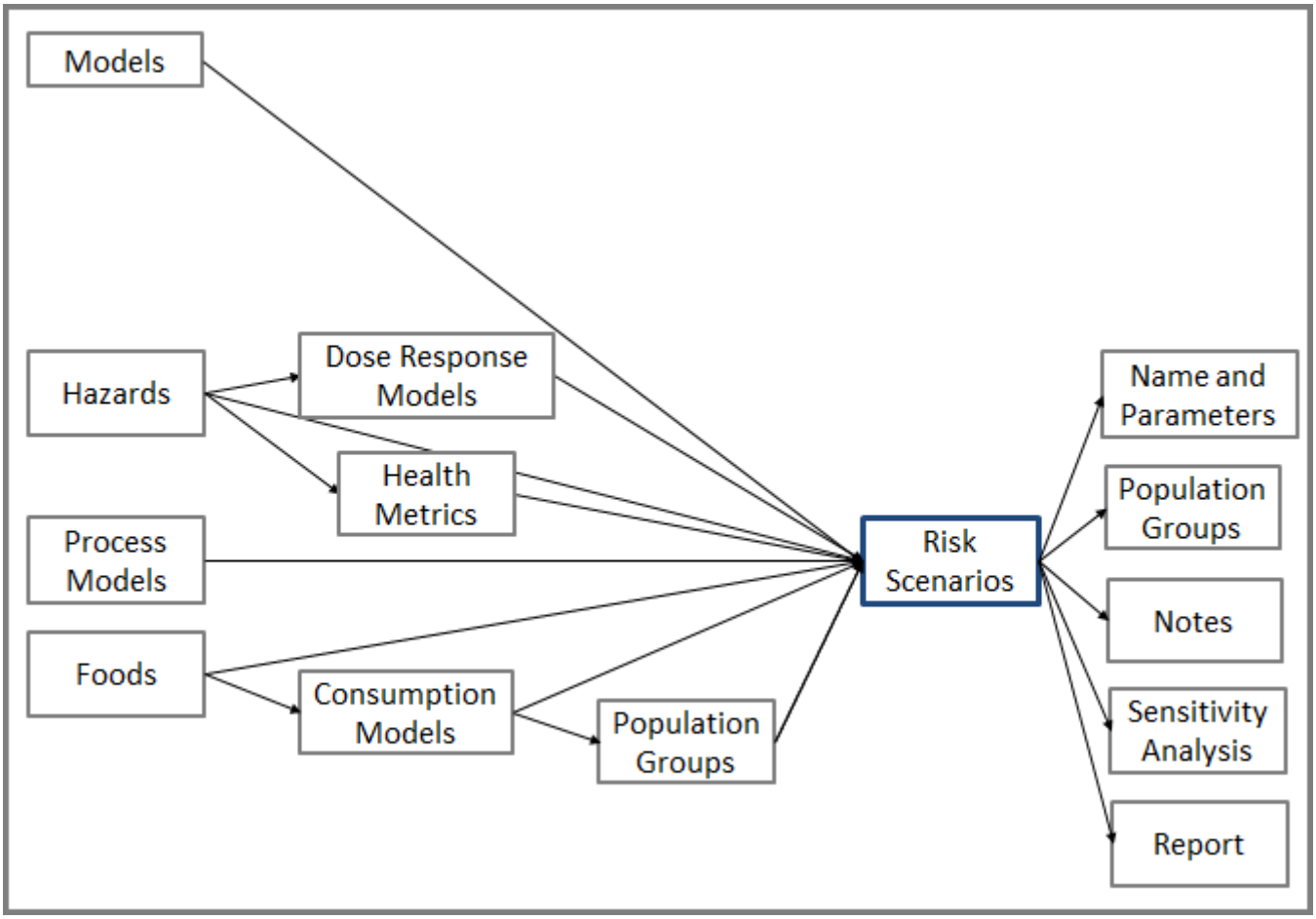
Importing a Note

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:

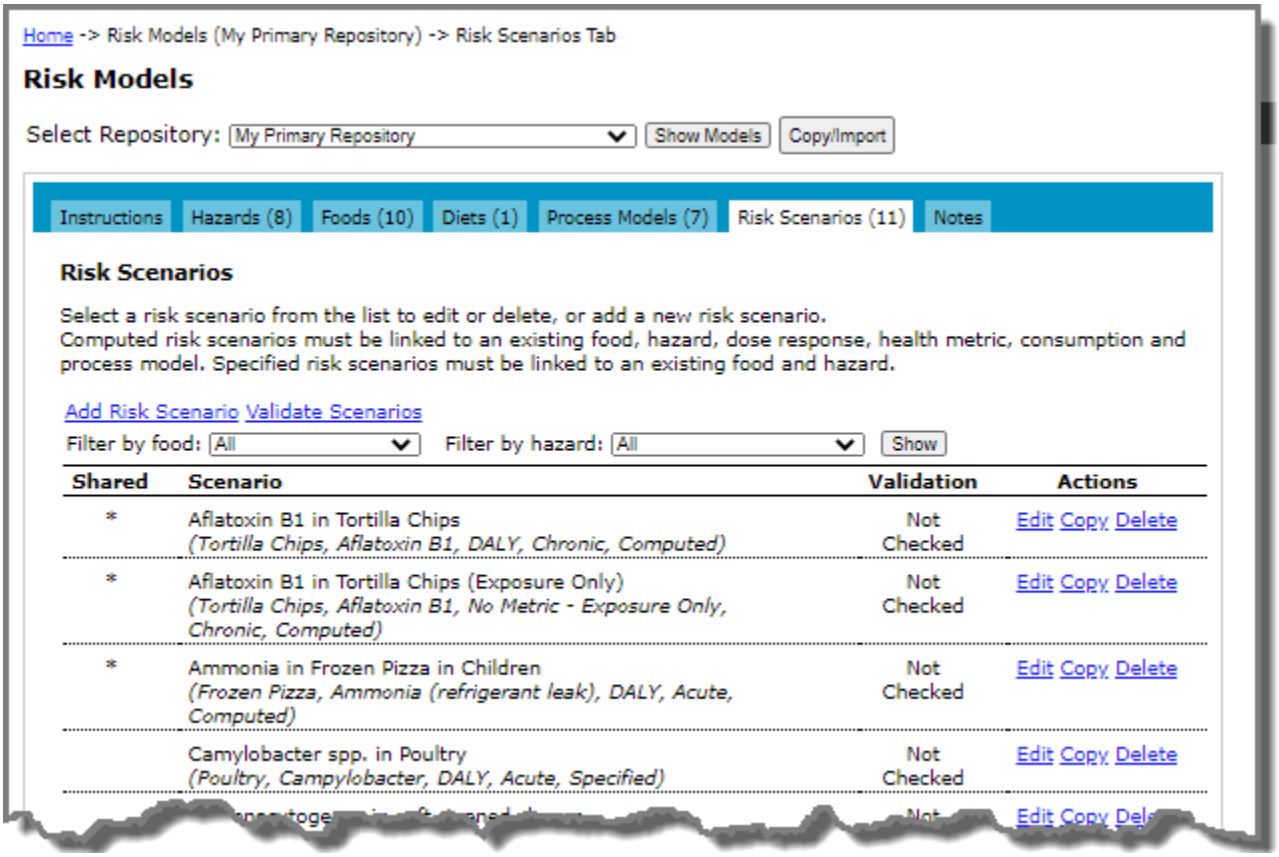


For risk scenarios involving chronic exposures, a "full lifetime" set of life stages take the place of the population groups shown here.

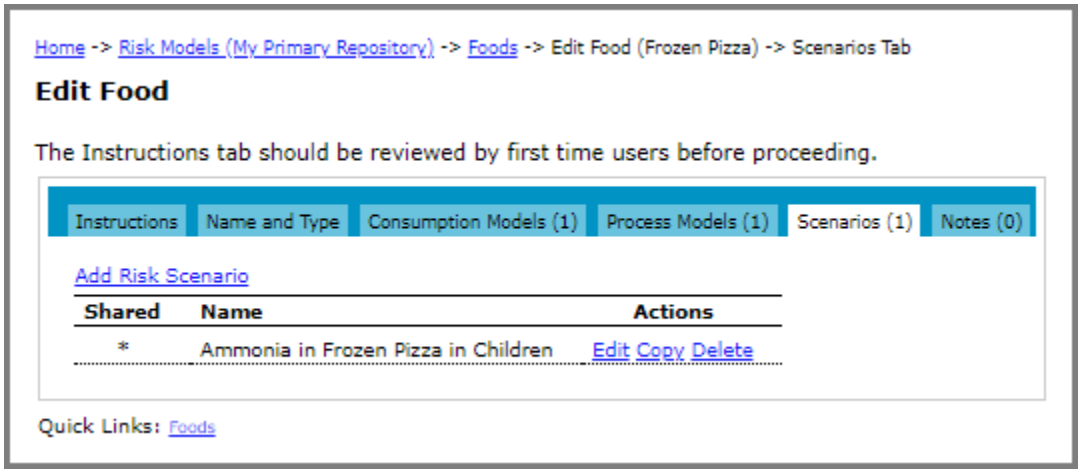
Navigating to Risk Scenarios

You navigate to the risk scenarios in the following ways:

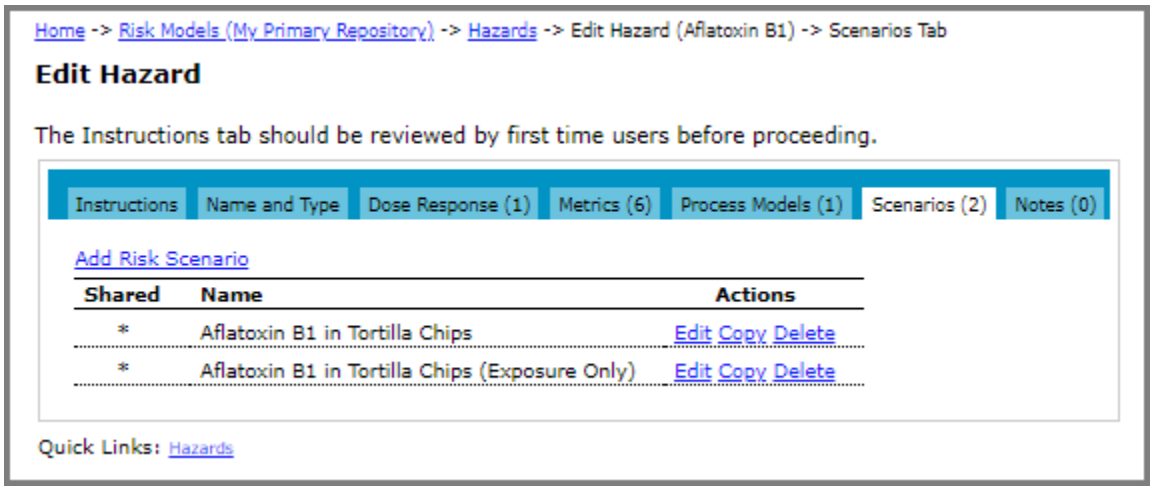
- Click the **Risk Scenarios** tab on the Risk Models page. Select a repository and click **Show Models**. A complete list of risk scenarios displays; however, you can filter the list by food or hazard. (The number on the tab, e.g. (10) indicates the number of risk scenarios.)



- 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.



- 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.



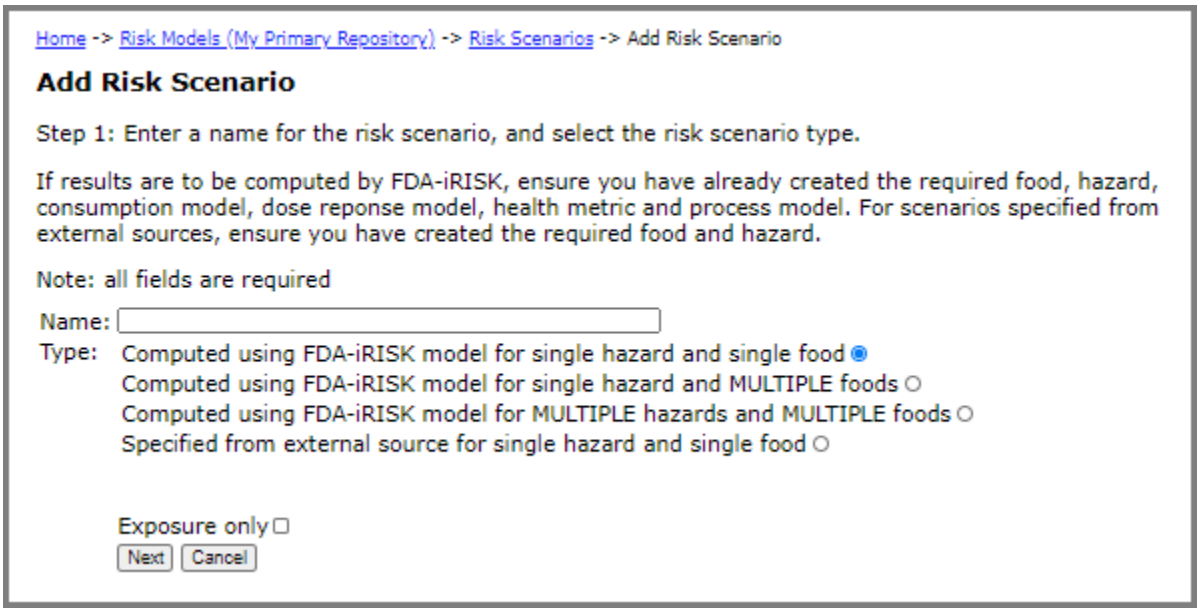
Adding a Risk Scenario

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)

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.

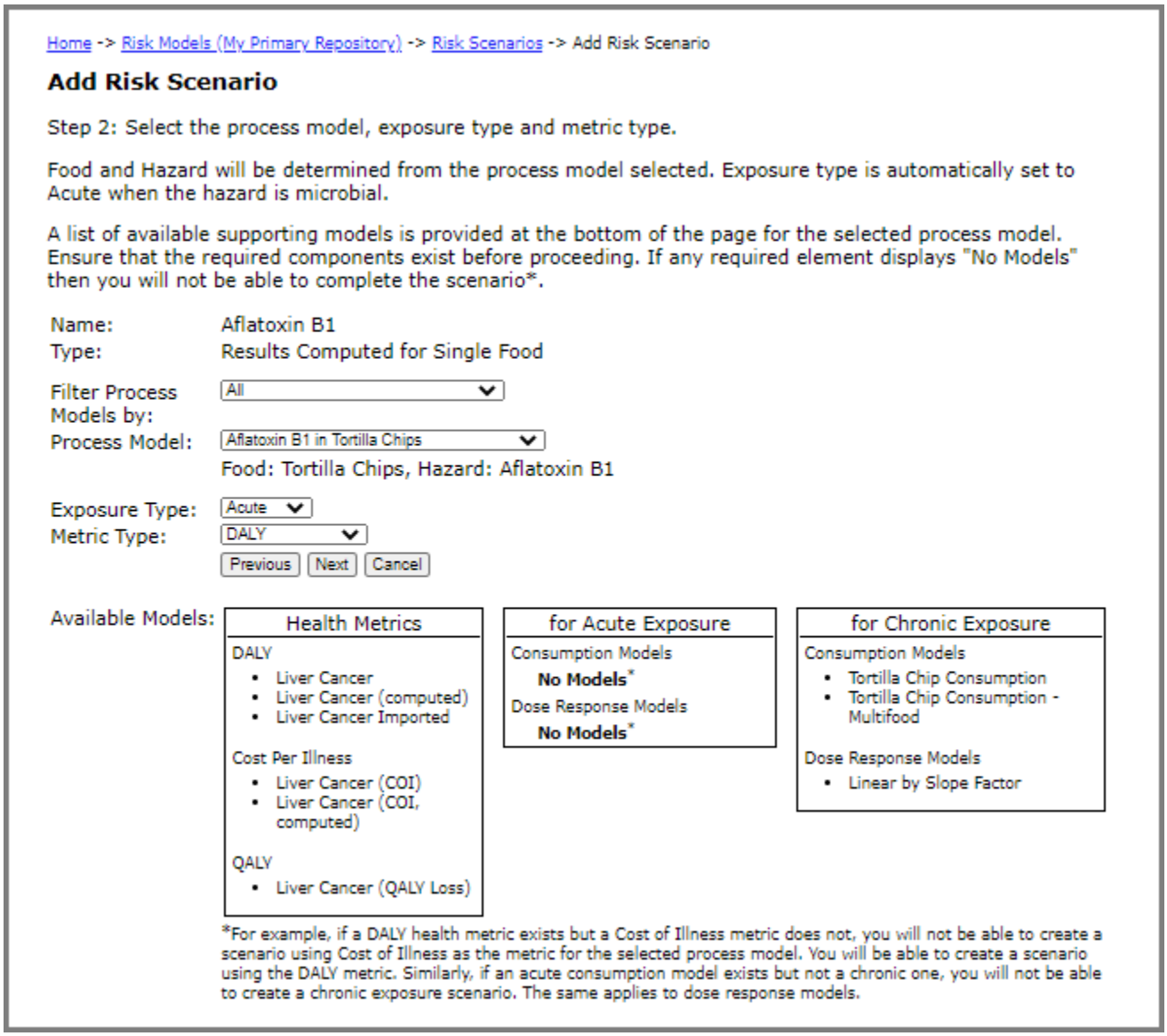


3 In the **Name** input field, enter a name for the risk scenario.

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.

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*.

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



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.

6 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.

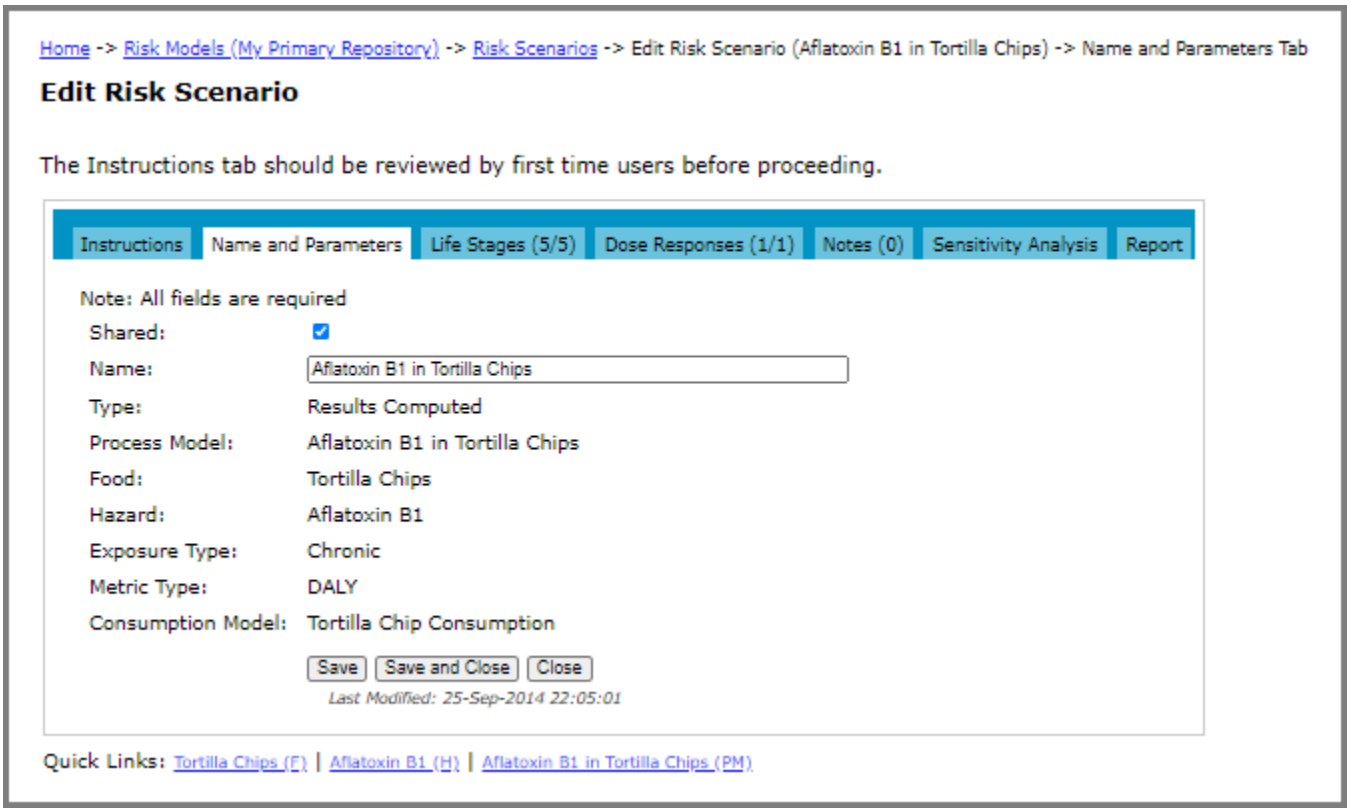
7 In the **Exposure Type** drop-down list, select the exposure type that the risk scenario will evaluate. (This is fixed as Acute if the process model selected involves a microbial hazard.)

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.



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)

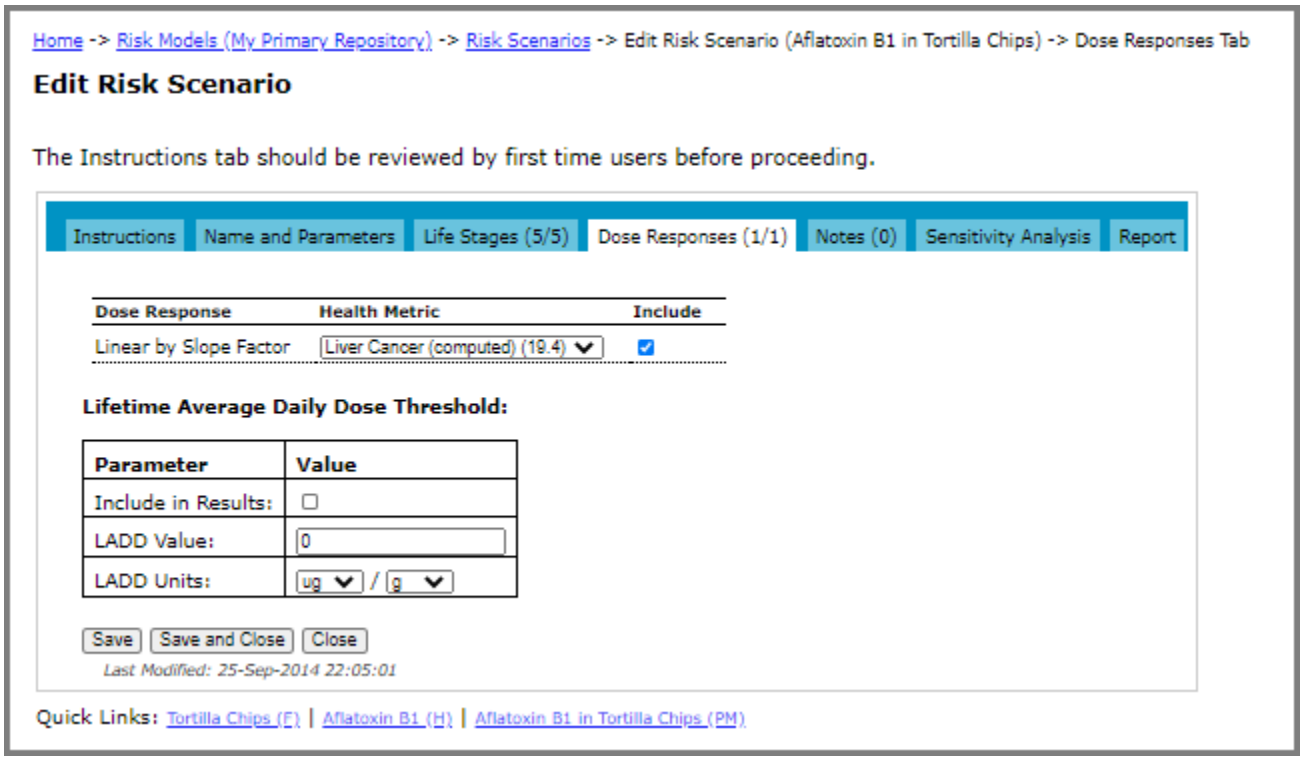
lifetime exposure, all must be selected. The total span in years covered by the selected life stages is calculated when the Save button is clicked.

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

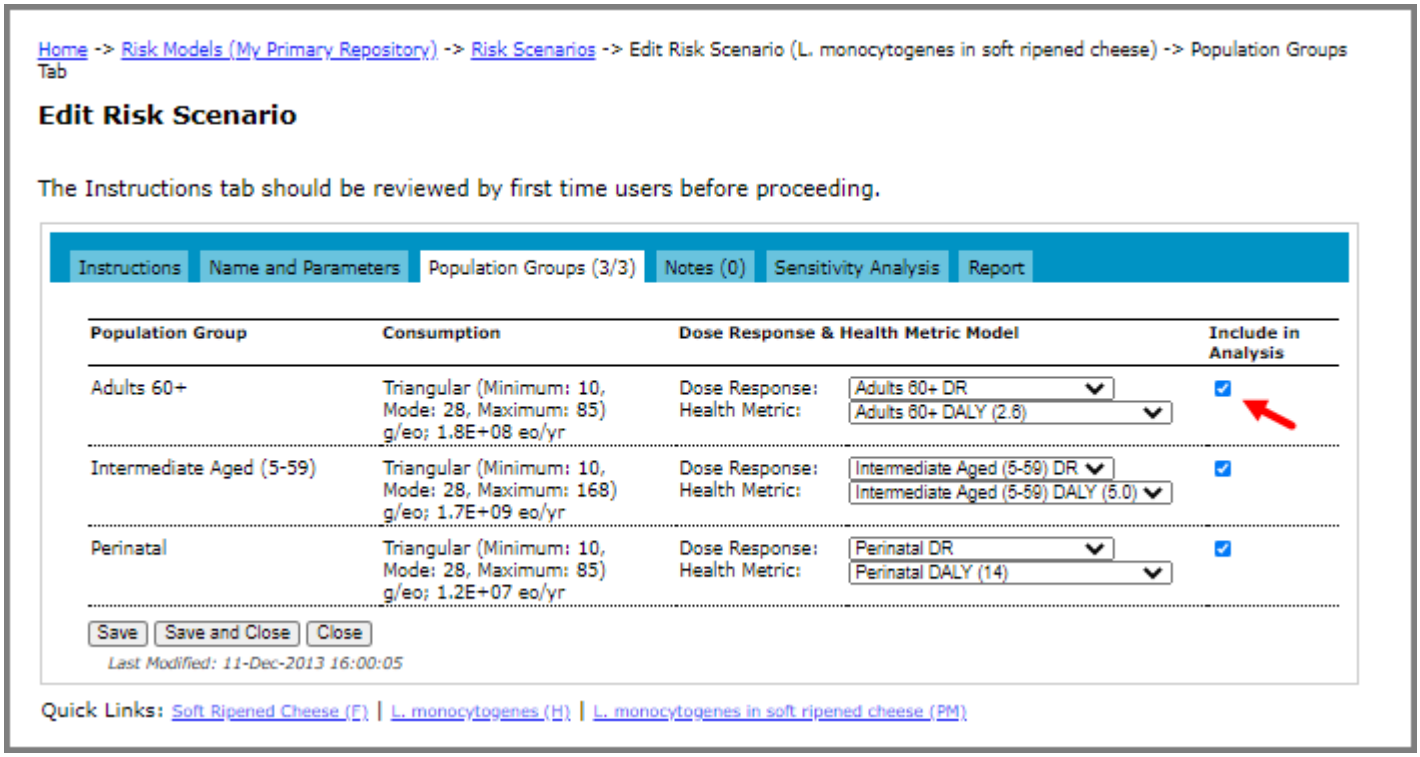
(LADD Value) and LADD units. To include the result in the report, select the Include in Results check box. Save and close.



- **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).



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.

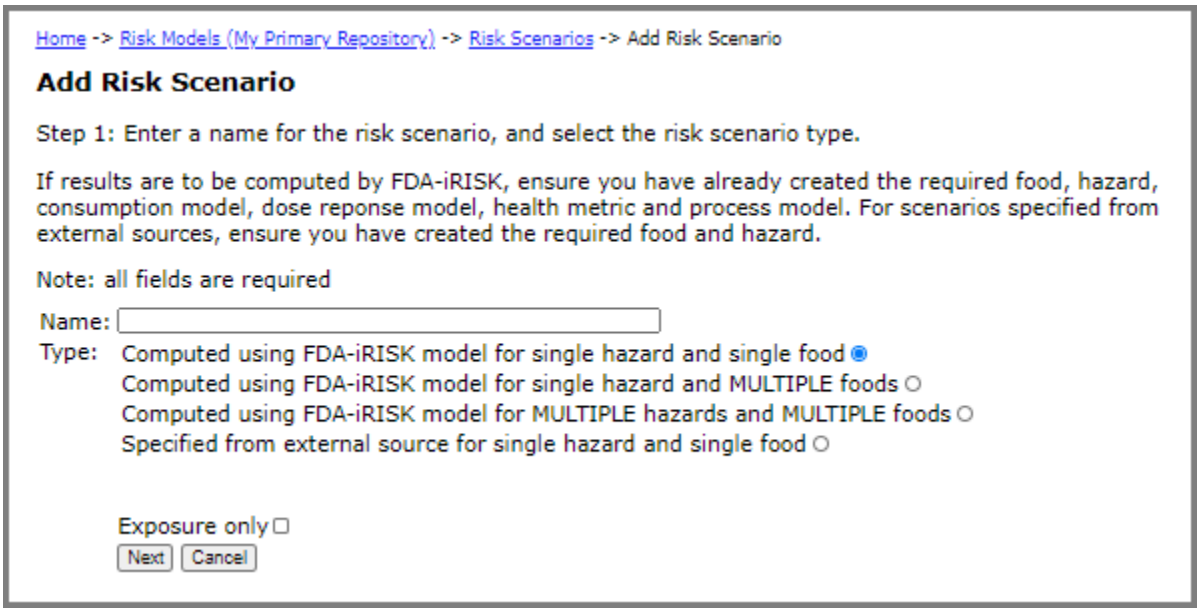
14 Do one of the following:

- 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.

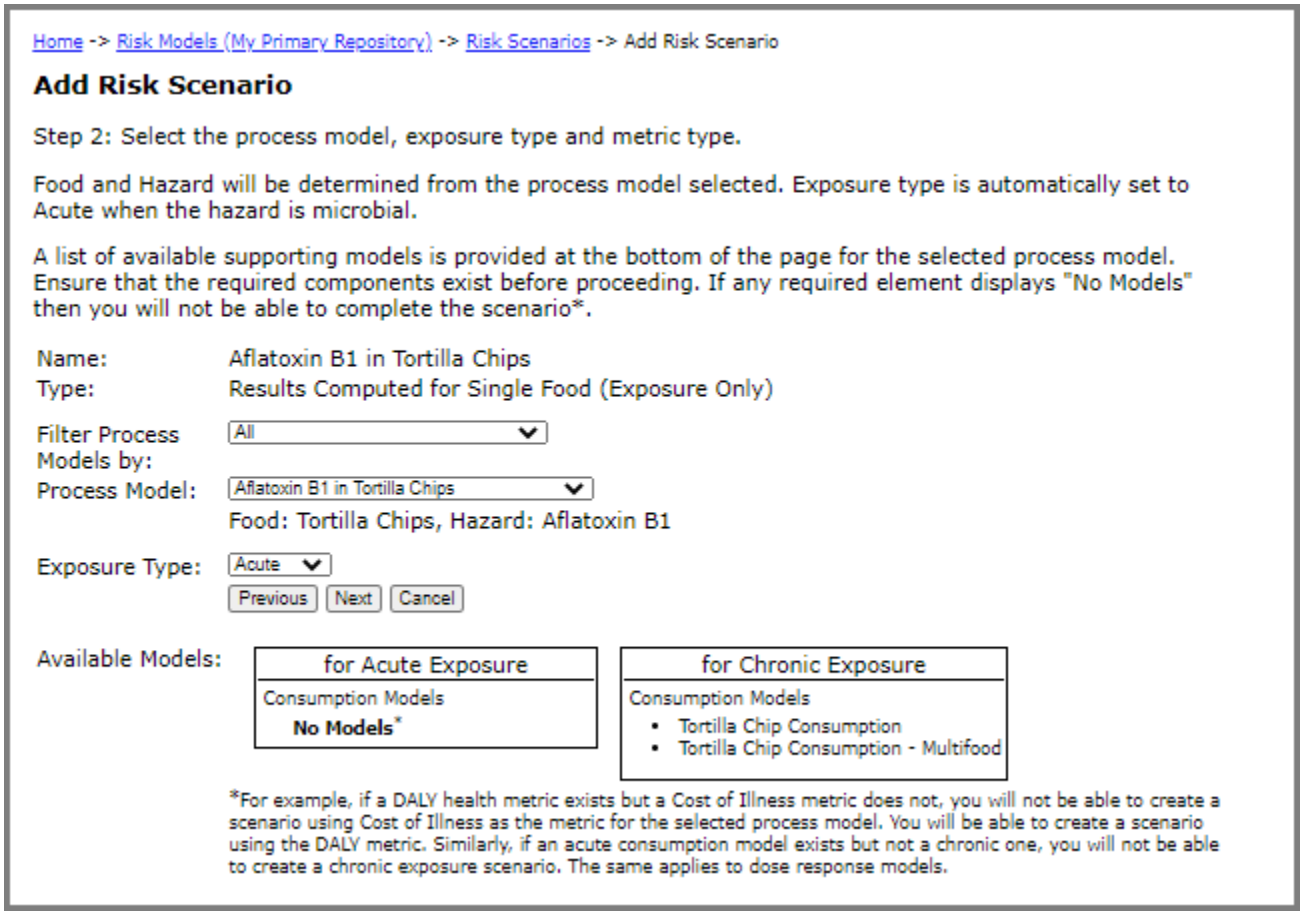


3 In the **Name** input field, enter a name for the risk scenario.

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.



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.

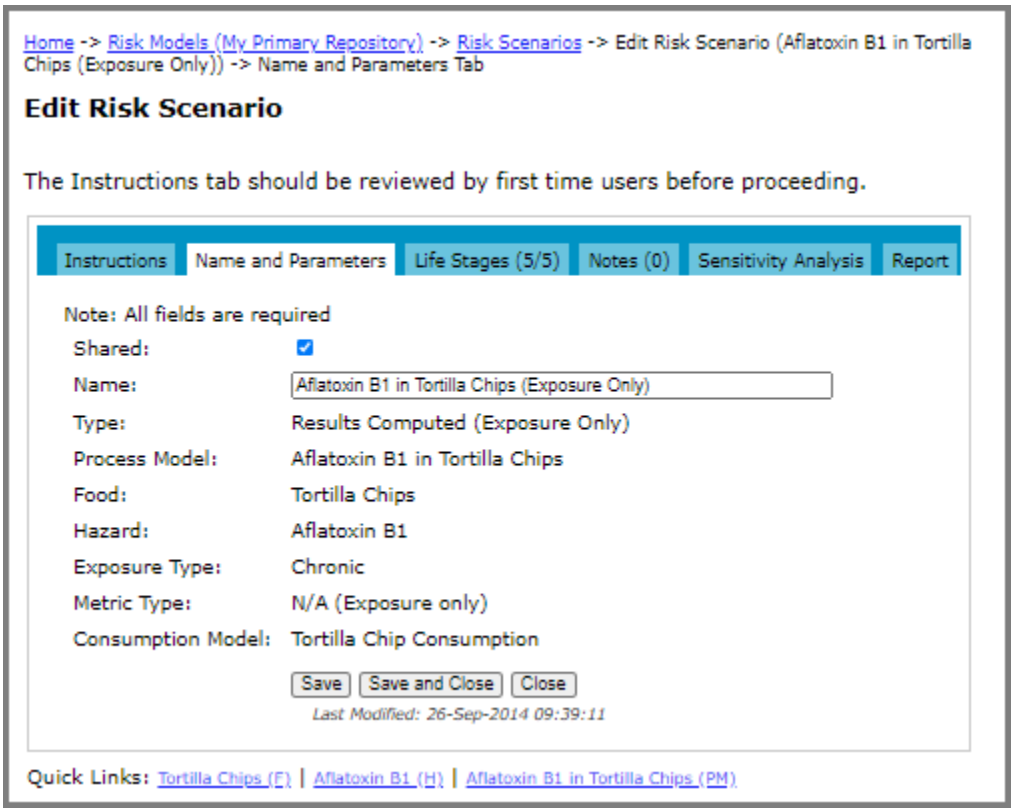
8 In the **Exposure Type** drop-down list, select the exposure type that the risk scenario will evaluate.

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.

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.



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.

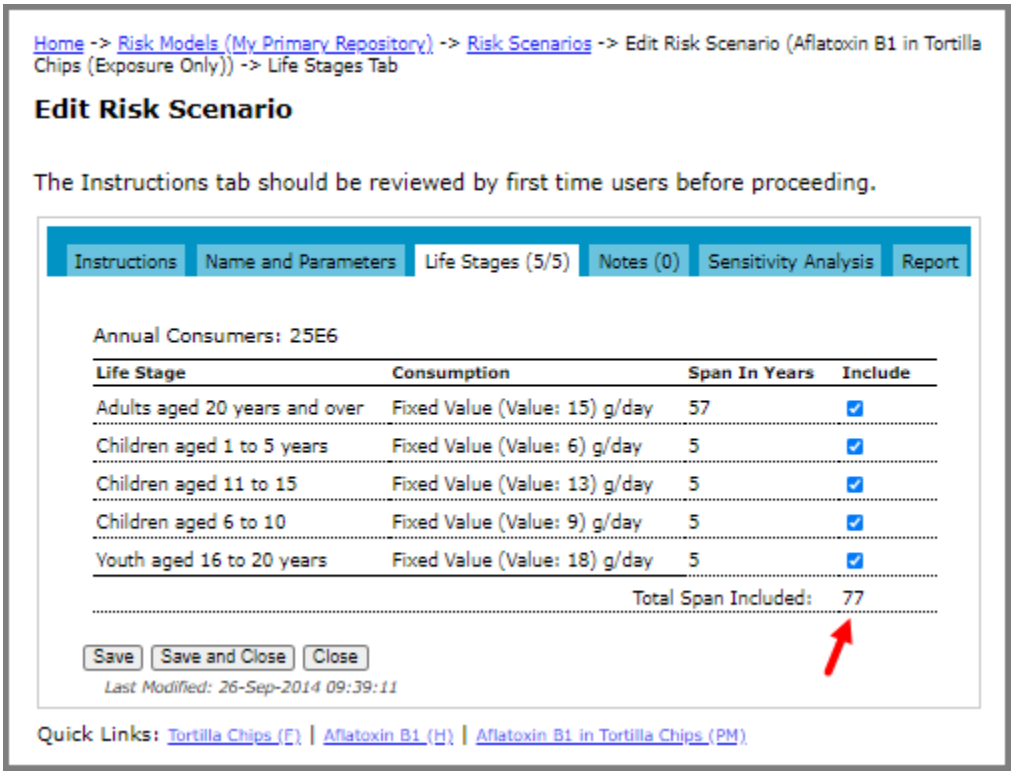
13 To complete this procedure, do one of the following:

- **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**.

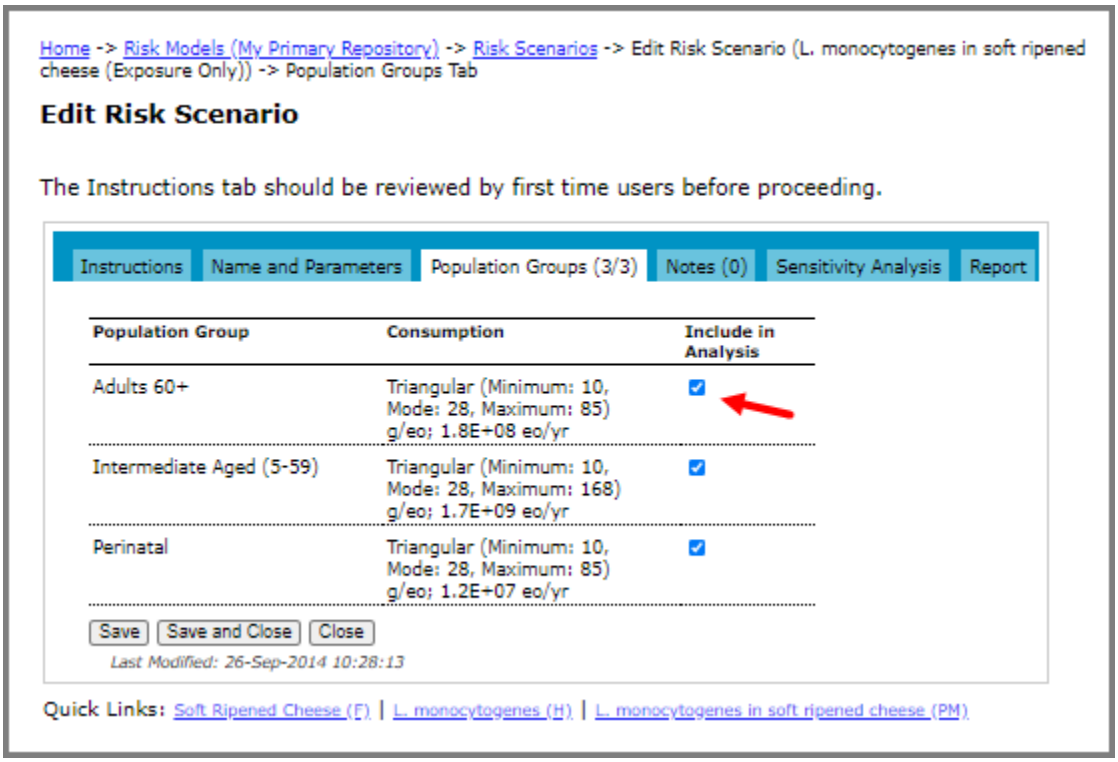
  In the following example, five groups have been defined for the consumption model. Because the groups have been defined in order to describe the (chronic) lifetime exposure, all must be selected. The total span in years covered by the selected life stages is calculated when the **Save** button is clicked.



- **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).



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)

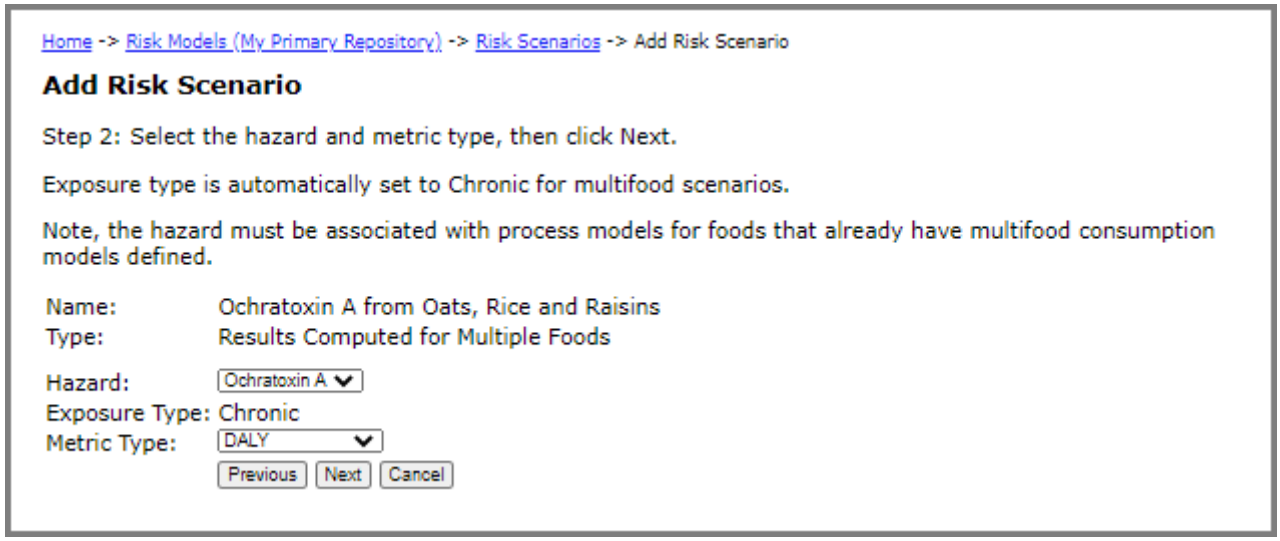
1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.

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.

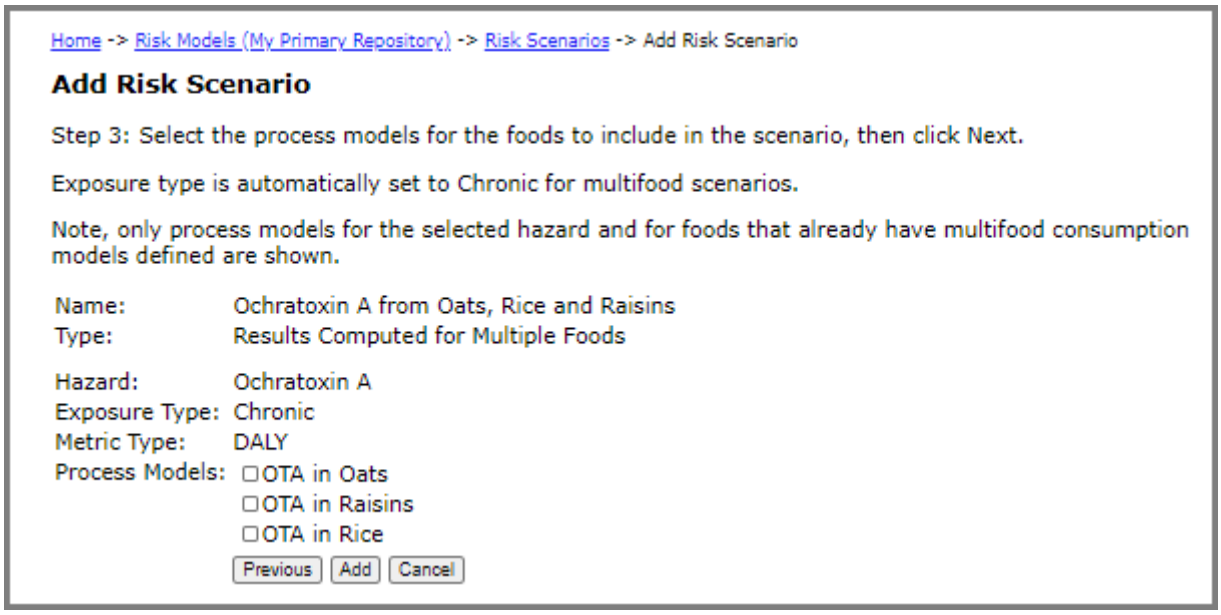
5 Click **Next**. The Add Risk Scenario, Step 2 page opens.



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.



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.

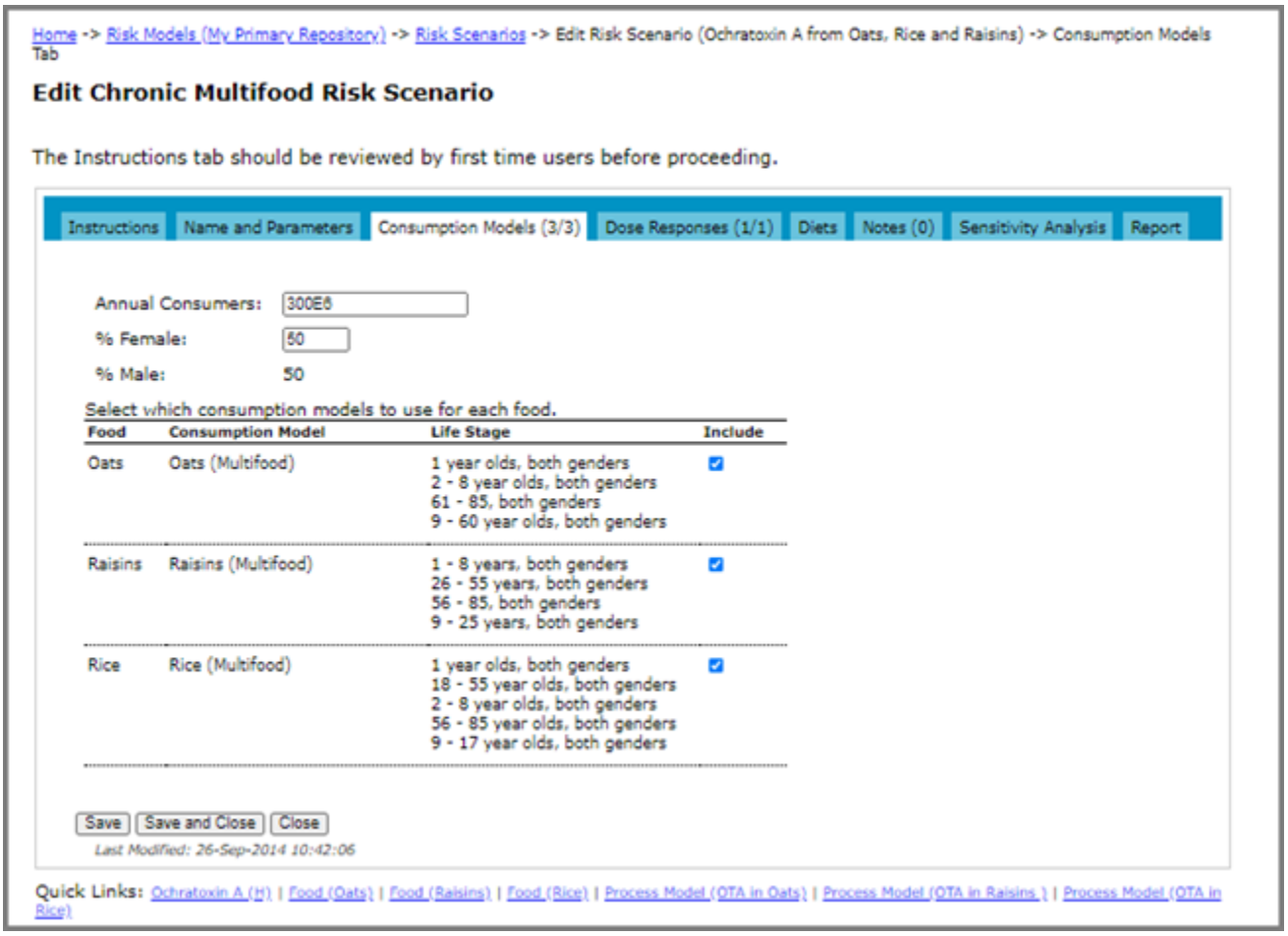
Note: Messages appearing in green text on this page serve as a reminder of any remaining step(s) necessary to define the scenario.

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.



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)

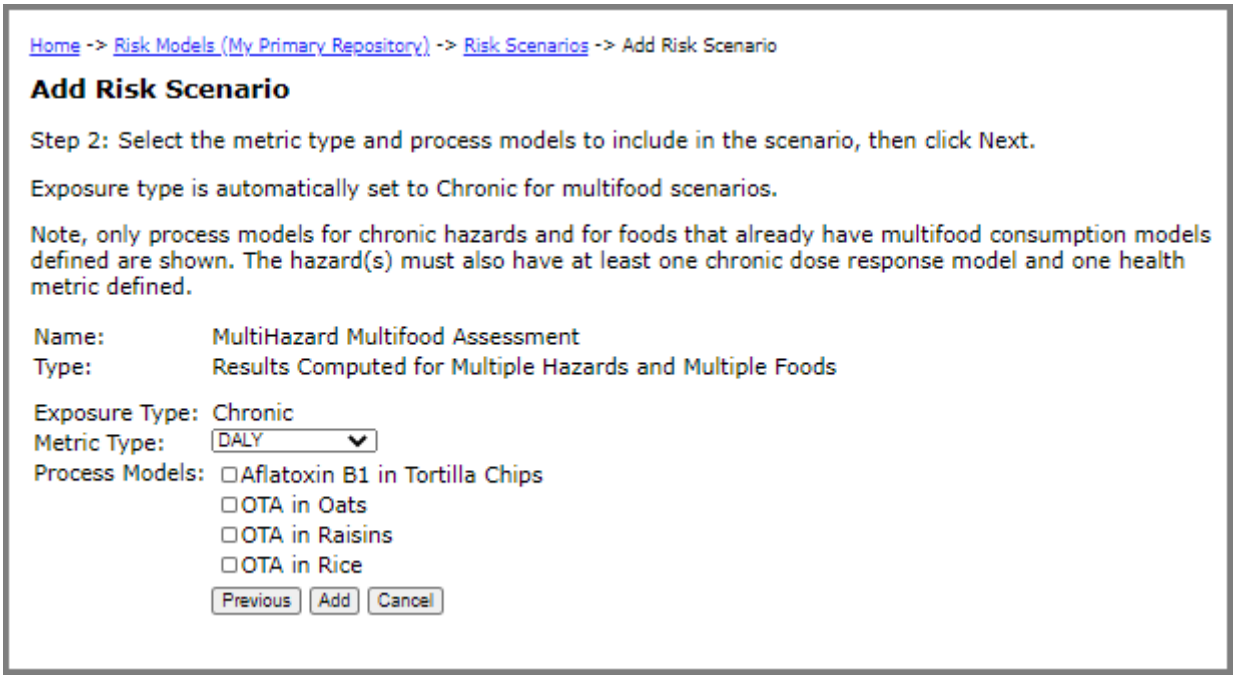
1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.

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.

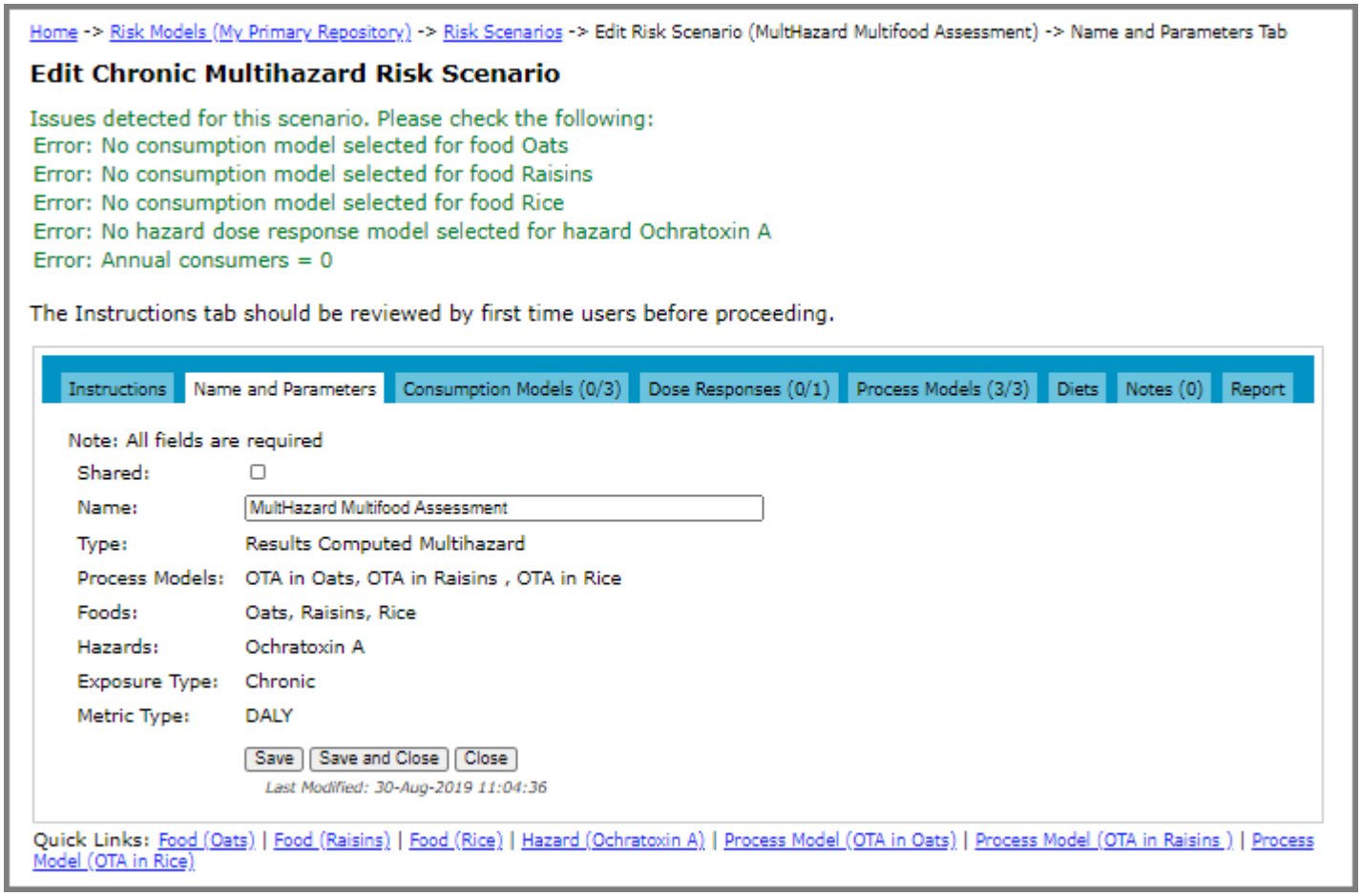
5 Click **Next**. The Add Risk Scenario, Step 2 page opens.



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.



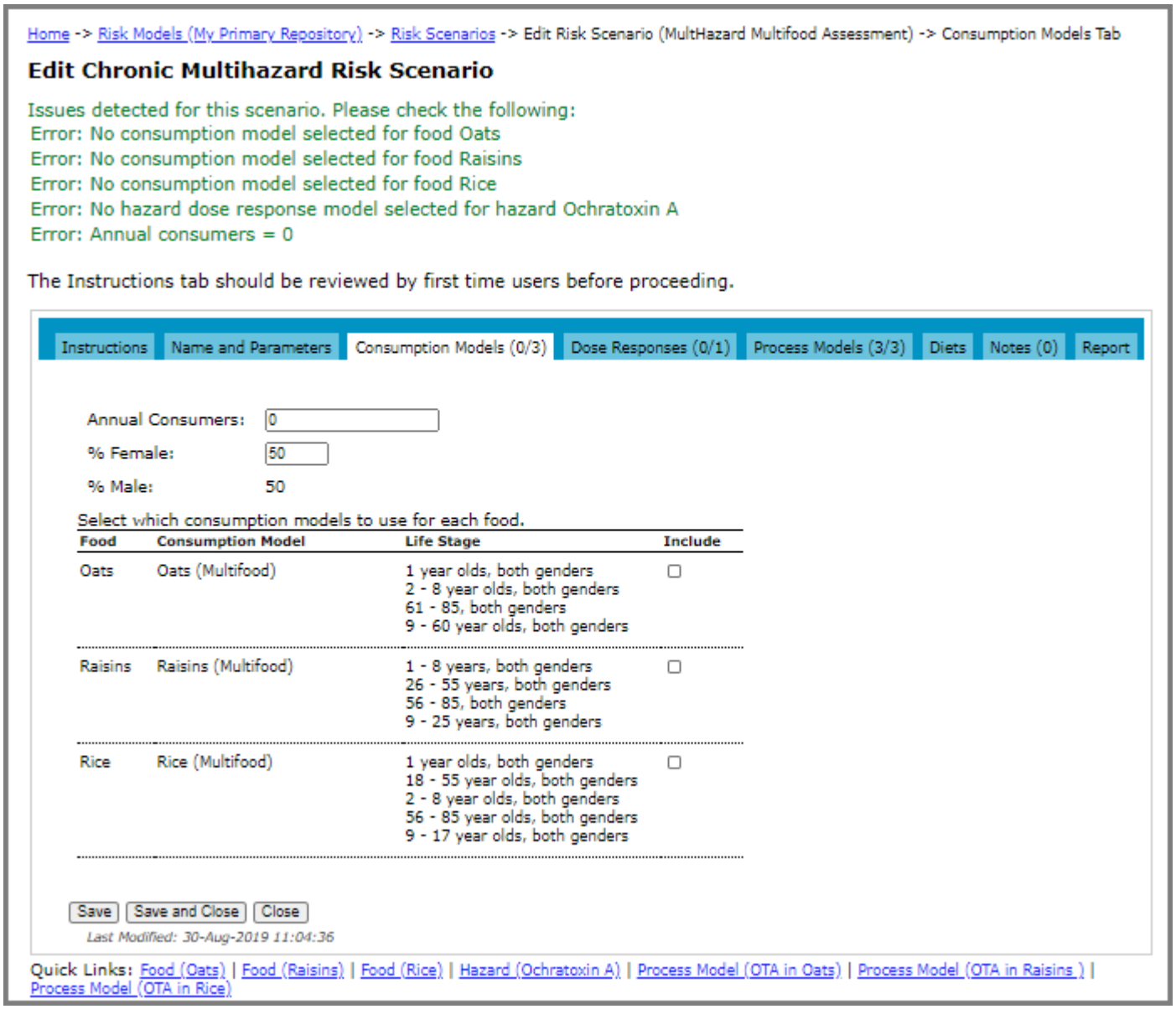
Note: Messages appearing in green text on this page serve as a reminder of any remaining step(s) necessary to define the scenario.

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.



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:

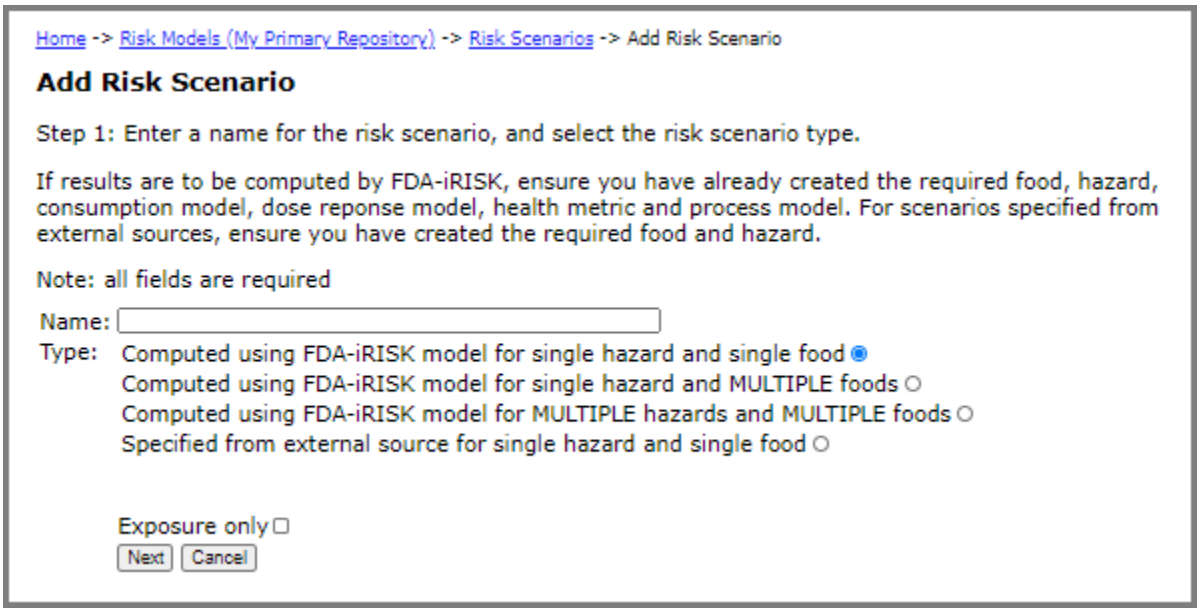
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.

- 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.



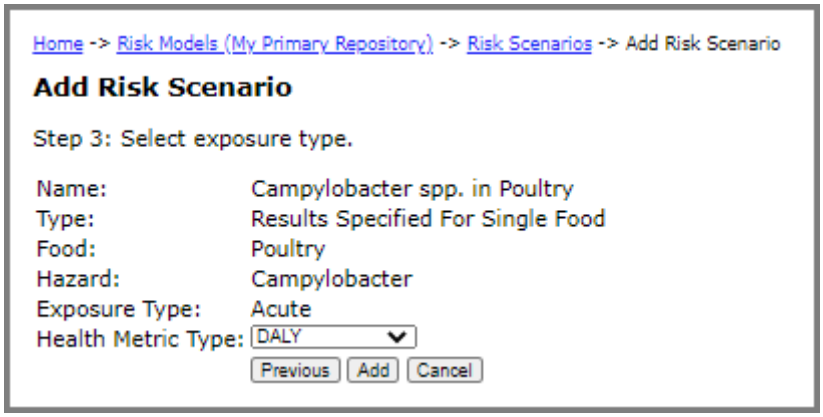
3 In the **Name** input field, enter a name for the risk scenario.

4 Select the **Specified from external source for single hazard and single food** option.

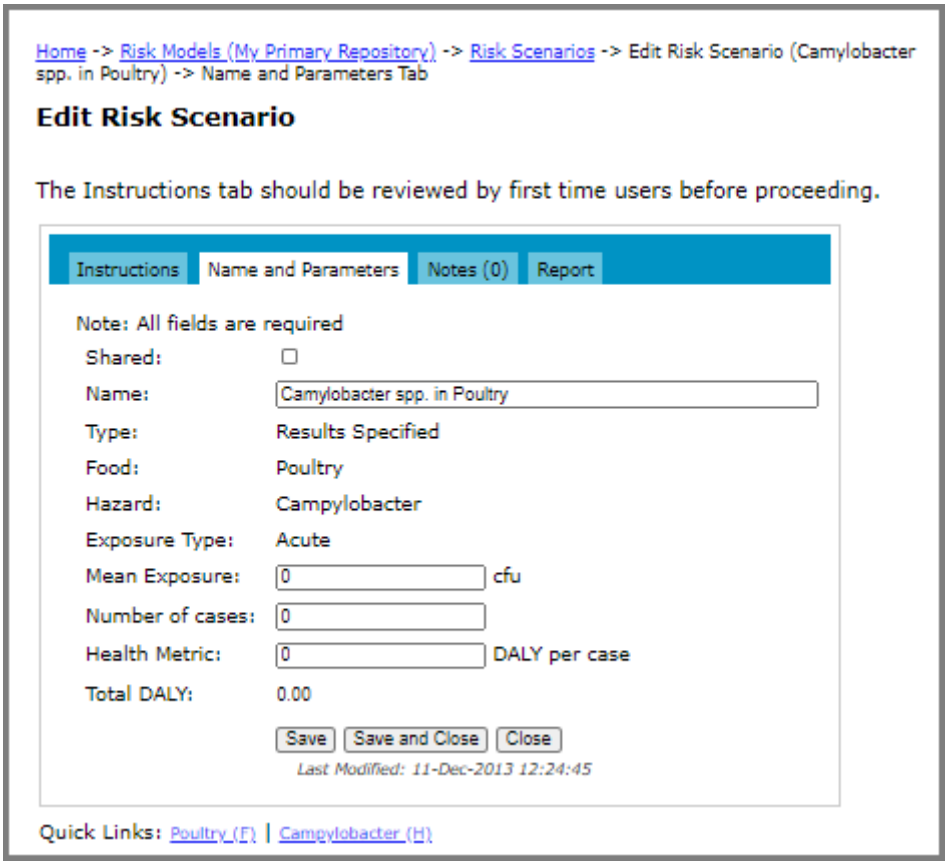
5 Click **Next**. The Add Risk Scenario page opens.

6 Select the food and hazard from the drop-down lists.

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



8 Click **Add**.



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).

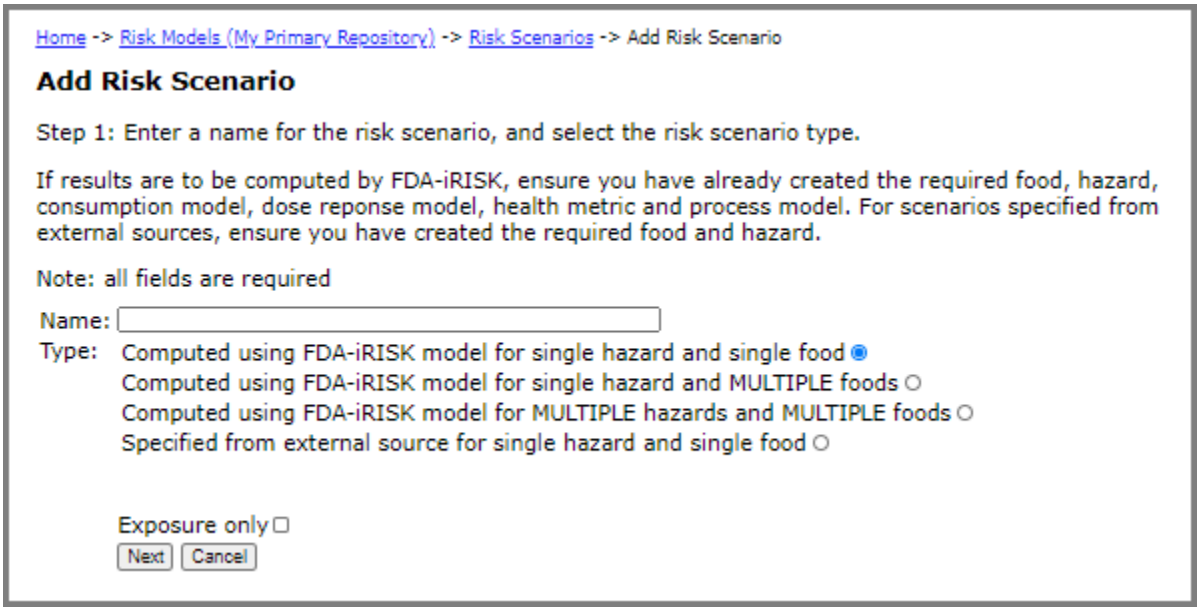
13 To calculate and display one of the following, click Save.
- The total DALY incurred according to the entered values for incidence and burden per case.
- The total cost incurred if the entered values refer to incidence and cost per illness.
- The total QALY loss incurred according to the entered values 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.



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 Click **Add**.

10 In the **Mean Exposure** field, enter the mean exposure in the units of the hazard.

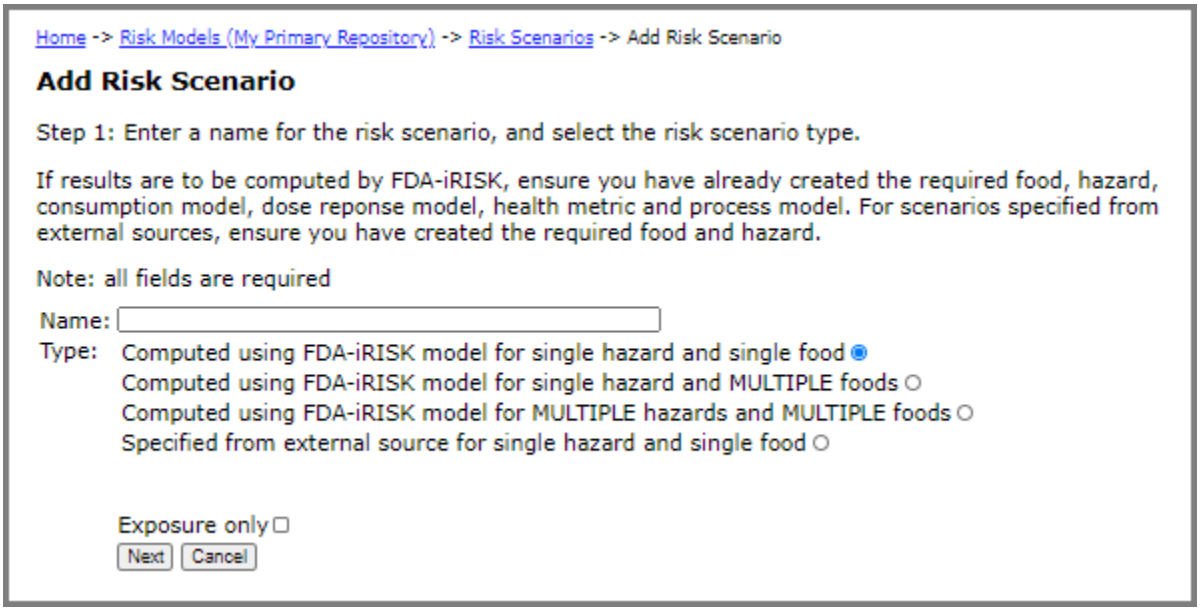
11 Do one of the following:

- 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.



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.

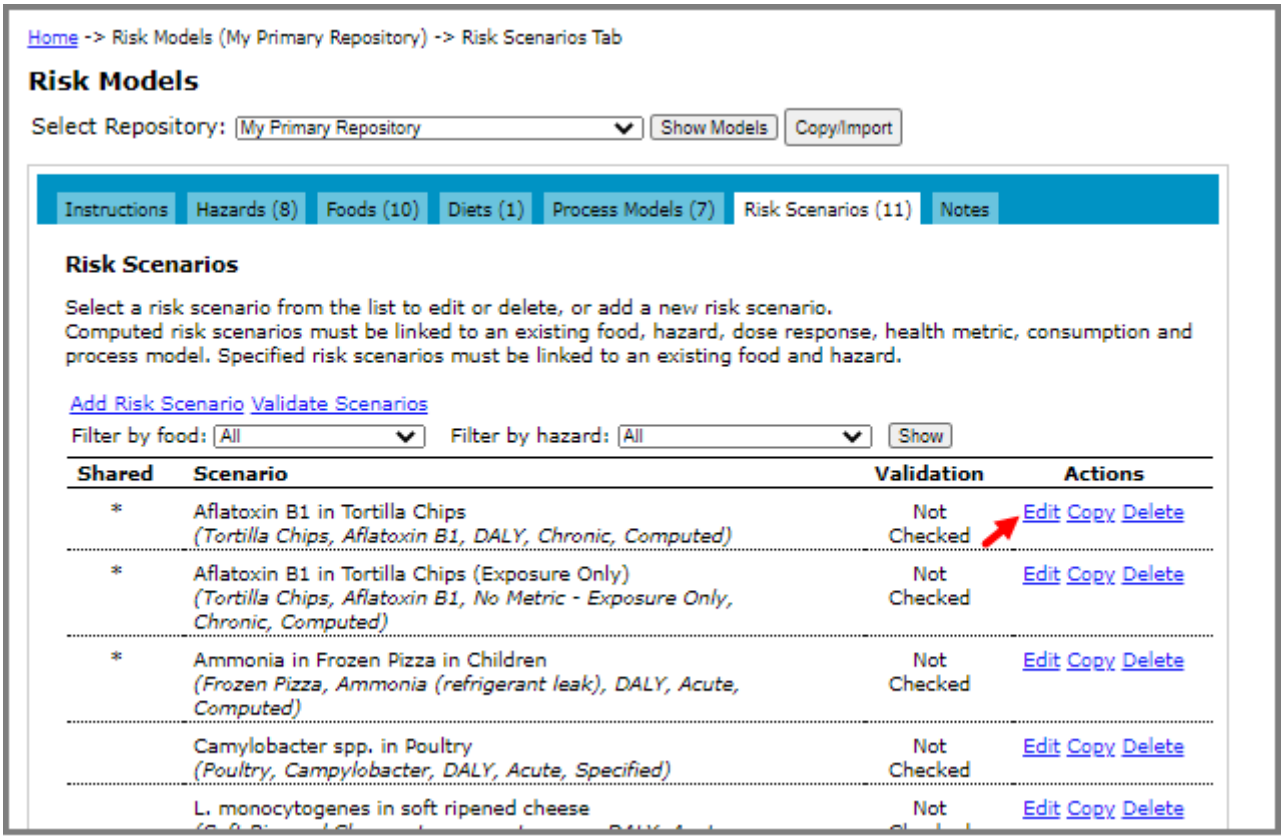
12 Do one of the following:

- 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*.

2 On the **Risk Scenarios** tab, click the **Edit** link to the right of the risk scenario that you want to edit.



3 Make the required changes. For more information about which elements may be edited see *"Adding a Risk Scenario" on page 108*.

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**.

Deleting a Risk Scenario

Deleting a scenario does not delete any of the component models used in its creation.

1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.

2 On the **Risk Scenarios** tab, click the **Delete** link to the right of the risk scenario that you want to delete.

3 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:

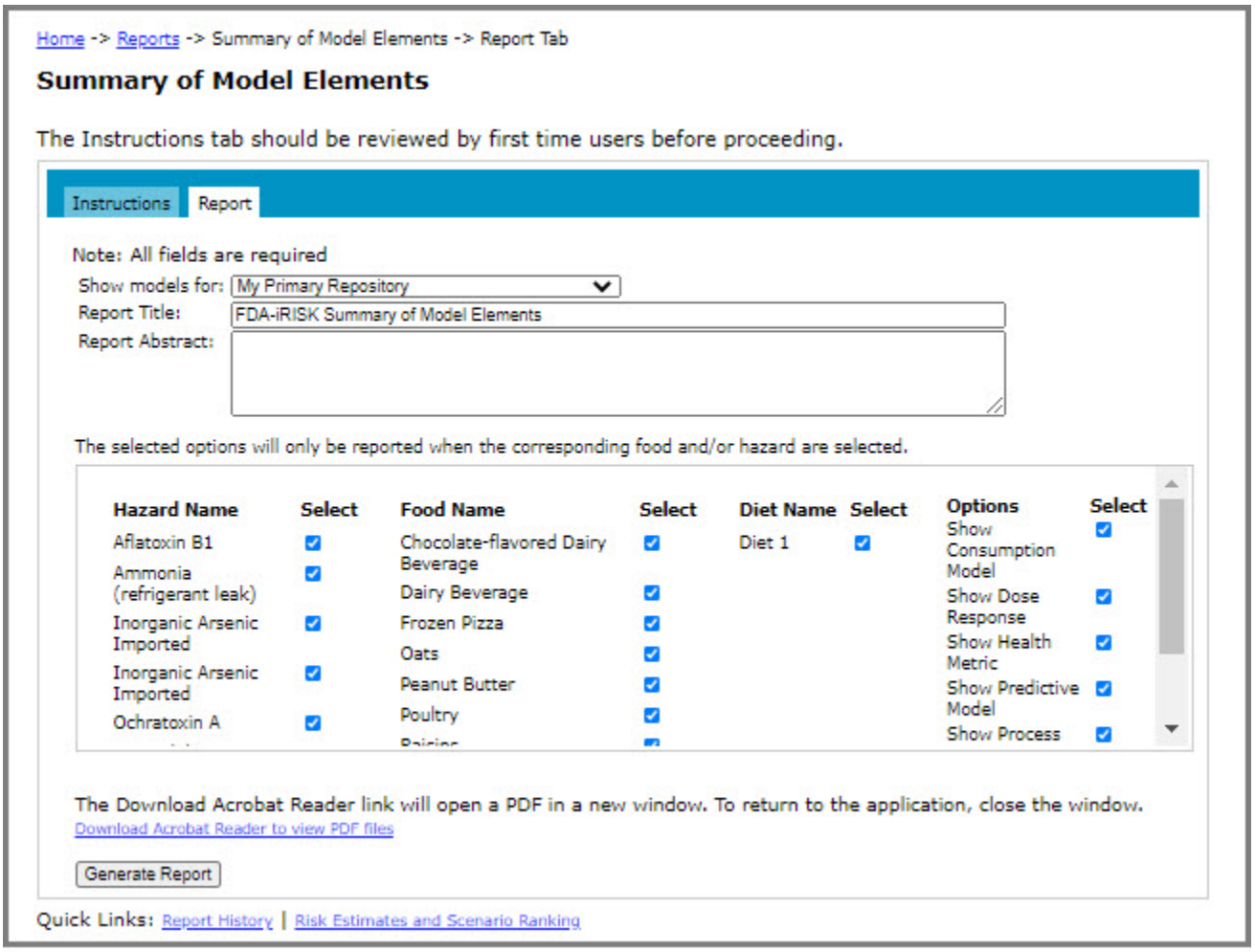
- **Risk Estimates and Scenario Ranking** Creates a report with risk estimates and ranking results for one or more scenarios including full documentation of model inputs.
- **Summary of Model Elements** Creates a report summarizing model elements with no risk estimates. The scenarios are not computed.

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.

2 Click the **Create** link to the left of the Summary of Model Elements report type. The Summary of Model Elements page opens.



3 In the **Select Repository** drop-down list, select the model repository to view.

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 Select the check boxes beside the hazards and foods that you want to include in the report.

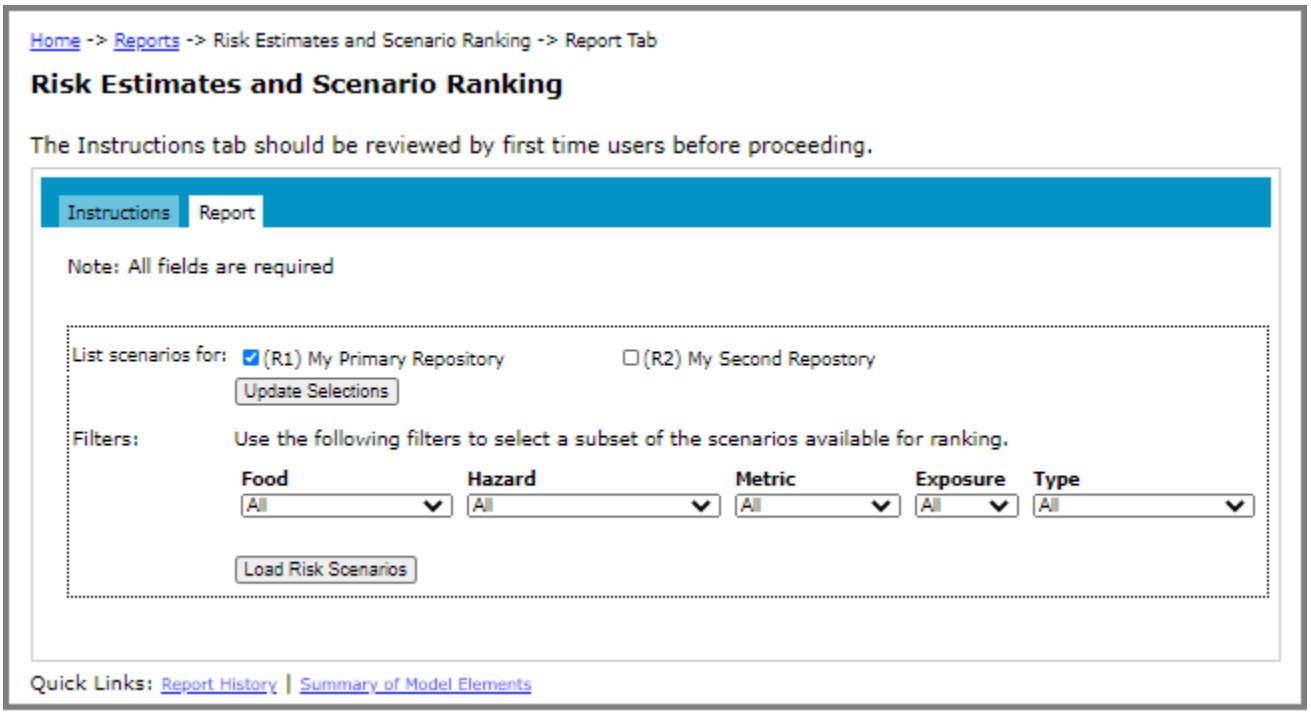
6 Select the check boxes beside the elements listed under Options that you want to include in the report.

7 Click **Generate Report**. The report is created in PDF format.

Creating the Risk Estimates and Scenario Ranking Report

1 Click the **Reports** tab on the main tab bar.

2 Click the **Create** link to the left of the Risk Estimates and Scenario Ranking report type. The Risk Estimates and Scenario Ranking page opens.



3 In the **List scenarios for** section, select one or more model repositories and click **Update Selections**.

4 You can use the drop-down list filters (i.e. Food, Hazard, Metric, Exposure, Type) to refine the list of available scenarios.

5 Click **Load Risk Scenarios**.

6 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*.

7 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.

8 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.)

9 In the **Report Title** input field, enter a name for the report, and enter an abstract in the **Report Abstract** input field (optional).

10 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:

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*.

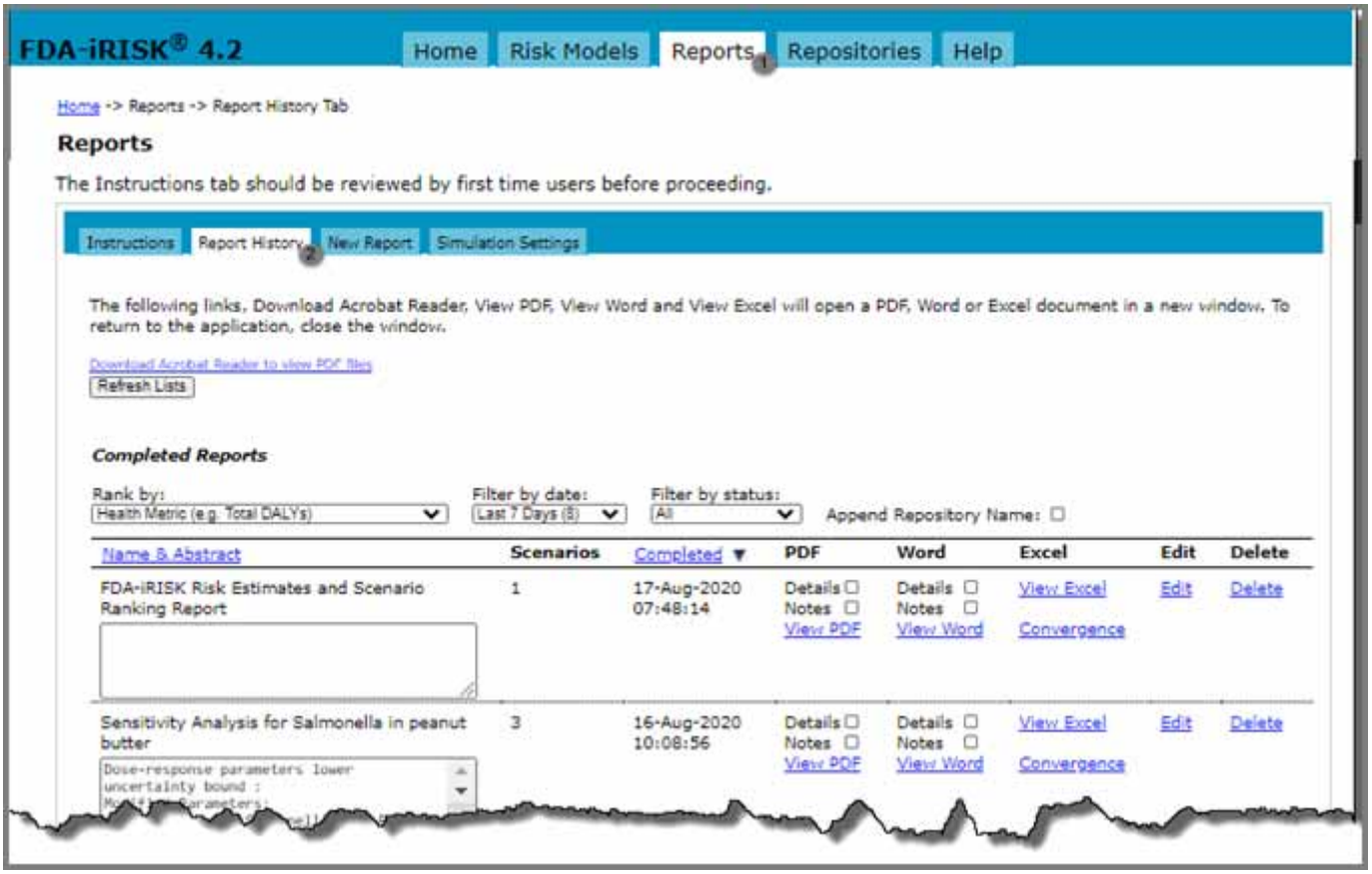
In some situations, two or more scenarios may be required to characterize fully the risk for a food-hazard combination, with each scenario contributing a proportion of the risk. To achieve this, you might apply the appropriate population sizes to each scenario or try some other mechanism.

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.

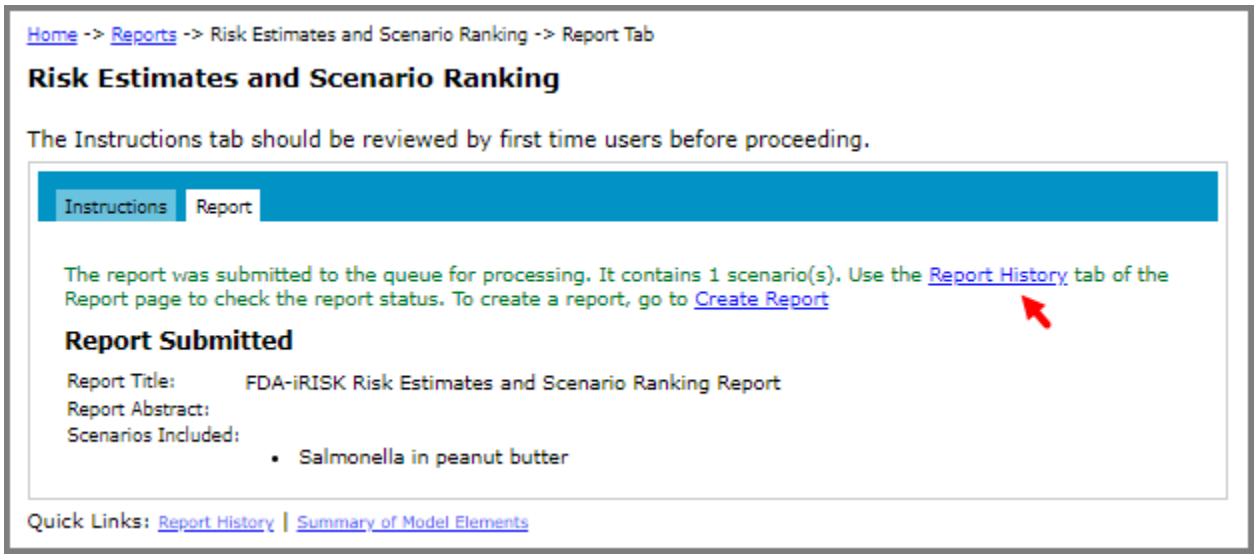
Viewing Reports

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.

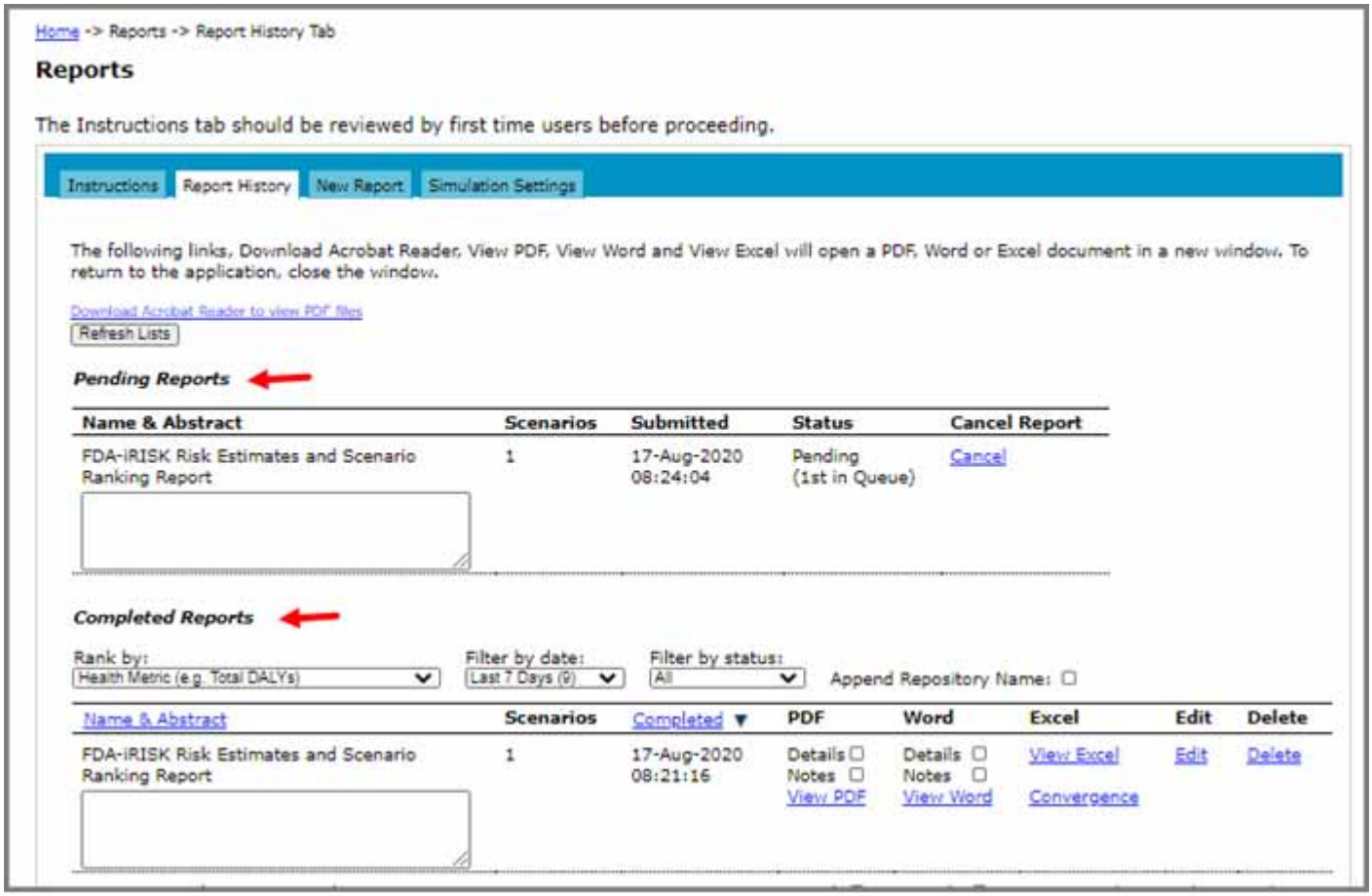


- Create and generate a report on the New Report tab. (See *"Creating the Summary of Model Elements Report" on page 133* and *"Creating the Risk Estimates and Scenario Ranking Report" on page 134*.) Click the **Report History** link.



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.



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

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

Scenario or Scenario Group	Total DALYs per Year	Uncertainty Results
Salmonella in peanut butter - 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)

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

Scenario	Lifecourse Duration	Eating Occasions or Consumers	Total Illnesses	Mean Risk of Illness	Total DALYs per Year	DALYs Per EO or Consumer	Total DALYs per Year (Weighted)
Salmonella in peanut butter	N/A	1.70E+10	3280	1.93E-7	62.4	3.67E-9	62.4
L. monocytogenes in soft ripened cheese	N/A	1.89E+9	2.79	1.48E-9	15.7	8.27E-9	15.7
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 log10 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) Minimum: 0.7 Mode: 1.3 Maximum: 2 Computed Mean: 1.33 mg/g	**0.000617 g/g**
Unit Mass:	Fixed Value (g) Value: 150	**150 g**

* 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 Body Weight: Fixed Value (Units: Kg) Value: 0	Eating Occasions: 1.3E9 eo/yr Per Eating Occasion: Triangular (Units: g/eo) Minimum: 100 Mode: 150 Maximum: 300	Ammonia Non-Threshold Linear Non-Threshold Linear (Dose unit: mg) Risk at Reference Point: 0.21 Reference Point: 118 Probability of adverse effect: 100%	Ammonia (oral) DALY (0.001 DALYs)

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.

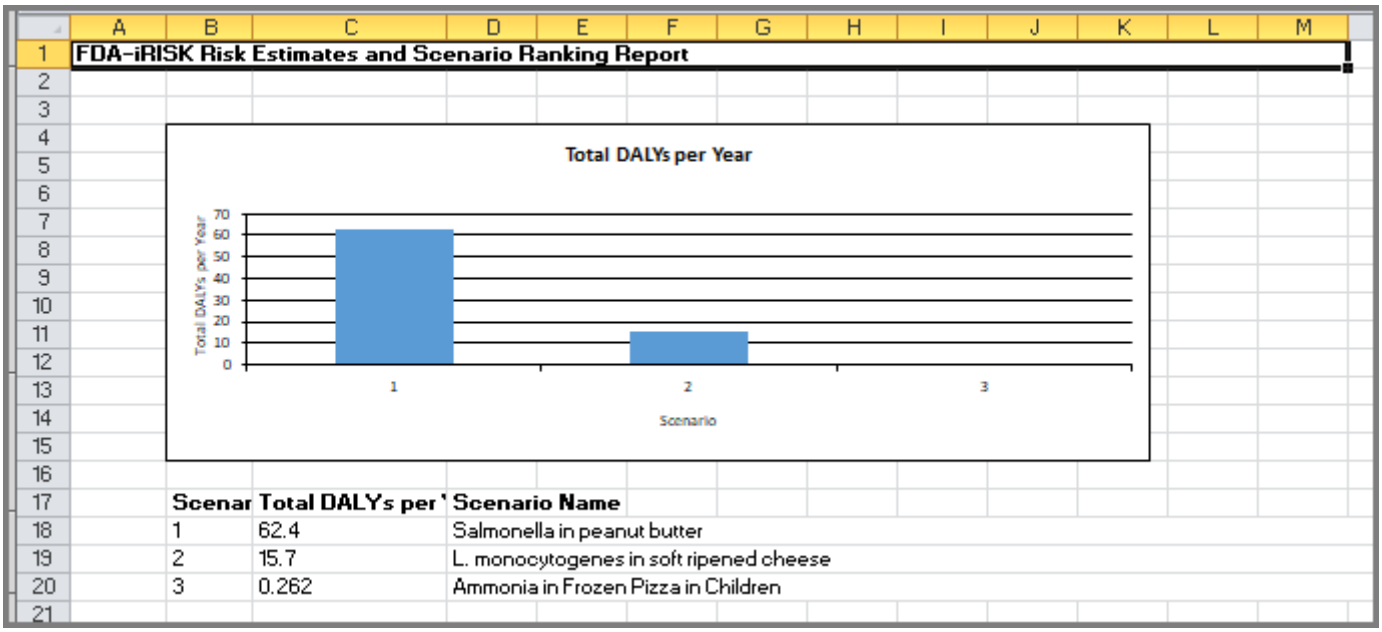
The next section summarizes the health metric details.

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

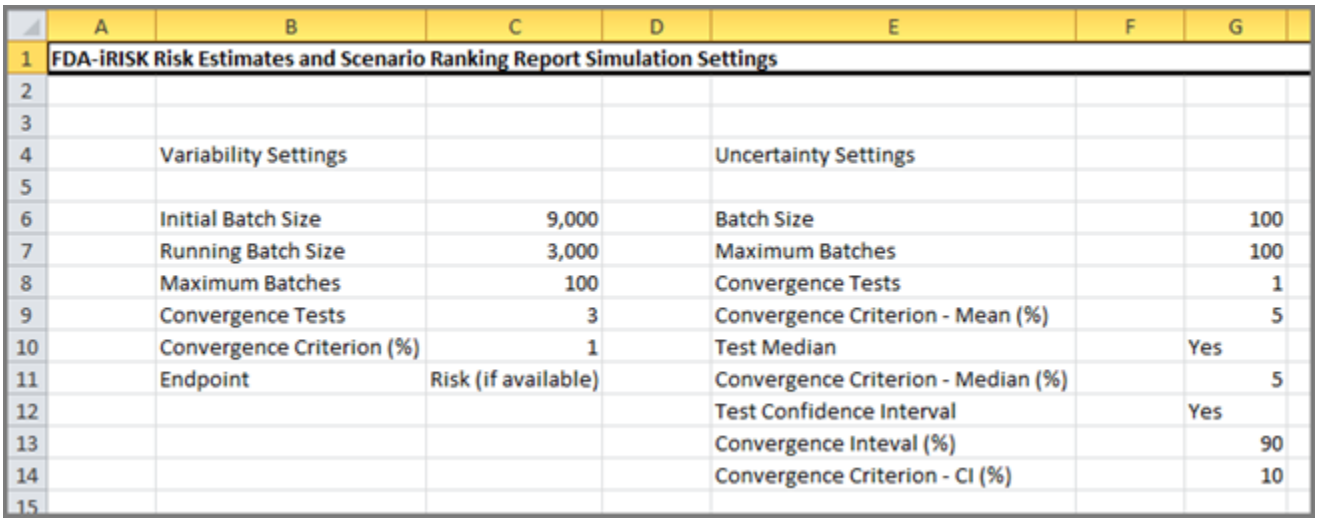
The FDA-iRISK Convergence report is an Excel file.

The first sheet provides a summary of the results and a list of scenarios in the report:



Scenar	Total DALYs per '	Scenario Name
1	62.4	Salmonella in peanut butter
2	15.7	L. monocytogenes in soft ripened cheese
3	0.262	Ammonia in Frozen Pizza in Children

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 Inteval (%)	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

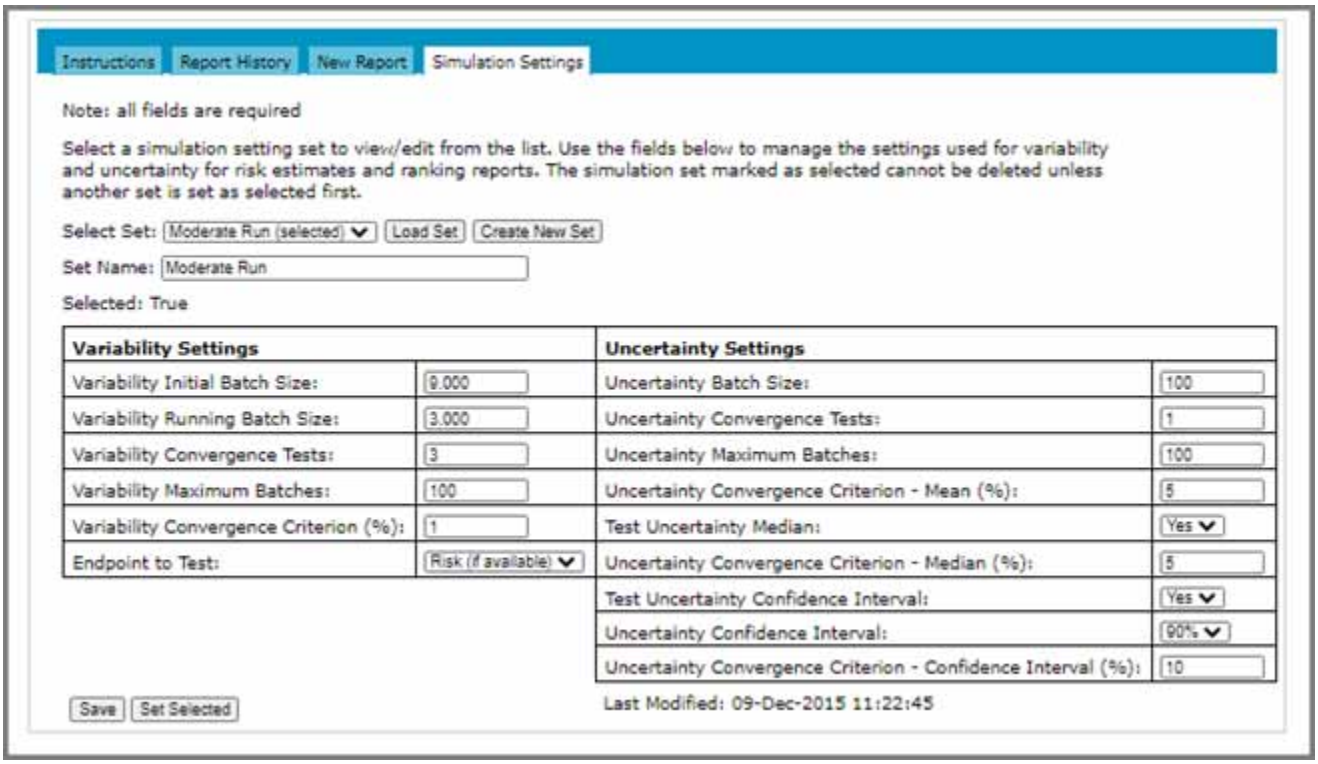
You can manage the settings used for variability and uncertainty for risk estimates and ranking reports on the Simulation Settings tab.

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*.



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.

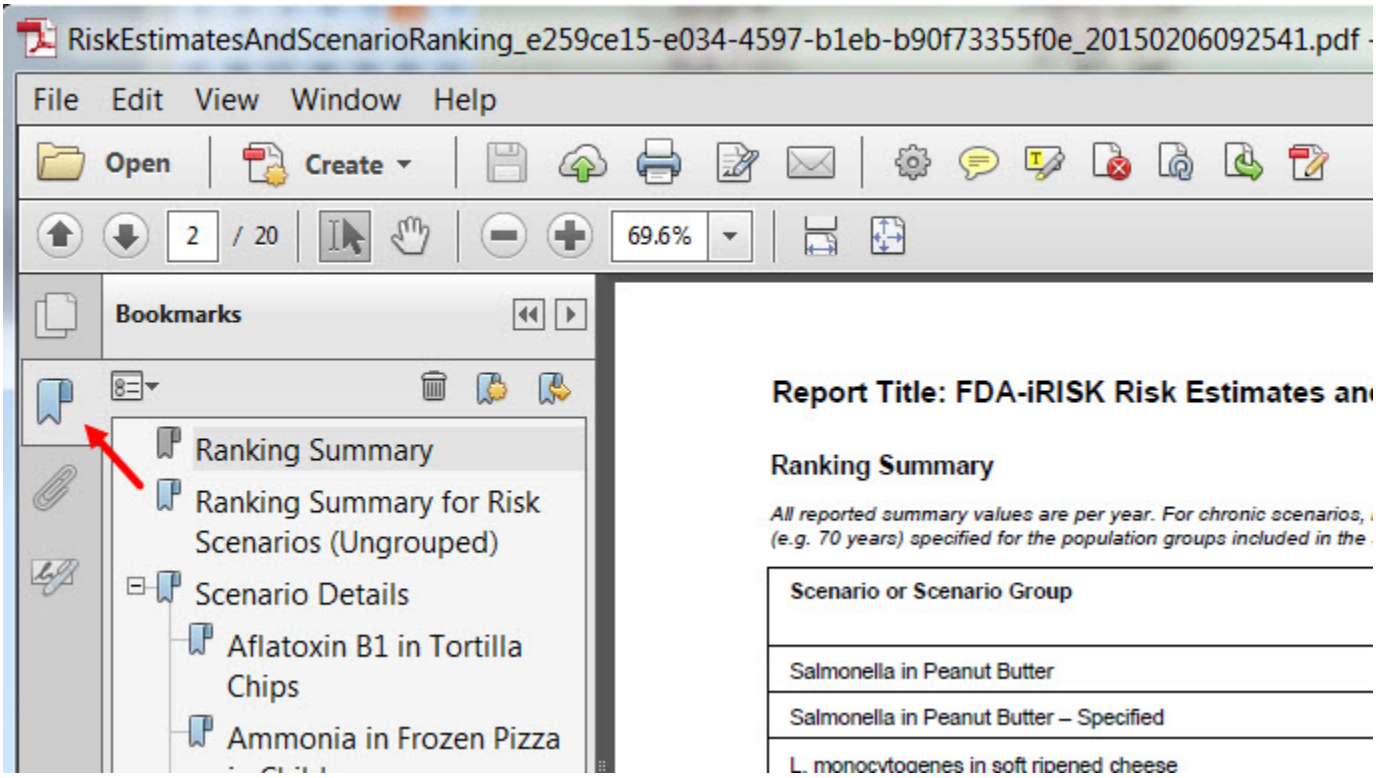
2 Click the **Simulation Settings** tab.

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.

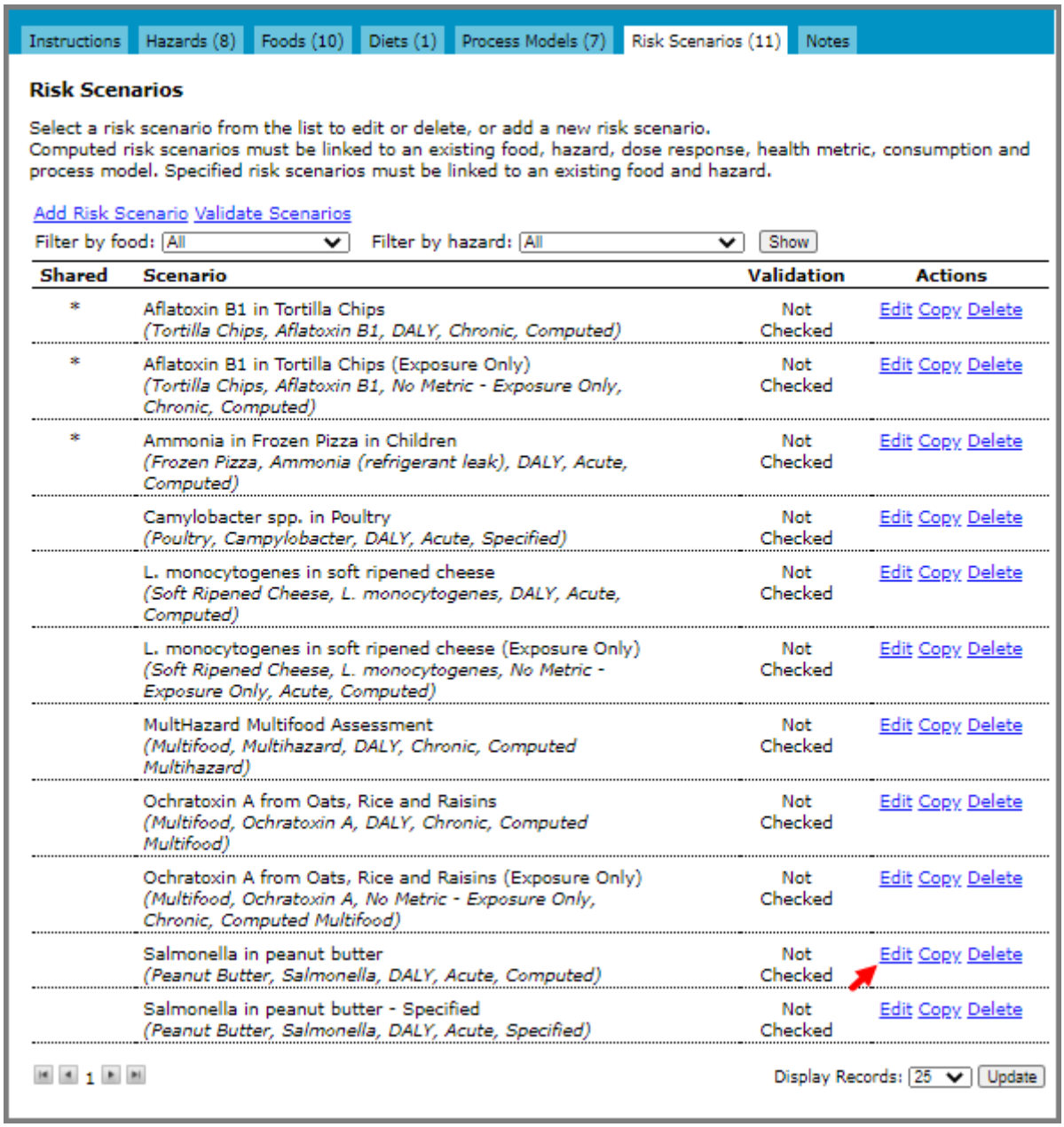
Note: You can change a parameter set in any one of the four model elements in the risk scenario under evaluation: process model, consumption model, dose response model, and health metric.

Running Sensitivity Analysis

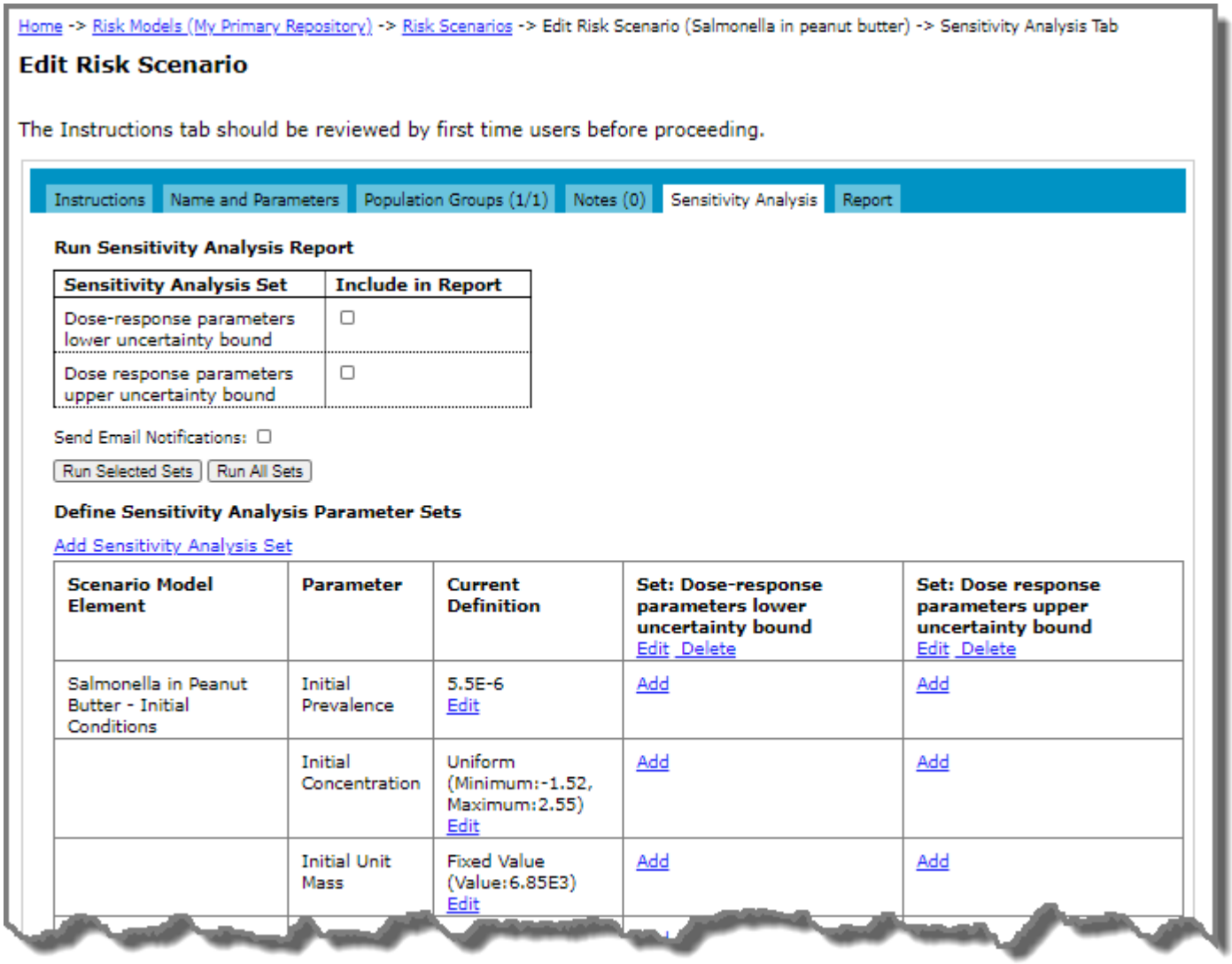
Before you begin: One or more sensitivity analysis sets on which to run sensitivity analysis must exist. For more information, see *"Sensitivity Analysis Sets" on page 152*.

1 Navigate to the Risk Scenarios page. See *"Navigating to Risk Scenarios" on page 107*.

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



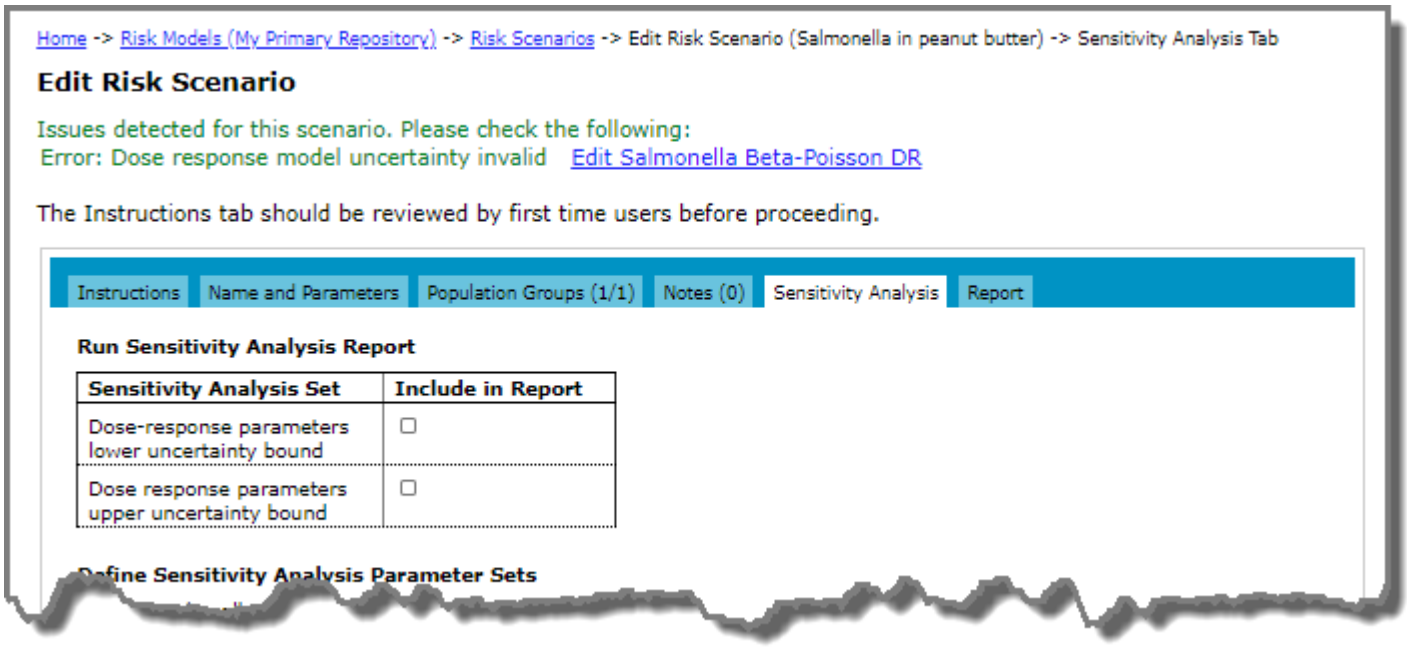
3 Click the **Sensitivity Analysis** tab. The Sensitivity Analysis tab lists existing sensitivity analysis sets as well as all scenario model elements for which sensitivity analysis may be defined, and any sensitivity analysis sets currently associated with the sensitivity analysis.



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.



4 Select the check box to the right of the sets to include in the report.

5 To receive an email notification when the sensitivity analysis completes, select the **Send Email Notifications** check box.

6 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.

7 Click the **Report History** link.

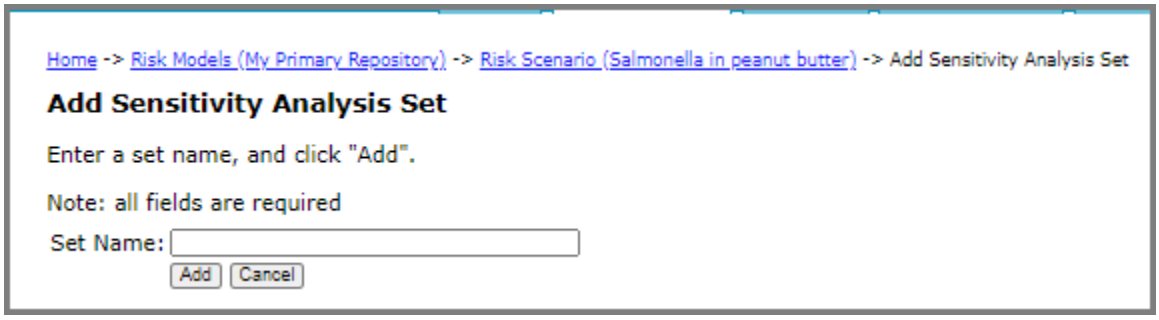
For sensitivity analysis reports, the Excel report is often the preferred option to select as it provide a graphical summary of the results for the different values defined. For more information about reports, see *"Viewing Reports" on page 137*.

Sensitivity Analysis Sets

Adding a Sensitivity Analysis Set

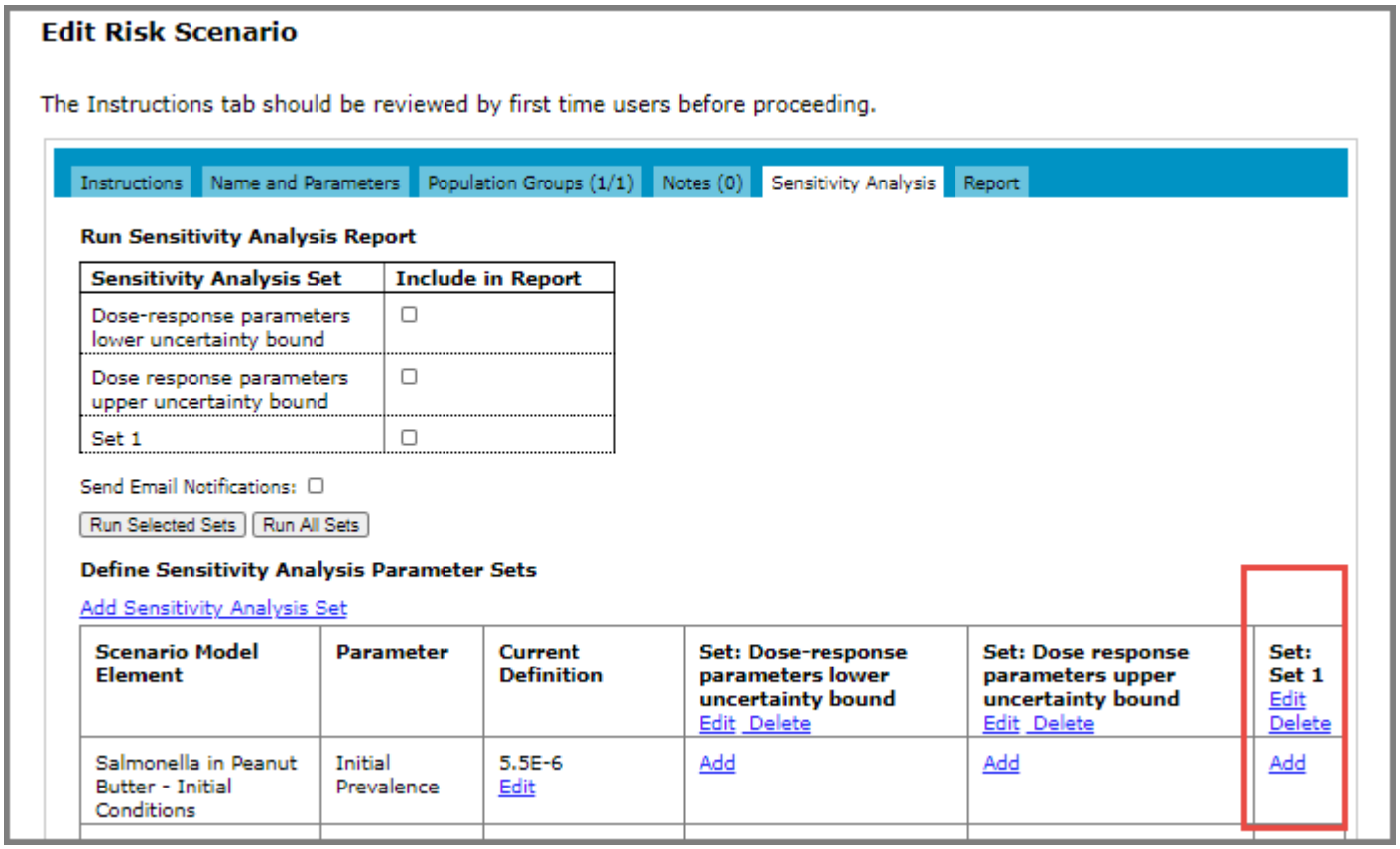
1 Navigate to the Sensitivity Analysis tab. See *"Running Sensitivity Analysis" on page 149*.

2 Click the **Add Sensitivity Analysis Set** link. The Add Sensitivity Analysis Set page opens.



3 In the **Set Name** input field, enter a name for the set.

4 Click **Add**. A column for the new set is added to the table.



5 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.

6 Enter an alternate value for the parameter as part of the sensitivity analysis set you are building.

7 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:

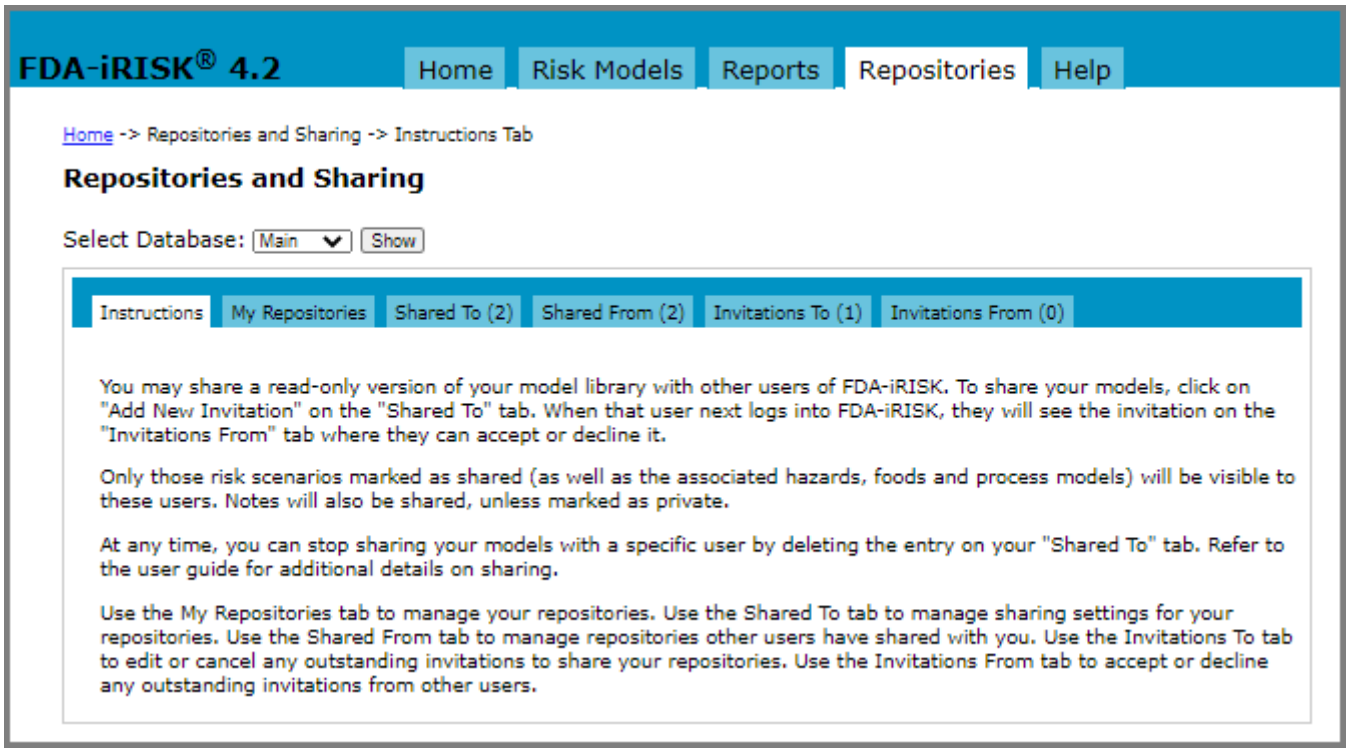
- To save the changes and remain on the page, click **Save**. The page remains open and if required, you can access the other tabs on the page.
- To save the changes and close the page, click **Save and Close**.
- To close the page without saving the changes, click **Close**.

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

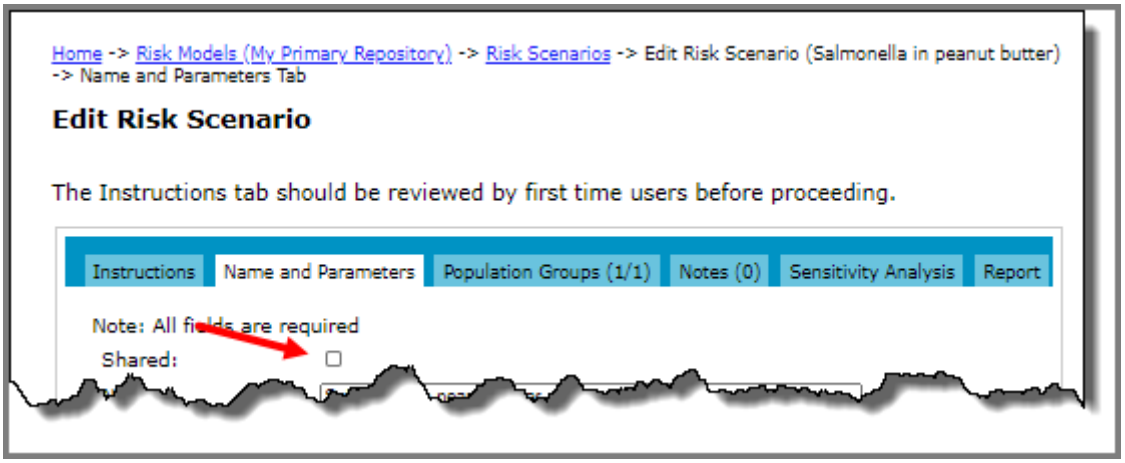
On the Risk Models page with the Risk Scenarios tab selected, scenarios in the list that have been designated as "to be shared" are indicated by an asterisk in the "Shared" column. Risk scenarios not marked by an asterisk are not accessible to people to whom you extend sharing invitations. See *"Inviting 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).