

FDA-iRISK®4.2
Food Safety Modeling Tool

Quick Start

March 2021

Disclaimer

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March 2021

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Preface

About this Guide

This guide is designed to introduce you to the FDA-iRISK® interface and lead you through the creation of several different types of risk scenarios. It is the recommended place to start for new users.

For more information about FDA-iRISK, please refer to the *FDA-iRISK® User Guide* and the *FDA-iRISK® 4.2 Technical Document*.

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 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.

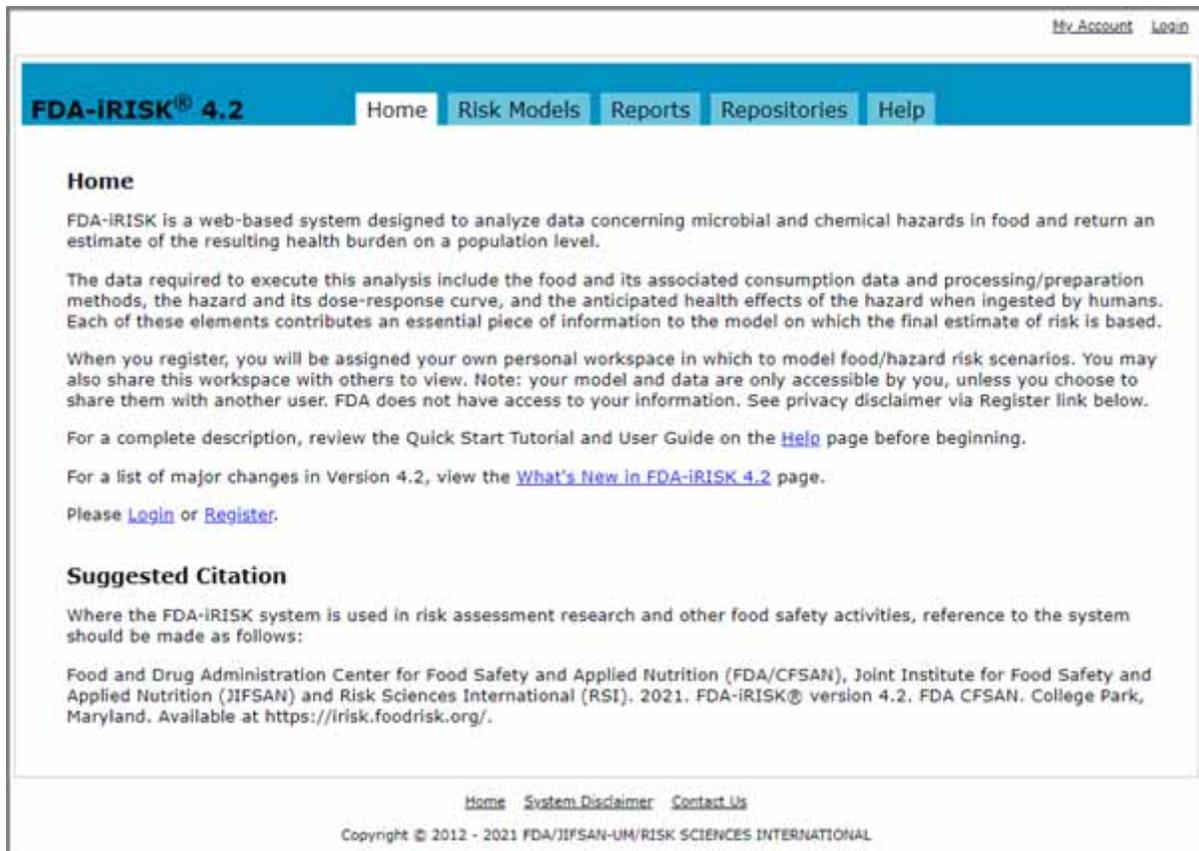
Each of these elements contributes an essential piece of information to the model on which the final estimate of risk is based.

FDA-iRISK includes two types of scenarios for estimating risk:

- **Computed scenarios** Generate risk estimates using a Monte Carlo simulation of model elements that you define (e.g. contamination levels, dose-response models and process models).
- **Specified risk scenarios** Uses risk estimates that you provide. The structure of risk scenarios also differs between acute microbial hazards in a single food and chronic chemical hazards in a single food.

FDA-iRISK Home Page

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



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

- **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:

Title:

Organization:

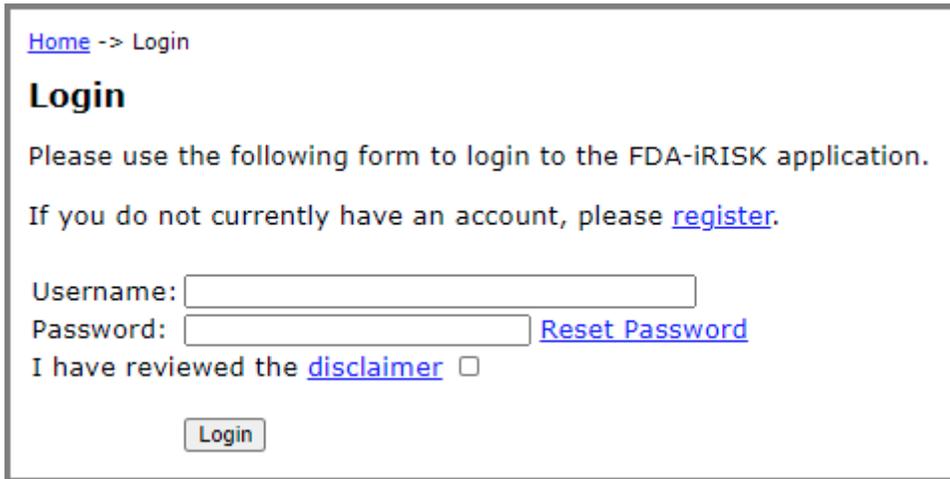
Telephone:

- 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 in to 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.



[Home](#) -> Login

Login

Please use the following form to login to the FDA-iRISK application.

If you do not currently have an account, please [register](#).

Username:

Password: [Reset Password](#)

I have reviewed the [disclaimer](#)

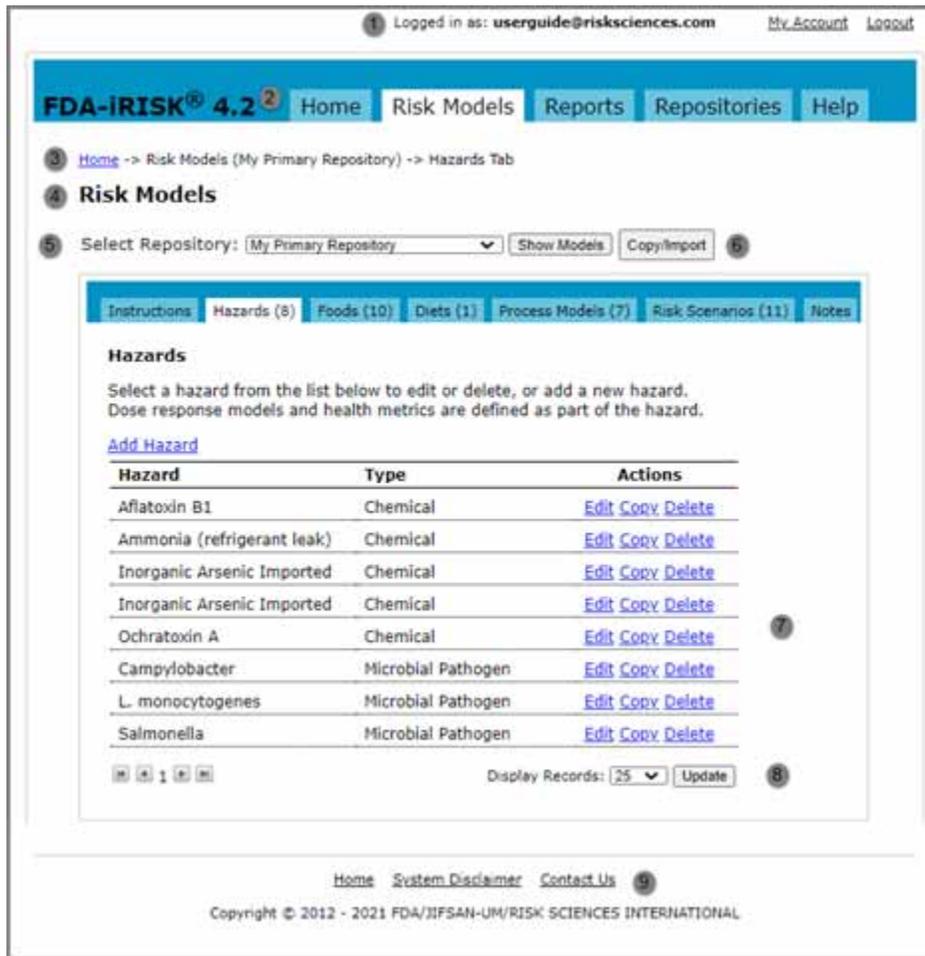
- 2 Enter your username and password and click the **Disclaimer** link to review the information.
- 3 Select the **I have reviewed the disclaimer** check box.
- 4 Click **Login**. The Risk Models page opens.

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 pages in FDA-iRISK, all data must be saved on the current page before opening a new page. Otherwise, the 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.
3	Breadcrumbs The breadcrumb string indicates the location in the site hierarchy of the page presently visible. You can navigate back through the hierarchy by clicking the appropriate breadcrumb link.
4	Page Title Identifies the current page.
5	Repository Selector 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.

Area	Description
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.

About the Example Risk Scenarios in this Guide

The practical examples in this guide illustrate FDA-iRISK features and give you an opportunity to work with the FDA-iRISK interface. Note that these risk scenarios are for illustration purposes only.

- Examples of computed acute microbial hazard risk scenarios:
 - Scenario 1 - A single food-hazard pair in one population group
 - Scenario 2 - A single food-hazard pair in three population groups
- Example of a specified acute microbial hazard risk scenario
- Examples of computed chemical risk scenarios:
 - Scenario 1 - A single food-hazard pair involving an acute chemical hazard
 - Scenario 2 - A single food-hazard pair involving a chronic chemical hazard
- Example of sensitivity analysis for a single food-hazard pair

For your convenience, the first example provides step-by-step instructions and screen shots to guide you through how to navigate FDA-iRISK and create a risk scenario. As you progress to the other examples, the instructions become more general and screen shots are only provided for clarity.

Note: Once you have defined a food and a hazard, FDA-iRISK is extremely flexible in terms of the order in which you define the elements of a risk scenario. The sequence of the steps presented in the examples in this guide is just one way.

At any time during an exercise to develop a risk scenario, you can save the changes on the current page, exit FDA-iRISK and then resume working from where you left off at a later time.

To begin creating a risk scenario, you must have an FDA-iRISK account and be logged in.

CHAPTER 2

Examples of Computed Risk Scenarios for Acute Microbial Hazard

An FDA-iRISK computed risk scenario includes seven elements:

- Food
- Hazard
- Population of consumers
- Process model (i.e., food production, processing and handling practices)
- Consumption patterns in the population
- Dose-response relationships
- Burden of disease measures associated with health effects (e.g., losses in Disability Adjusted Life Years, or DALYs)

You must define all of the constituent parts (i.e., the seven elements) of a scenario before you define the scenario, itself.

This section provides two examples of computed risk scenarios for acute microbial hazards. They are intended to be reviewed in sequence.

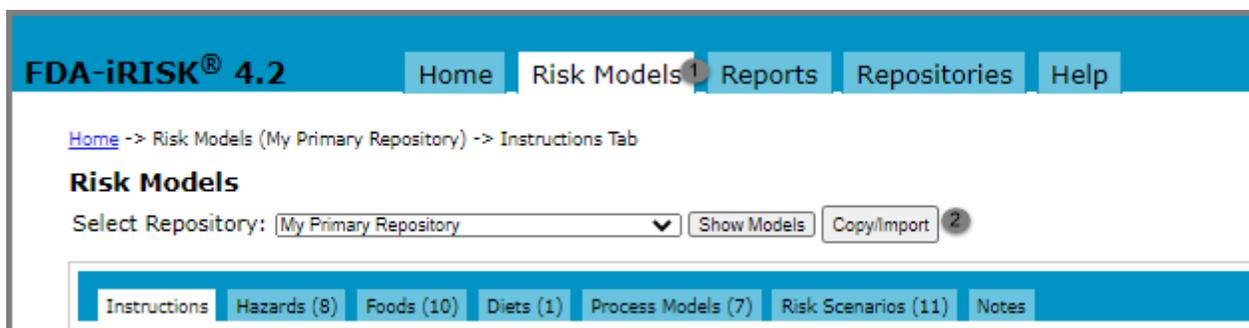
Scenario 1 - A single food-hazard pair in one population group

This section describes how to create an FDA-iRISK computed scenario for *Salmonella* spp. (nontyphoidal) in peanut butter that estimates the population health burden for a single food-hazard pair.

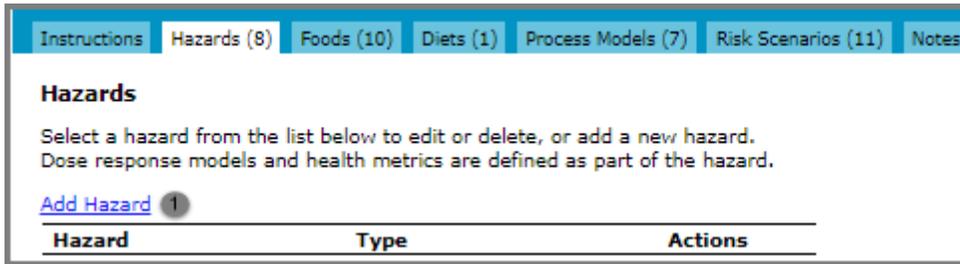
Step 1: Create the Hazard

On the FDA-iRISK window, click the Risk Models tab and then the Hazards tab. On the Risk Models page, verify that My Primary Repository is selected in the Show Models For drop-down list. Note that when you are using FDA-iRISK for the first time, the count of hazards and all other elements will be zero as no model elements have been defined.

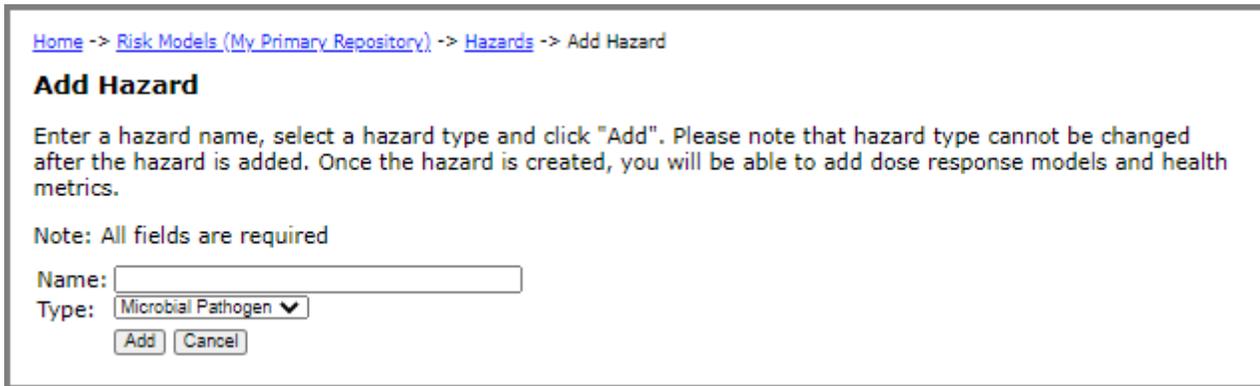
Note: The numbers in the figures throughout the guide highlight important areas or indicate where action is required.



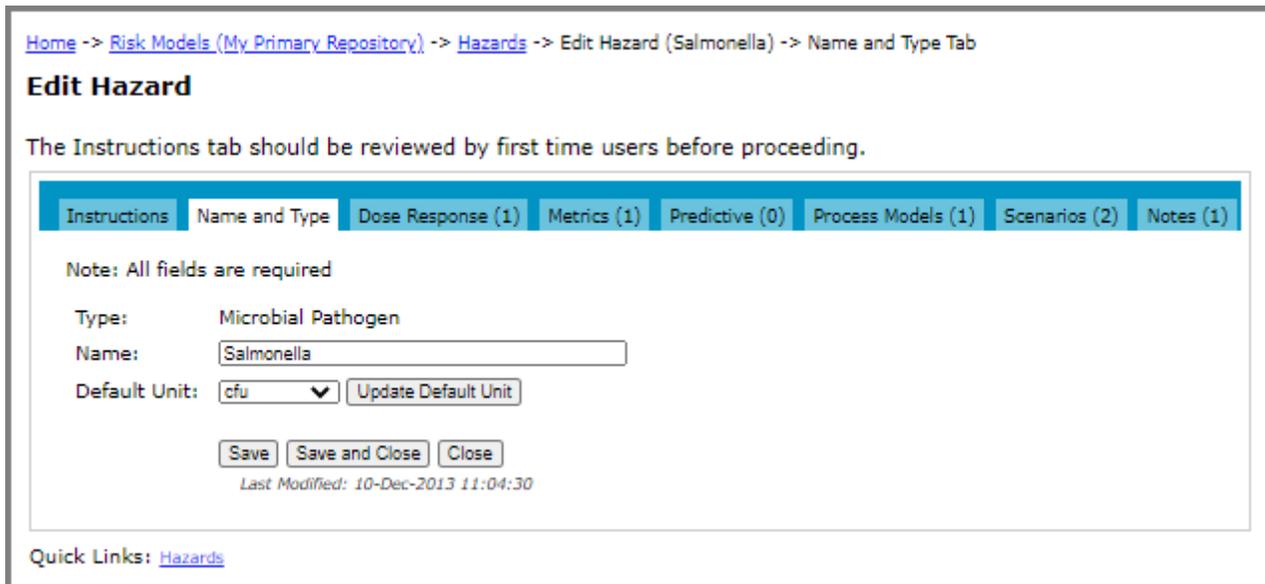
Click the Add Hazard link.



On the Add Hazard page, enter "Salmonella"¹ as the hazard name and leave the type as "Microbial Pathogen". Click Add.



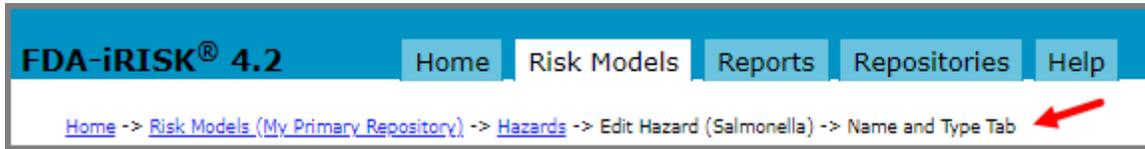
The Edit Hazard page opens. Leave the default unit for the hazard as "cfu".



¹ Note that italic font is currently not supported in the FDA-iRISK tool, itself. Therefore, the name of a microorganism, such as *Salmonella* or *Listeria monocytogenes*, displays in non-italic font both on the screen and when entered as text in an FDA-iRISK field.

Notice the following on the FDA-iRISK window:

- The breadcrumbs show the current location in FDA-iRISK and provide links back to each previous page that you navigated through to get to the current page.



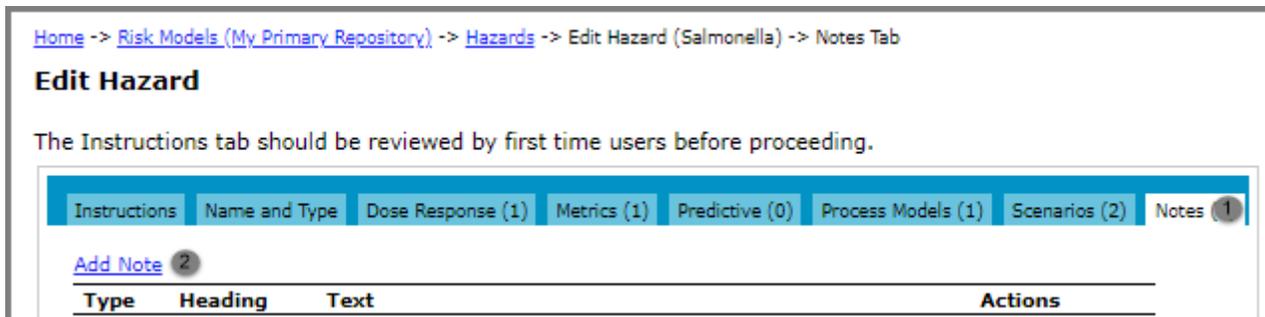
- The quick links at the bottom of the page that provide direct access to related areas of FDA-iRISK. These links change depending on the current page.



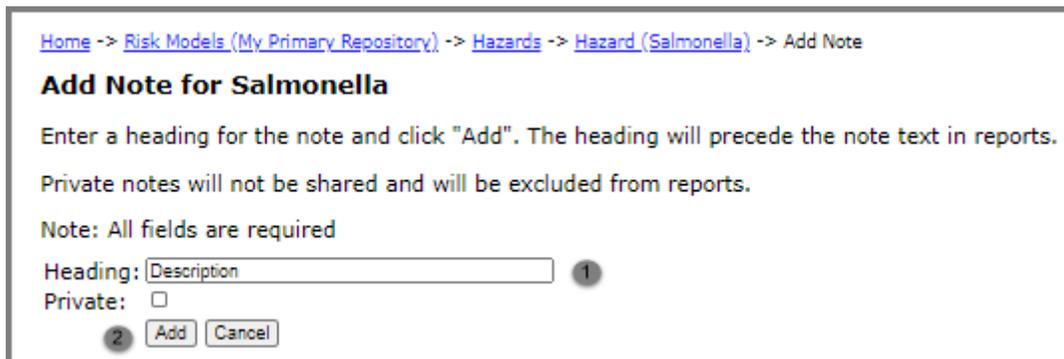
Click Save. Remember to always save the changes before you navigate away from or close a page. Otherwise, the changes will be lost.

Step 2: Add Notes for the Hazard

You can add one or more notes to most elements in FDA-iRISK. Click the Notes tab and then click the Add Note link.



On the Add Note for *Salmonella* page, enter "Description" as the heading. Optionally, you can select the Private check box to prevent notes from being shared or included on reports. Leave the check box unselected for the purpose of this exercise. Click Add.



On the Edit Note page, add the following text to the Note text box. (For convenience, you can copy and paste the text.) Then, click Save and Close.

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

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Salmonella) -> Edit Note (Description)

Edit Note

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

Note: all fields are required

Private:

Heading: Description

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

Save Save and Close Close

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The text displays on the Note tab and can be edited or deleted at any time.

Click the Add Note link to add a second note. Enter “References” as the heading and add the following text:

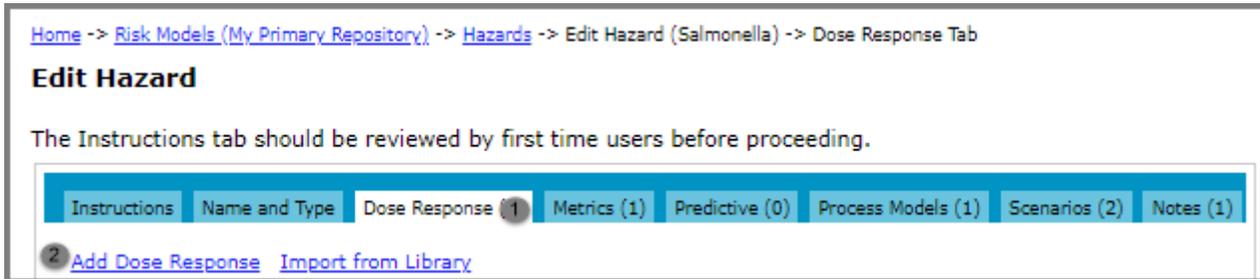
“Food and Drug Administration (FDA). 2012. Bad Bug Book - Foodborne Pathogenic Microorganisms and Natural Toxins, 2nd ed. Salmonella species, pp. 12-14;. Available at <http://www.fda.gov/Food/FoodSafety/Foodbornellness/FoodbornellnessFoodbornePathogensNaturalToxins/BadBugBook/default.htm>. Accessed May 7, 2012.

Scott, V. N., Y. Chen, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. A. Smoot, S. Hood, J. Shebuski, and J. Banks. 2009. Control of Salmonella in low-moisture foods I: minimizing entry of Salmonella into a processing facility. Food Prot. Trends. 29:342-353.”

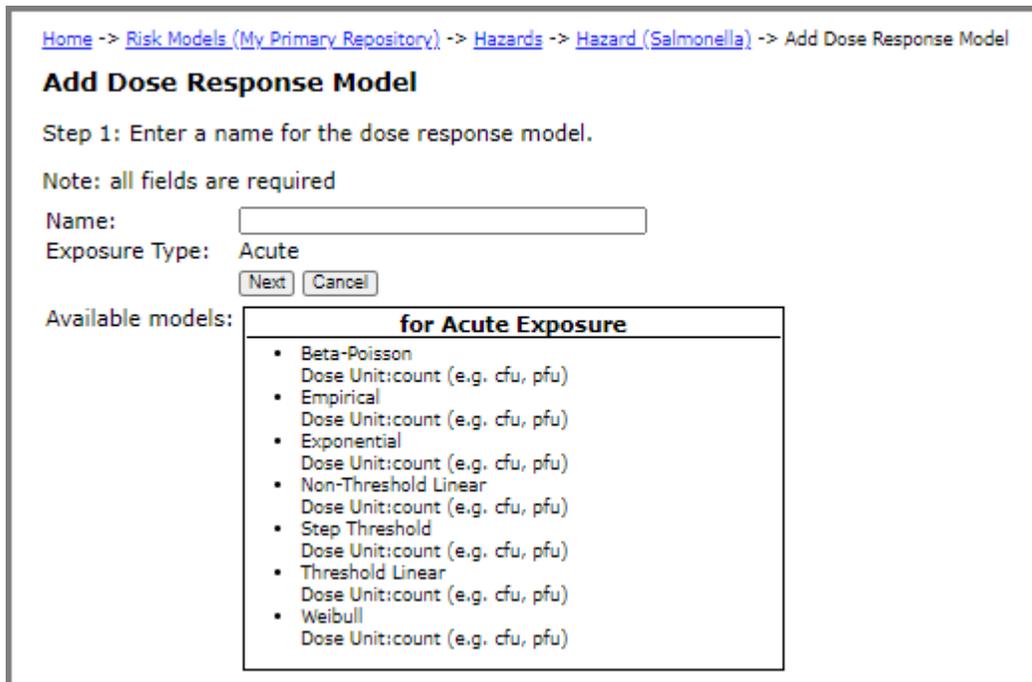
Click Save and Close.

Step 3: Add a Dose Response Model

Click the Dose Response tab and then click the Add Dose Response link.



On the Add Dose Response Model page, enter “Salmonella Beta-Poisson DR” as the name for the dose response model. Note that only acute exposure types are available for microbial pathogens and the list of available dose response types is listed on the page. Click Next.



Confirm the dose units that will be used for the dose response model. For microbial hazards, these will be the default units selected for the hazard. Click Next.

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

Add Dose Response Model

Step 2: Confirm units for the dose

Name: Salmonella Beta-Poisson DR
Exposure Type: Acute
Dose Units: 1 cfu

Previous Next Cancel

Available models: **for Acute Exposure**

- Beta-Poisson
Dose Unit:count (e.g. cfu, pfu)
- Empirical
Dose Unit:count (e.g. cfu, pfu)
- Exponential
Dose Unit:count (e.g. cfu, pfu)
- Non-Threshold Linear
Dose Unit:count (e.g. cfu, pfu)
- Step Threshold
Dose Unit:count (e.g. cfu, pfu)
- Threshold Linear
Dose Unit:count (e.g. cfu, pfu)
- Weibull
Dose Unit:count (e.g. cfu, pfu)

Finally, select “Beta-Poisson” as the response type to use for this dose response model, and then click Add.

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

Add Dose Response Model

Step 3: Select dose response type, then click Add

Name: Salmonella Beta-Poisson DR
Exposure Type: Acute
Dose Units: cfu
Response Type: Beta-Poisson

Previous Add Cancel

The Edit Dose Response Model page opens. Enter "0.1324" for alpha and "51.45" for beta. Leave the probability of adverse effect at 100%. Click Save. The parameter values are saved to the database and the chart for the dose response model displays.

Home -> Risk Models (Mv Primary Repository) -> Hazards -> Hazard (Salmonella) -> Edit Dose Response Model (Salmonella Beta-Poisson DR) -> Name and Parameters Tab

Edit Dose Response Model

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

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

Note: all fields are required
 Model Name:

Parameter	Value	Uncertainty
Exposure Type:	Acute	N/A
Dose Unit:	cfu	N/A
Response Type:	Beta-Poisson	N/A
alpha: (No units; min > 0; no max)	<input type="text" value="0.1324"/>	Add
beta: (No units; min > 0; no max)	<input type="text" value="51.45"/>	Add
Probability of adverse effect given response: (%; 100 when dose response is for adverse effect)	<input type="text" value="100"/>	Add

The chart below describes the probability of response for the dose response model specified above for a range of doses. The chart is only updated if the page is saved or the Refresh Chart button is clicked.

Dose Response Chart

Probability

Log Dose

— Probability of Response and Adverse Effect

Last Modified: 16-Dec-2013 11:27:52

Quick Links: [Salmonella \(H\)](#)

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. For example, when defining a dose response relationship or a contamination distribution.

On the Notes tab, click the Add Note link. Enter "Rationale" as the heading and then click Add. Add the following text to the Note text box:

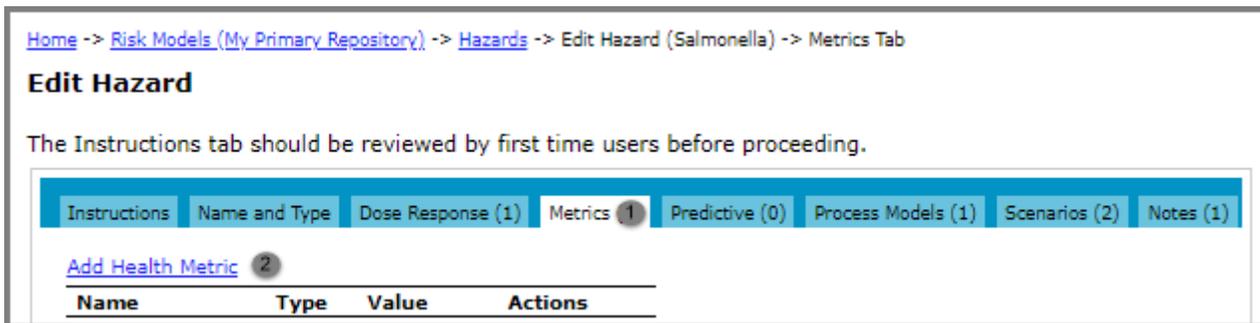
"Maximum Likelihood techniques were used by an expert panel (FAO/WHO, 2002; Table 3-16) to generate the best-fitting dose response relationship using real world data including outbreak data. The best fit results were used to generate the expected values of parameters alpha and beta. The dose response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

Food and Agriculture Organization of the United Nations, World Health Organization (FAO/WHO). 2002. Risk assessments of Salmonella in eggs and broiler chickens. Technical report. Microbiological Risk Assessment Series 2. FAO/WHO. Rome. Available at <http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/salmonella0/en/>. Accessed May 7, 2012."

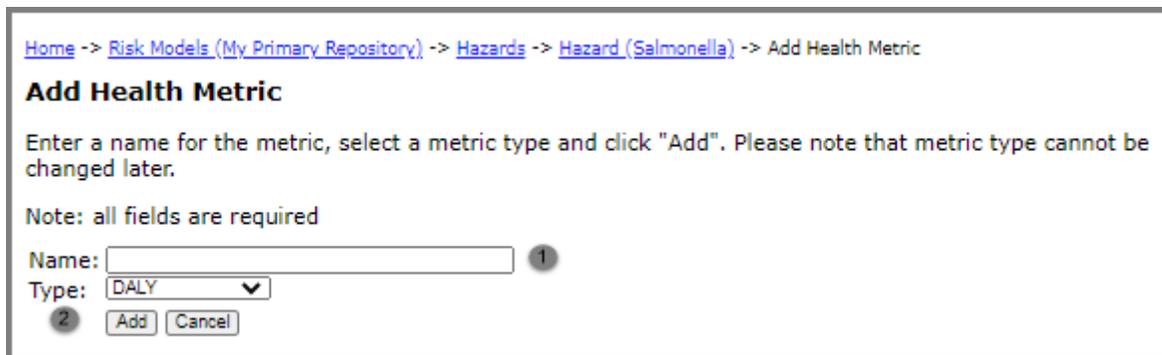
Click Save and Close.

Step 4: Add a Health Metric

To add a health metric for *Salmonella*, click the *Salmonella* quick link or breadcrumb. Then, click the Metrics tab and the Add Health Metric link.



On the Add Health Metric page, enter "Salmonella DALY" as the name. Leave the type as DALY, and click Add.



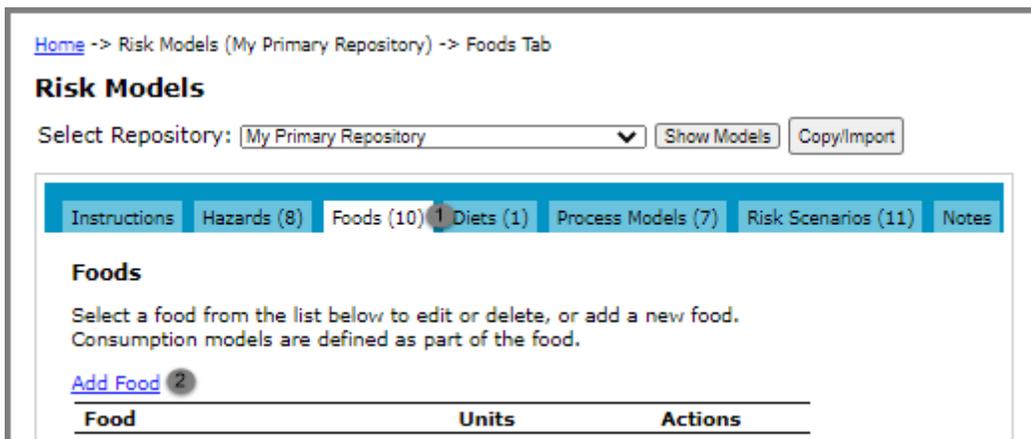
On the Edit Health Metric page, enter "0.019" as the value, and click Save and Close. (The Compute from Health Endpoints link allows you to compute the DALY total from distinct health endpoints and is covered in a later exercise.)



Step 5: Create the Food

On the Edit Hazard Page, click the My Primary Repository breadcrumb to return to the Risk Models page.

On the Risk Models page, click the Foods tab, and then the Add Food link.



On the Add Food page, enter “Peanut Butter” as the name and leave Mass as the unit type for measuring food quantity. Click Add.

Home -> Risk Models (My Primary Repository) -> Foods -> Add Food

Add Food

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

Note: all fields are required

Name: (1)

Measured using: (2)

(3)

Step 6: Add a Consumption Model

On the Edit Food page, click the Consumption Models tab, then click the Add Consumption Model link.

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

Edit Food

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

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

[Add Consumption Model](#) (2) [Import from Library](#)

Model	Exposure Type	Multifood	Population Groups /Life Stages	Actions
-------	---------------	-----------	--------------------------------	---------

On the Add Consumption Model page, enter “Peanut Butter Annual Consumption” as the name, and leave exposure type as Acute. Click Add.

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

Add Consumption Model

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

Note: all fields are required

Name: (1)

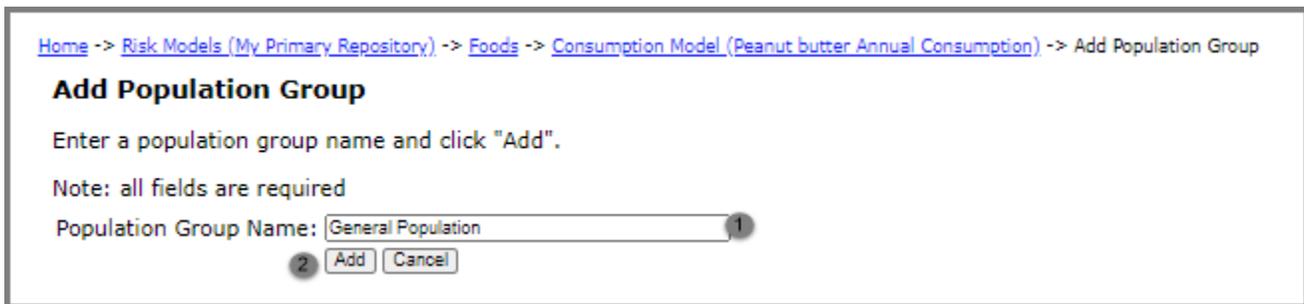
Exposure Type: (2)

(3)

Consumption models require one or more population groups. On the Edit Acute Consumption Model page, click the Population Groups tab, and then the Add Population Group link.



On the Add Population Group page, enter "General Population" as the population group name. Click Add.



For acute consumption, you need to specify the number of eating occasions per year, as well as the amount per eating occasion. Body weight can be left at "0" for this scenario because body weight is not considered in a risk scenario for a microbial hazard.

On the Edit Population Group and Consumption page, enter “1.7E10” (i.e. 17 billion) for the number of eating occasions per year. Leave the units as “grams”, and the variability distribution option as “Fixed Value”. Set a value of “30” for the amount per eating occasion. Click Save and Close.

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

Edit Population Group and Consumption

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

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

Note: All fields are required

Name:

Parameter	Value	Uncertainty
Eating occasions per year:	<input type="text" value="1.7E10"/> ①	Add

Amount per eating occasion:

Parameter	Value	Uncertainty
Unit:	<input type="text" value="g"/> ②	N/A
Variability Distribution:	<input type="text" value="Fixed Value"/> ③	N/A
Value:	<input type="text" value="30"/> ④	Add

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

Body Weight (kg):

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

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

Number of servings per person:

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

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

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

Spearman (Rank) Correlation:

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

⑤

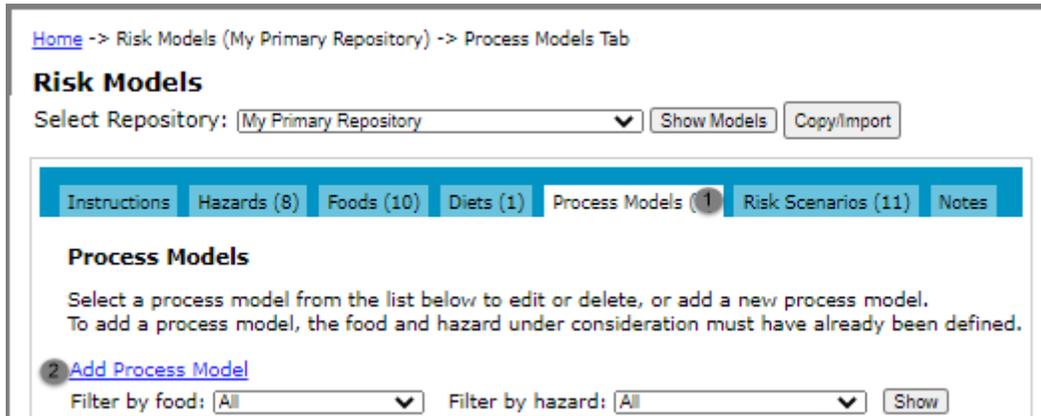
Last Modified: 16-Dec-2013 11:43:14

Quick Links: [Peanut Butter \(F\)](#) | [Peanut butter Annual Consumption \(CM\)](#)

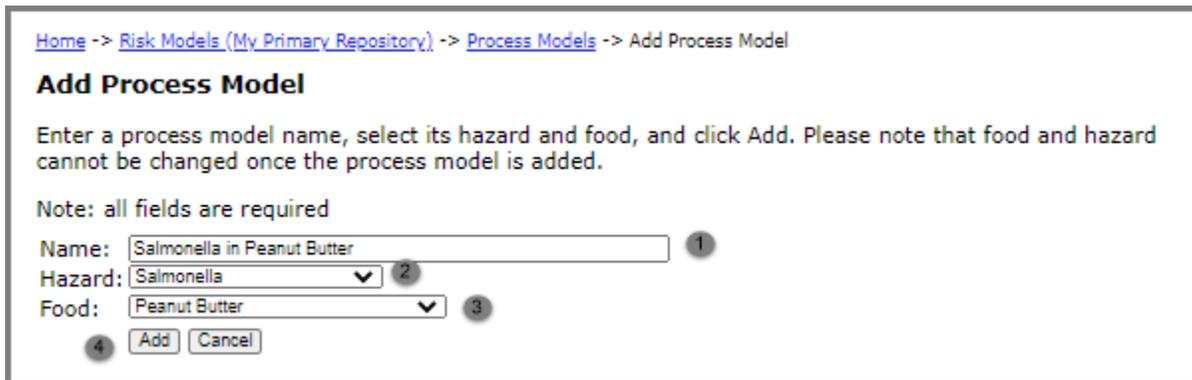
Step 7: Add a Process Model

Now that you have defined the food and hazard, you are ready to construct a process model. Click the My Primary Repository breadcrumb, or the Risk Models tab on the main tab bar, to return to the Risk Models page.

On the Risk Models page, click the Process Models tab and then the Add Process Model link.



Enter “Salmonella in Peanut Butter” as the name and leave the selected hazard and food as “Salmonella” and “Peanut Butter”, respectively. Click Add.



On the Edit Process Model page, specify the initial contamination, unit size, and prevalence, and initial mass, and initial concentration values for the process model. The initial concentration must describe the concentration among contaminated units only, and must result in at least one cfu per unit mass defined. The prevalence value must represent the proportion of contaminated units of the unit mass specified.

Leave the box indicating that some initial units are contaminated checked. Set the initial prevalence at “5.5E-6”, and the mass units to “kg”.

Changes the variability distribution option for initial unit mass to “Fixed Value” and enter 6.85E3.

Change the variability distribution option for initial concentration to “Uniform” distribution. After the page reloads, enter a minimum value of “-1.52” and a maximum value of “2.55”. Note that this is on the log scale. Leave the units for initial concentration as “Log10 cfu/g”. Leave the maximum population density as “9 log10 cfu/g”. Click the Save button to remain on the Edit Process Model page. Next, you will define process stages.

Note: It is important that you click Save before adding process stages, or any changes will be lost.

[Home](#) → [Edit Hazards \(by Entity/Scenario\)](#) → [Process Models](#) → [Edit Process Model \(Salmonella in Peanut Butter\)](#) → Name and Initial Conditions Tab

Edit Process Model

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

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

Note: All fields are required

Model Name:

Define Initial Conditions Using:

Single Set of Parameters **Multiple Sets of Parameters (0)**
Upstream Process Model (0)

[Change Values](#)

Initial Contamination, Unit Size and Prevalence:

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

Parameter	Value	Uncertainty
Hazard:	Salmonella	N/A
Food:	Peanut Butter	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/> <input type="checkbox"/>	N/A
Initial Prevalence:	<input type="text" value="0.001"/> <input checked="" type="radio"/> Add	
Select Mass Units:	<input type="text" value="g"/> <input checked="" type="radio"/>	N/A

Initial Unit Mass:

Distribution Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/> <input checked="" type="radio"/>	N/A
Value:	<input type="text" value="0.001"/> <input checked="" type="radio"/> Add	

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

Initial Concentration:

Parameter	Value	Uncertainty
Units:	<input checked="" type="radio"/> <input type="radio"/> <input type="text" value="log10 cfu/g"/> <input checked="" type="radio"/> Update	N/A
Variability Distribution:	<input type="text" value="Uniform"/> <input checked="" type="radio"/>	N/A
Minimum:	<input type="text" value="0.001"/> <input checked="" type="radio"/> Add	
Maximum:	<input type="text" value="0.001"/> <input checked="" type="radio"/> Add	

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

Probability Density and Cumulative Distribution

Count Per Unit (CFU/g)

[Refresh Chart](#)

Maximum Population Density (MPD):

Note: The value specified for MPD is not applied when charting Initial Concentration above.

Parameter	Value	Uncertainty
Restrict concentration to MPD:	<input type="checkbox"/>	N/A
Units:	<input checked="" type="radio"/> <input type="radio"/> <input type="text" value="log10 cfu/g"/> <input checked="" type="radio"/>	N/A
Value:	<input type="text" value="0"/> <input checked="" type="radio"/> Add	

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

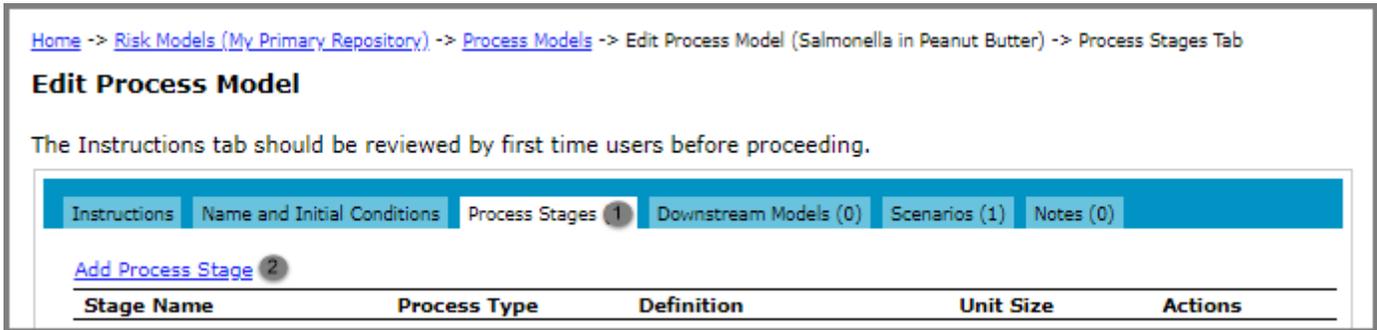
Last Modified: 2/10/2017 11:51:28

Quick Links: [Peanut Butter \(1\)](#) | [Salmonella \(1\)](#)

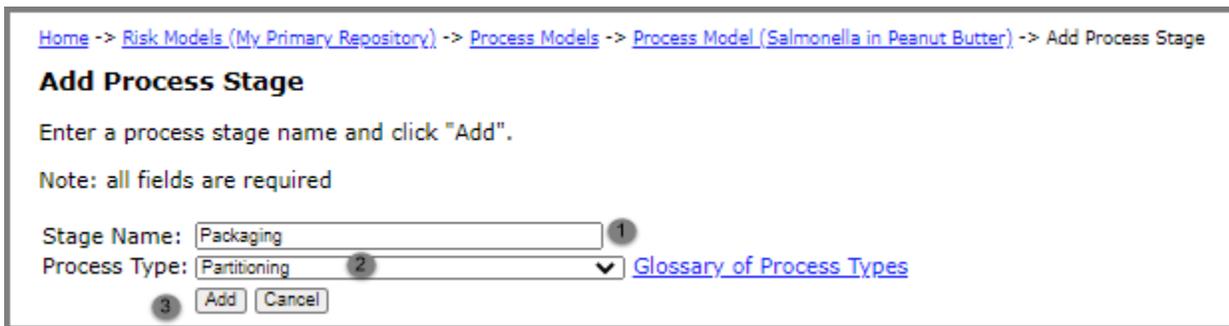
Note that the Quick Links at the bottom of this page provide links back to both the food and the hazard associated with the process model.

Step 8: Add Process Stages

On the Edit Process Model page, click the Process Stages tab, and then click the Add Process Stage link.



On the Add Process Stage page, enter "Packaging" for the stage name, and select "Partitioning" as the process type. (The Glossary of Process Types link provides a description of the process types.) Click Add.



Partitioning divides the current unit mass into new units of the size defined for this stage, adjusting concentration and prevalence as required. On the Edit Process Stage page, enter “250 g” as the final unit size, then click Save and Close.

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

Edit Process Stage

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

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

Note: All fields are required

Stage Name:

Process Model: Salmonella in Peanut Butter

Process Type: Partitioning

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

Final Unit Size:

Distribution Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="250"/> <input type="button" value="1"/>	Add

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

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

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

On the Edit Process Model page, click the Add Process Stage link.

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

Edit Process Model

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

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

[Add Process Stage](#)

Stage Name	Process Type	Definition	Unit Size	Actions
------------	--------------	------------	-----------	---------

On the Add Process Stage page (not shown) create a new stage with a name “Storage” and a process type of “Decrease”. Click Add.

On the Edit Process Stage page for the storage step, change the variability distribution to “Uniform” with a minimum and maximum of “0.49” and “3.47” respectively. This will apply a log reduction of that amount to the units in question. Click Save and Close.

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

Edit Process Stage

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

Instructions | Name and Parameters | Notes (1)

Note: All fields are required

Stage Name:

Process Model: Salmonella in Peanut Butter

Process Type: Decrease

Reduction in Microbial Population (log10 scale):

Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Uniform"/> 1	N/A
Minimum:	<input type="text" value="0.49"/> 2	Add
Maximum:	<input type="text" value="3.47"/> 3	Add

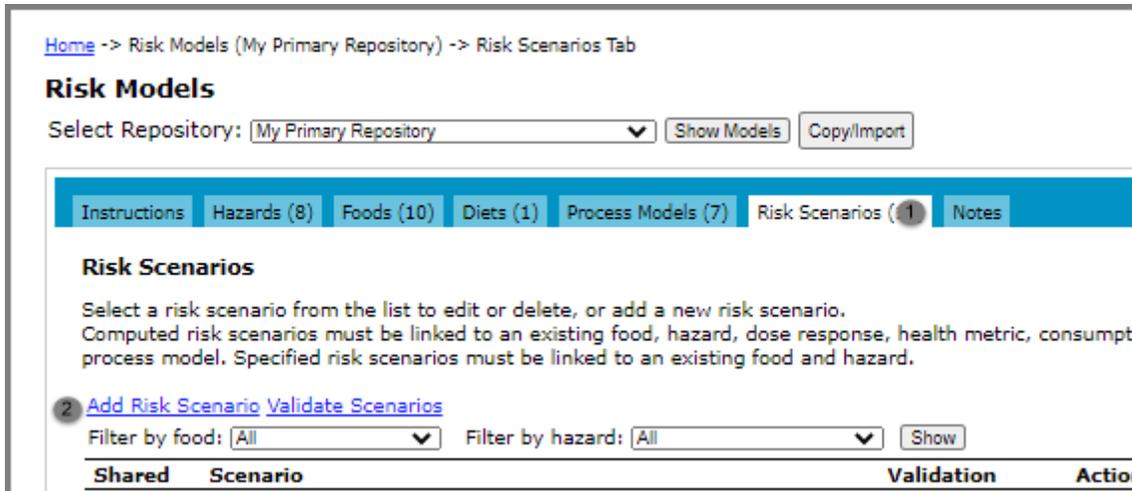
The chart below displays the probability density function (PDF) and cumulative distribution function (CDF) or probability histogram for the variability distribution based on the parameters above. Please note that the left vertical axis measures *probability density* and should not be interpreted as measuring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

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

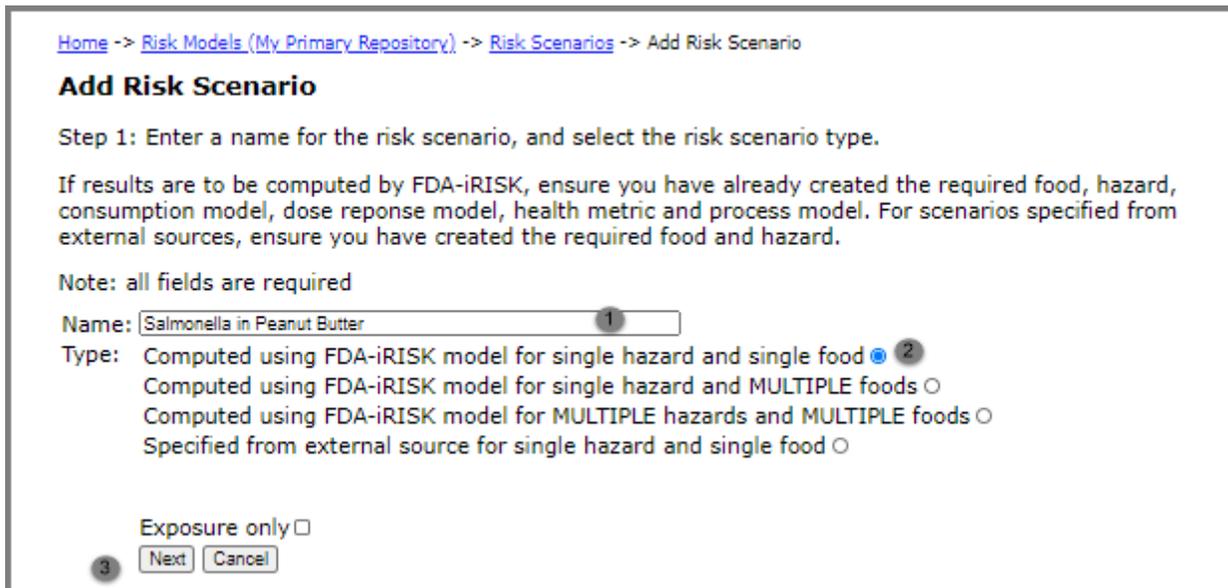
Quick Links: [Peanut Butter \(F\)](#) | [Salmonella \(H\)](#) | [Salmonella in Peanut Butter \(PM\)](#)

Step 9: Create the Risk Scenario

You have now defined all required elements for the risk scenario. Click the Risk Models tab on the main tab bar to return to the Risk Models page. Then, click the Risk Scenarios tab and the Add Risk Scenario link.



On the Add Risk Scenario page, enter “Salmonella in Peanut Butter” as the name and leave the type as “Computed using FDA-iRISK model for a single hazard and single food.” Click Next.



Select the process model to use for the scenario as well as the metric type. Because all scenarios use acute exposure for microbial pathogens, this option is assigned automatically. This page also provides a summary of model elements associated with the selected process model (and its food and hazard) for review.

Leave the process model as “Salmonella in Peanut Butter” and the metric type as “DALY”. Click Next.

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

Add Risk Scenario

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

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

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

Name: Salmonella in Peanut Butter
 Type: Results Computed for Single Food

Filter Process Models by:

Process Model: 1
 Food: Peanut Butter, Hazard: Salmonella

Exposure Type: Acute
 Metric Type: 2

Available Models:

Health Metrics	for Acute Exposure
DALY <ul style="list-style-type: none"> Salmonella DALY Cost Per Illness <p>No Models*</p> QALY <p>No Models*</p>	Consumption Models <ul style="list-style-type: none"> Peanut butter Annual Consumption Peanut Butter by General Population Dose Response Models <ul style="list-style-type: none"> Salmonella Beta-Poisson DR

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

Finally, select the Consumption Model to use for the scenario. For the purpose of this scenario, leave the consumption model selected as “Peanut Butter Annual Consumption”. Click Add.

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

Add Risk Scenario

Step 3: Select consumption model.

Name: Salmonella in Peanut Butter
 Type: Results Computed For Single Food
 Process Model: Salmonella in Peanut Butter
 Food: Peanut Butter
 Hazard: Salmonella
 Exposure Type: Acute
 Health Metric Type: DALY

Consumption Model: 1

2

All required elements are now added to the scenario. Next, you must select the population groups from the consumption model to include in the model. These are not assigned by default as you must confirm the dose response model and the health metric to use for each population group in the consumption model. In this scenario, there is only one option for each.

It is required that population groups be selected. Otherwise, you will be unable to run the scenario.

On the Edit Risk Scenario page, click the Population Groups tab. This tab also shows the number of population groups currently assigned out the total available (i.e. 0/1). On the Population Groups page, select the "Include in Analysis" check box for the population group and leave the selected dose response model and health metric as "Salmonella Beta-Poisson DR" and "Salmonella DALY (0.019)"; respectively. Click Save and Close.

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

Edit Risk Scenario

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

Instructions | Name and Parameters | Population Groups (1/1) | Notes (0) | Sensitivity Analysis | Report

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

Save | Save and Close | Close

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

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

The scenario is now ready to run.

Step 10: Generate the Risk Estimates and Scenario Ranking Report

Click the Report tab on the Edit Risk Scenario page and then click Generate Report for Risk Scenario.

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

Edit Risk Scenario

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

Instructions | Name and Parameters | Population Groups (1/1) | Notes (0) | Sensitivity Analysis | Report **1**

Report Title:

Report Abstract:

Send Email:

Include Uncertainty: Not available

2

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

The report is submitted to the queue for Monte Carlo simulation. The reloaded page includes a link to the Report History page where you can monitor the process of the report as it moves through the queue.

Click the link to see the Report History page, which shows the location of the report in the queue.

Report History **1** of the Report page to check the report status.' Quick links are provided at the bottom: 'Peanut Butter (F)', 'Salmonella (H)', and 'Salmonella in Peanut Butter (PM)'."/>

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

Edit Risk Scenario

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

Instructions | Name and Parameters | Population Groups (1/1) | Notes (0) | Sensitivity Analysis | Report

Report Title:

Report Abstract:

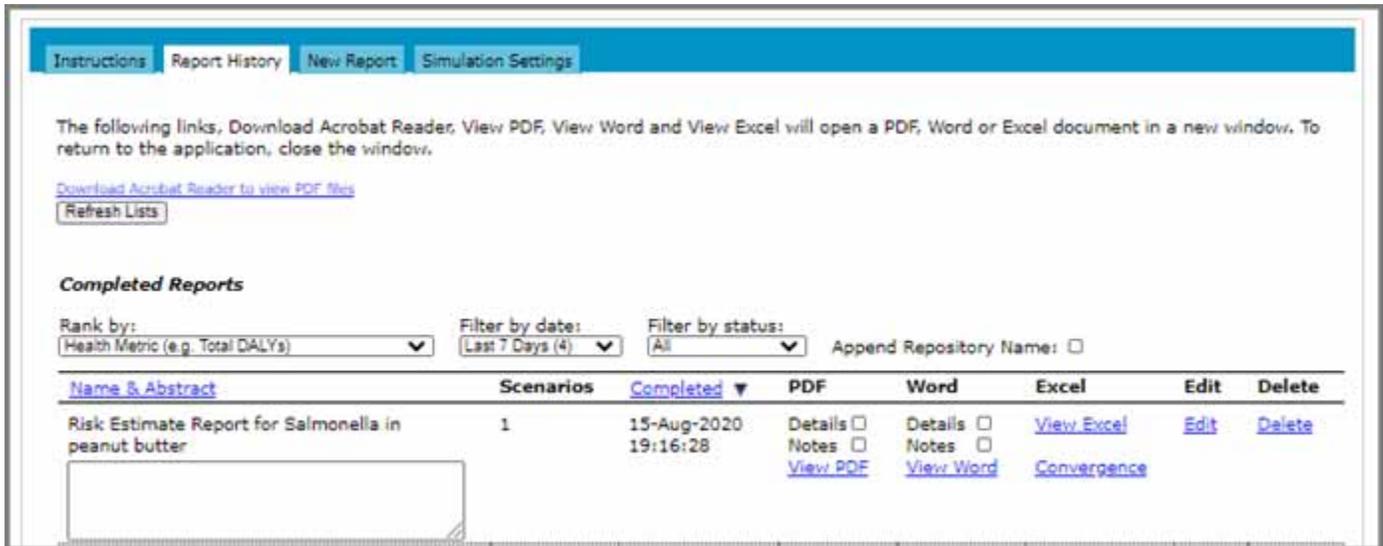
Send Email:

Include Uncertainty: Not available

The report was submitted to the queue for processing. Use the [Report History](#) **1** of the Report page to check the report status.

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

Click the Refresh Lists button to update the status. The report status changes from Pending, to In Process, and then Complete. Once the report is complete, it moves to the Completed Reports section where you can view the report in PDF or Microsoft Word format.



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.

You can optionally include details and notes by selecting the appropriate check box(es) prior to clicking the View PDF or Word links.

Click the Delete link to remove any reports that are no longer of interest.

Step 11: Interpreting the Report

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

Report Title: Risk Estimate Report for Salmonella in peanut butter

Ranking Summary

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

Scenario or Scenario Group	Total DALYs per Year	Uncertainty Results
Salmonella in peanut butter	62.4	N/A

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

The report summary is divided by health metric. For example, if the report contained both DALY and Cost of Illness scenarios, they would be ranked separately.

Note: These results are from a Monte Carlo simulation using Random Latin Hypercube. As such, slight variations in results from those displayed here should be expected.

If you provide a group ID when you submit the report, it will appear in the Scenario or Scenario Group column and the names of all the scenarios in the group will be listed.

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

Report Title: Risk Estimate Report for Salmonella in peanut butter

Ranking Summary for Risk Scenarios (Ungrouped)

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

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

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

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

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

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

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

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

Process Model: Salmonella in Peanut Butter				
	Initial Conditions		Model Outputs*	
Prevalence:	5.5E-6		4.19E-6	
Concentration:	Uniform (Units: log10 cfu/g)		0.352 log10 cfu/g	
	Minimum: -1.52 Maximum: 2.55			
	Computed Mean (Arithmetic): 1.58 log10 cfu/g			
Unit Mass:	Fixed Value (kg)		250 g	
	Value: 6850			
* Final prevalence and Prevalence-Weighted mean concentration				
Maximum Population Density (MPD):	Not applied			
Process Stages for Salmonella in Peanut Butter:				
Process Stage	Process Type	Definition	Concentration (log10 cfu/g)	Prevalence
Packaging	Partitioning	Fixed Value (g)	1.58	5.50E-6
		Value: 250		
Storage	Decrease	Uniform	0.352	4.19E-6
		Minimum: 0.49 Maximum: 3.47		

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

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

Result Summary			
Mean Exposure:	See population groups	Total Number of Illnesses:	3280
		Total DALY/Year:	62.4

Population Group Definitions:					
Population Group	Consumption	Dose Response	Health Metric		
General Population	Eating Occasions: 1.7E10 eo/yr Per Eating Occasion: Fixed Value (Units: g/eo) Value: 30 Number of Servings per Person: Include in Results: No Fixed Value (Serving Units: per day) Value: 0	Salmonella Beta-Poisson DR Beta-Poisson (Dose unit: cfu) alpha: 0.1324 beta: 51.45 Probability of adverse effect: 100%	Salmonella DALY (0.019 DALYs)		
Correlation Option: No Correlation					
Population Group Results:					
Population Group	Mean Dose* (cfu)	Mean** Prevalence in Servings	Mean Probability of Illness	Number of Illnesses per year	Total Metric Per Year (DALYs)
General Population	91.8	3.08E-6	1.93E-7	3280	62.4
* Mean dose per Contaminated serving		** Proportion of contaminated servings			

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

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

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

This scenario describes how to create an FDA-iRISK computed scenario for *L. monocytogenes* in soft ripened cheese. Most of the steps are similar to Scenario 1; however, this scenario uses three population groups, each with its own dose-response model, DALY metric, and consumption data.

Step 1: Create the Hazard

Create a new hazard with the name “L. monocytogenes”. Leave the type as “Microbial Pathogen” and the default unit as “cfu”.

Step 2: Add Dose Response Models

Add the following dose response models to the hazard:

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

When complete, the dose response model list on the Edit Hazard page for *L. monocytogenes* should display as:

Home -> Risk Models (My Primary Repository) -> Hazards -> Edit Hazard (L. monocytogenes) -> Dose Response Tab

Edit Hazard

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

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

u: Uncertainty distribution defined for this parameter

Quick Links: [Hazards](#)

Step 3: Add Health Metrics

Add the following health metrics to the hazard:

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

When complete, the health metric list for the hazard should display as:

The screenshot shows the 'Edit Hazard' page for 'L. monocytogenes'. The breadcrumb trail is: Home -> Risk Models (My Primary Repository) -> Hazards -> Edit Hazard (L. monocytogenes) -> Metrics Tab. The page title is 'Edit Hazard'. A message states: 'The Instructions tab should be reviewed by first time users before proceeding.' Below this is a tabbed interface with tabs for: Instructions, Name and Type, Dose Response (3), Metrics (3), Predictive (0), Process Models (1), Scenarios (2), and Notes (0). The 'Metrics (3)' tab is active, showing a table with the following data:

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

Below the table, it says: 'u: Uncertainty distribution defined for this parameter'. At the bottom left, there are 'Quick Links: [Hazards](#)'.

Step 4: Create the Food

Add a food with the name "Soft Ripened Cheese" measured using "Mass". Click Add. (Hint: Save the changes but do not close the page so that you can follow the steps in the next section to add a consumption model.)

Step 5: Add a Consumption Model

Create a consumption model with the name "Total Consumption" with exposure type of "Acute".

Step 6: Add Population Groups

Add the following population groups with the following parameters:

Name	Eating occasions per year	Amount per eating occasion (in grams)	Body Weight
Adults 60+	1.8E+08	Triangular(10,28,85)	Fixed Value: 0
Intermediate Aged (5-59)	1.7E+09	Triangular(10,28,168)	Fixed Value: 0
Perinatal	1.2E+07	Triangular(10,28,85)	Fixed Value: 0

When complete, the population group list should display as:

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> [Food \(Soft Ripened Cheese\)](#) -> Edit Acute Consumption Model (Total Consumption) -> Population Groups Tab

Edit Acute Consumption Model

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

Instructions | Name and Parameters | Population Groups (3) | Scenarios (2) | Notes (0)

[Add Population Group](#)

Population Group	eo/yr	Consumption	Body Weight	Servings/Person	Actions
Adults 60+	1.8E+08	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo	Fixed Value (Value: 0) Kg	Fixed Value (Value: 0)/day	Edit Copy Delete
Intermediate Aged (5-59)	1.7E+09	Triangular (Minimum: 10, Mode: 28, Maximum: 168) g/eo	Fixed Value (Value: 0) Kg	Fixed Value (Value: 0)/day	Edit Copy Delete
Perinatal	1.2E+07	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo	Fixed Value (Value: 0) Kg	Fixed Value (Value: 0)/day	Edit Copy Delete

u: Uncertainty distribution defined for this parameter

Quick Links: [Soft Ripened Cheese \(F\)](#)

Step 7: Add a Process Model

Add a process model with the name "L. monocytogenes in soft ripened cheese" and select "L. monocytogenes" as the hazard and "Soft Ripened Cheese" as the food. Set the initial prevalence as "0.0104". Set the initial unit mass as

“227 g”. Set the initial concentration as “Triangular (-1.39, -1.15, 0.699) log₁₀ cfu/g”. Set the maximum population density to “9 log cfu/g”. Save the changes.

Home > Tool Models (By Process/ Scenario) > Food > Food/Soft Spread Cheese > Risk Process Model (L. monocytogenes in soft spread cheese) > Name and Initial Conditions Tab

Edit Process Model

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

Instructions | Name and Initial Conditions | Process Model (1) | Assessment Model (1) | Controller (1) | Views (1)

Note: All fields are required.

Model Name:

Define Initial Conditions Using:

Single Set of Parameters

Multiple Sets of Parameters

Upstream Process Model

[General Help](#)

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:	L. monocytogenes	N/A
Food:	Soft Spread Cheese	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/>	N/A
Initial Prevalence:	<input type="text" value="1.0000"/>	Add
Select Mass Units:	<input type="text" value="g"/>	N/A

Initial Unit Mass:

Distribution Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="227"/>	Add

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

Initial Concentration:

Parameter	Value	Uncertainty
Units:	<input type="text" value="log10 cfu/g"/> / <input type="text" value="g"/> (Units)	N/A
Variability Distribution:	<input type="text" value="Triangular"/>	N/A
Minimum:	<input type="text" value="-1.39"/>	Add
Mode:	<input type="text" value="-1.15"/>	Add
Maximum:	<input type="text" value="0.699"/>	Add

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

Probability Density and Cumulative Distribution

Count Per Unit (227 g)

[Refresh Chart](#)

Maximum Population Density (MPD):

Note: The value specified for MPD is not applied when charting Initial Concentration above.

Parameter	Value	Uncertainty
Restrict concentration to MPD:	<input type="checkbox"/>	N/A
MPD:	<input type="text" value="9.0000"/> log cfu/g	N/A
Value:	<input type="text" value="9"/>	Add

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

Last Modified: 11-Dec-2014 09:55:17

Quick Links: [Soft Spread Cheese \(1\)](#) / [L. monocytogenes \(1\)](#)

Step 8: Add Process Stages

Add one process stage with the name “Consumer Storage” and process type “Increase by Growth”. Click Add.

Set its variability distribution to “Triangular (0, 0.03, 5.79)” and save. The Edit Process Stage page with the Name and Parameters tab selected should look like this:

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Soft Ripened Cheese) -> Process Model (L. monocytogenes in soft ripened cheese) -> Edit Process Stage (Consumer Storage) -> Name and Parameters Tab

Edit Process Stage

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

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

Note: All fields are required

Stage Name:

Process Model: L. monocytogenes in soft ripened cheese

Process Type: Increase by Growth

Increase in Microbial Population (log10 scale):

Parameter	Value	Uncertainty
Variability Distribution:	Triangular <input type="button" value="v"/>	N/A
Minimum:	<input type="text" value="0"/>	Add
Mode:	<input type="text" value="0.03"/>	Add
Maximum:	<input type="text" value="5.79"/>	Add

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

Last Modified: 29-Aug-2019 08:39:48

Step 9: Create the Risk Scenario

Create a risk scenario with the name “L. monocytogenes in soft ripened cheese” and the type as “Computed using FDA-iRISK model for a single hazard and single food”. Click Next.

Select “L. monocytogenes in soft ripened cheese” as the process model, and “DALY” as the metric type. Click Next.

Select “Total Consumption” as the consumption model. Click Add. Save the changes.

On the Edit Risk Scenario page, click the Population Groups tab and set the values as follows, matching the population groups with the appropriate dose response model and health metric. Save the changes.

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

Edit Risk Scenario

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

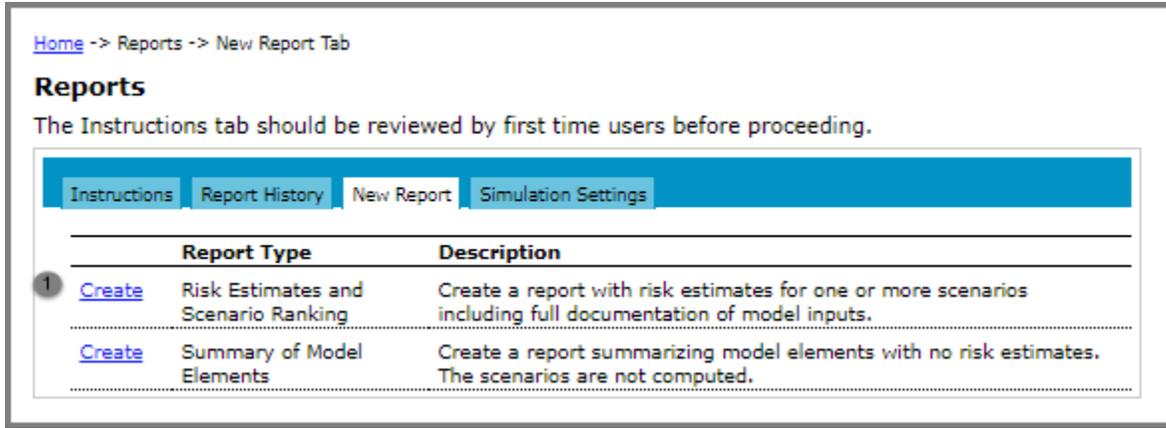
Population Group	Consumption	Dose Response & Health Metric Model	Include in Analysis
Adults 60+	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eq; 1.8E+08 eq/yr	Dose Response: Adults 60+ DR Health Metric: Adults 60+ DALY (2.6)	<input checked="" type="checkbox"/>
Intermediate Aged (5-59)	Triangular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

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

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

Step 10: Generate the Ranking Report

Click the Reports tab in the main tab bar, and then click the Create link beside the Risk Estimates and Scenario Ranking report type in the list of options.



Under List scenarios for: select the check box beside My Primary Repository, and then click the Update Selections button. Click the Load Risk Scenarios button.

Under Risk Scenarios Available for Ranking, select the Run check boxes for the "Salmonella in Peanut Butter" and "L. monocytogenes in soft ripened cheese" scenarios. The Group ID box is used to collect multiple scenarios into a group for ranking by entering the same ID into the box for all scenarios in the group. It can be left blank for this exercise.

Change the report title to "FDA-iRISK Ranking for Salmonella and L. monocytogenes". Optionally add an abstract.

Click Generate Report for Checked.

[Home](#) -> [Reports](#) -> Risk Estimates and Scenario Ranking -> Report Tab

Risk Estimates and Scenario Ranking

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

Instructions | **Report**

Note: All fields are required

List scenarios for: (R1) My Primary Repository (R2) My Second Repository

Filters: Use the following filters to select a subset of the scenarios available for ranking.

Food: Hazard: Metric: Exposure: Type:

Risk Scenarios Available for Ranking

Available Scenarios:

Run	Group ID	Scenario Weight	Include Uncertainty	Repository	Scenario Name and Details	Actions
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	Aflatoxin B1 in Tortilla Chips (Tortilla Chips, Aflatoxin B1, DALY, Chronic, Computed)	Edit
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	Aflatoxin B1 in Tortilla Chips (Exposure Only) (Tortilla Chips, Aflatoxin B1, Exposure Only, Chronic, Computed)	Edit
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	My Primary Repository	Ammonia in Frozen Pizza in Children (Frozen Pizza, Ammonia (refrigerant leak), DALY, Acute, Computed)	Edit
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	Campylobacter spp. in Poultry (Poultry, Campylobacter, DALY, Acute, Specified)	Edit
<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	L. monocytogenes in soft ripened cheese (Soft Ripened Cheese, L. monocytogenes, DALY, Acute, Computed)	Edit
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	L. monocytogenes in soft ripened cheese (Exposure Only) (Soft Ripened Cheese, L. monocytogenes, Exposure Only, Acute, Computed)	Edit
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	Ochratoxin A from Oats, Rice and Raisins (Multifood, Ochratoxin A, DALY, Chronic, Computed Multifood)	Edit
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	Ochratoxin A from Oats, Rice and Raisins (Exposure Only) (Multifood, Ochratoxin A, Exposure Only, Chronic, Computed Multifood)	Edit
<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	Salmonella in peanut butter (Peanut Butter, Salmonella, DALY, Acute, Computed)	Edit
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	n/a	My Primary Repository	Salmonella in peanut butter - Specified (Peanut Butter, Salmonella, DALY, Acute, Specified)	Edit

Simulation Settings: Moderate Run

Report Title:

Report Abstract:

Send Email:

Annualize Chronic Results

Use the buttons below to submit the scenarios for risk estimation and ranking. The request will be entered into the report queue and will be accessible from the Report History page when completed. This may require several minutes or longer.

View the status on the Report History tab of the Reports page. Refresh the page periodically until the report is available. Under PDF, select the Details check box and then click the View PDF link to view the report.

Step 11: Interpreting the Report

The report in this case contains two scenarios, ranking in descending order by total DALYs per year.

Ranking Summary

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

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

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

Report Title: FDA-iRISK Ranking for Salmonella and L. monocytogenes

Ranking Summary for Risk Scenarios (Ungrouped)

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

Scenario	Lifecycle 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

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

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

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

Population Group Definitions:			
Population Group	Consumption	Dose Response	Health Metric
Adults 60+	Eating Occasions: 1.8E+08 eo/yr Per Eating Occasion: Triangular (Units: g/eo) Minimum: 10 Mode: 28 Maximum: 85 Number of Servings per Person: Include in Results: No Fixed Value (Serving Units: per day) Value: 0	Adults 60+ DR Exponential (Dose unit: cfu) r: 8.39E-12 Probability of adverse effect: 100%	Adults 60+ DALY (2.6 DALYs)
Correlation Option: No Correlation			

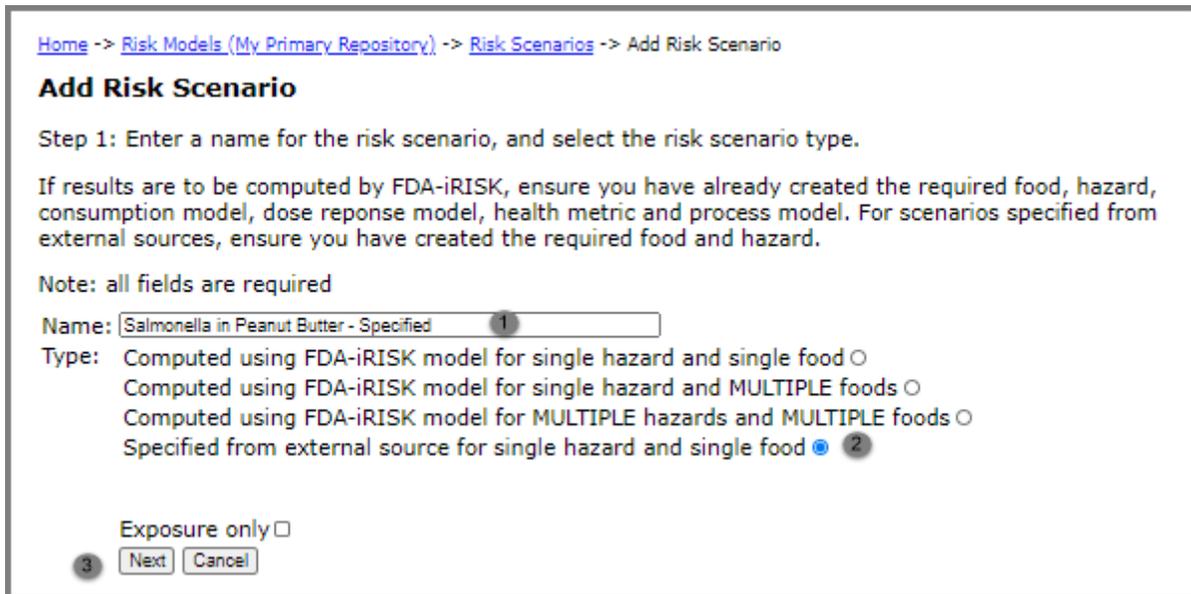
Intermediate Aged (5-59)	Eating Occasions: 1.7E+09 eo/yr	Intermediate Aged (5-59) DR Exponential (Dose unit: cfu)	Intermediate Aged (5-59) DALY (5.0 DALYs)		
	Per Eating Occasion: Triangular (Units: g/eo)	r: 5.34E-14			
	Minimum: 10 Mode: 28 Maximum: 168	Probability of adverse effect: 100%			
	Number of Servings per Person: Include in Results: No				
	Fixed Value (Serving Units: per day)				
	Value: 0				
Correlation Option: No Correlation					
Perinatal	Eating Occasions: 1.2E+07 eo/yr	Perinatal DR Exponential (Dose unit: cfu)	Perinatal DALY (14 DALYs)		
	Per Eating Occasion: Triangular (Units: g/eo)	r: 4.51E-11			
	Minimum: 10 Mode: 28 Maximum: 85	Probability of adverse effect: 100%			
	Number of Servings per Person: Include in Results: No				
	Fixed Value (Serving Units: per day)				
	Value: 0				
Correlation Option: No Correlation					
Population Group Results:					
Population Group	Mean Dose* (cfu)	Mean** Prevalence in Servings	Mean Probability of Illness	Number of Illnesses per year	Total Metric Per Year (DALYs)
Adults 60+	1.21E+5	0.0104	1.06E-8	1.90	4.94
Intermediate Aged (5-59)	2.09E+5	0.0104	1.16E-10	0.197	0.986
Perinatal	1.24E+5	0.0104	5.79E-8	0.695	9.73
* Mean dose per Contaminated serving		** Proportion of contaminated servings			

CHAPTER 3

Example of a Specified Risk Scenario for an Acute Microbial Hazard

FDA-iRISK supports directly entering results for a risk scenario. In this example, you will create a specified risk scenario using risk estimates that you provide.

Create a risk scenario. On the Add Risk Scenario page, enter “Salmonella in Peanut Butter - Specified” as the name and select “Specified from external source for single hazard and single food” as the type. Click Next.



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

Add Risk Scenario

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

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

Note: all fields are required

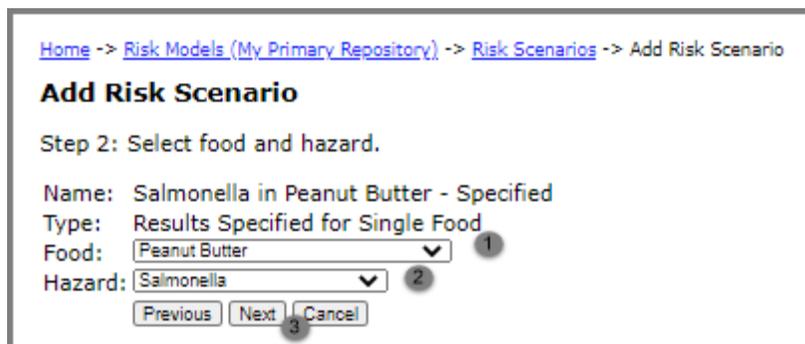
Name: 1

Type: Computed using FDA-iRISK model for single hazard and single food
 Computed using FDA-iRISK model for single hazard and MULTIPLE foods
 Computed using FDA-iRISK model for MULTIPLE hazards and MULTIPLE foods
 Specified from external source for single hazard and single food 2

Exposure only

3

Select “Peanut Butter” as the food and “Salmonella” as the hazard. Click Next.



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

Add Risk Scenario

Step 2: Select food and hazard.

Name: Salmonella in Peanut Butter - Specified

Type: Results Specified for Single Food

Food: 1

Hazard: 2

3

Finally, select "DALY" as the health metric type. Click Add.

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

Add Risk Scenario

Step 3: Select exposure type.

Name: Salmonella in Peanut Butter - Specified
Type: Results Specified For Single Food
Food: Peanut Butter
Hazard: Salmonella
Exposure Type: Acute
Health Metric Type: DALY

Previous Add Cancel

On the Edit Risk Scenario page, set the number of cases to "3400" and the health metric type to "0.019". Click Save. The Total DALY result at the bottom of the page is updated.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (Salmonella in peanut butter - Specified) -> Name and Parameters Tab

Edit Risk Scenario

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

Instructions Name and Parameters Notes (0) Report

Note: All fields are required

Shared:

Name: Salmonella in peanut butter - Specified

Type: Results Specified

Food: Peanut Butter

Hazard: Salmonella

Exposure Type: Acute

Mean Exposure: 0 cfu

Number of cases: 3400

Health Metric: 0.019 DALY per case

Total DALY: 64.6

Save Save and Close Close

Last Modified: 10-Sep-2019 06:11:09

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

This scenario may now also be included in the ranking reports. However, only those results that can be generated by the supplied information are reported and the details section for the scenario is just a summary of the data provided:

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 - Specified	N/A	N/A	3400	N/A	64.6	N/A	64.6

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.

Scenario Details for: Salmonella in peanut butter - Specified

Type:	Results Specified	Scenario Weight:	N/A
Hazard:	Salmonella (Microbial Pathogen)	Metric Type:	DALY
Food:	Peanut Butter	Exposure Type:	Acute
Mean Exposure:	0 cfu		
Number Of Cases:	3400	Total DALY/Year:	64.6
Health Metric:	0.019 DALY per case	Include Uncertainty:	No

CHAPTER 4

Examples of Computed Risk Scenarios for a Chemical Hazard

A computed risk scenario for an acute chemical hazard is structured in the same way as is a risk scenario for a microbial hazard, in that each eating occasion is considered an opportunity to become ill. The probability of illness applies to the eating occasion, whereas in chronic chemical risk scenarios the probability of illness applies to each consumer of the food.

This section provides an example of a computed acute chemical hazard risk scenario and a computed chronic chemical hazard risk scenario. They are intended to be reviewed in sequence.

Scenario 1 - A single food-hazard pair involving an acute chemical hazard

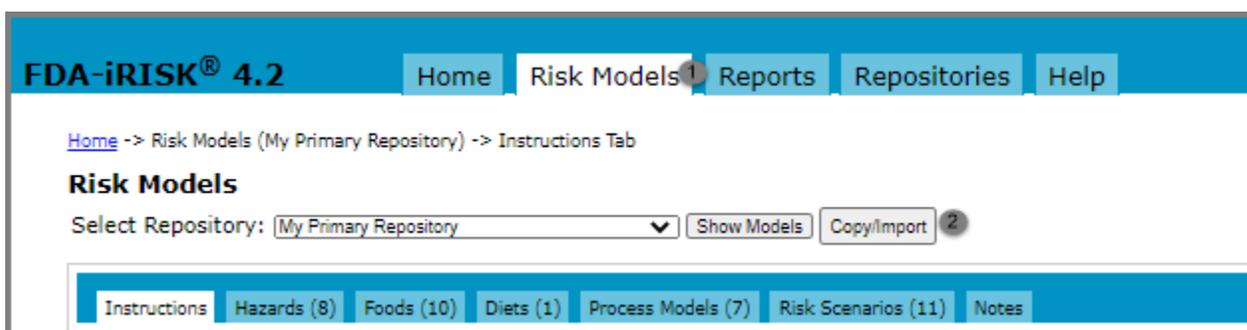
This section describes how to create a chemical risk scenario for an acute exposure to a chemical hazard, ammonia, occurring in frozen pizza as a result of a refrigerant leak. The pizza is consumed by a single population group of school children. You will define the following:

- The hazard and its dose response and burden (DALY or Cost of Illness).
- The food and its consumption pattern in the population group.
- The process model, which tracks the contamination of the food throughout production and processing to the point of consumption.

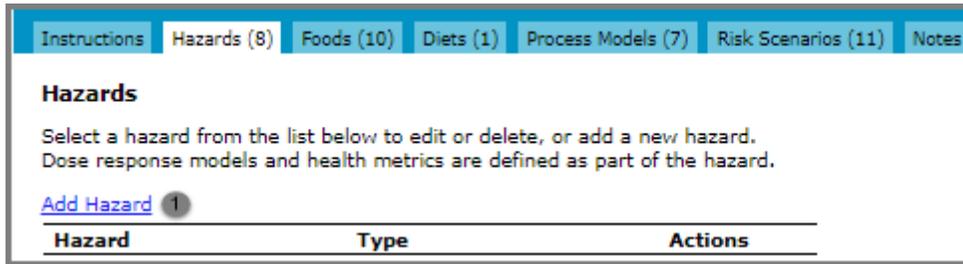
Step 1: Create the Hazard

On the FDA-iRISK window, click the Risk Models tab and then the Hazards tab. On the Risk Models page, verify that My Primary Repository is selected in the Show Models For drop-down list. Note that when you are using FDA-iRISK for the first time, the count of hazards and all other elements will be zero as no model elements have been defined.

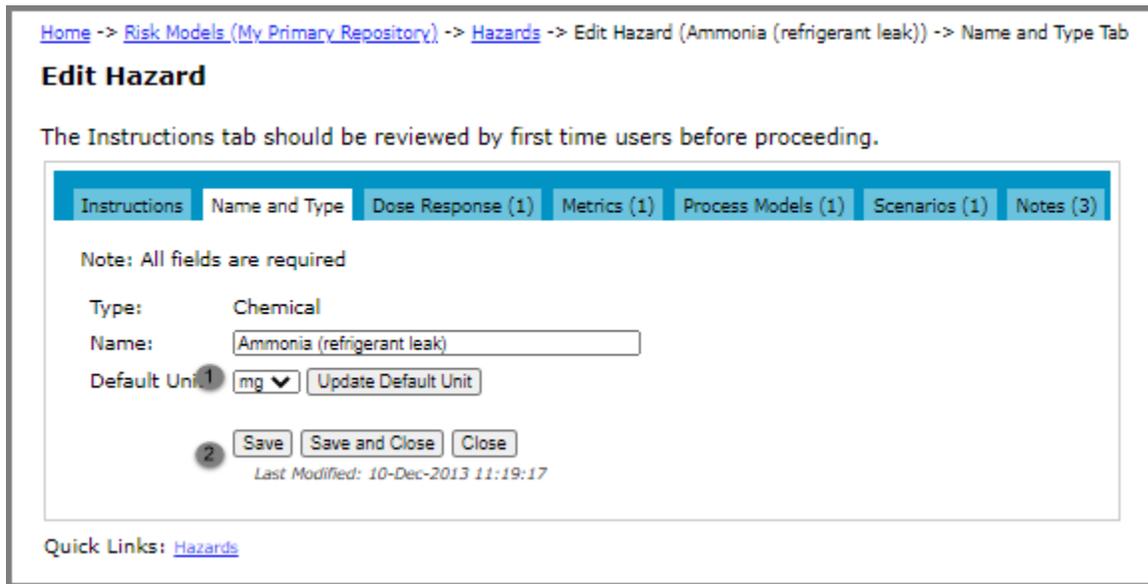
Note: The numbers in the figures throughout the guide highlight important areas or indicate where action is required.



Click the Add Hazard link.



Create a new hazard with the name “Ammonia (refrigerant leak)” and select “Chemical” as the type. Click Add. Leave the default units as “mg”. Click Save.



Step 2: Add Notes for the Hazard

On the Notes tab on the Edit Hazard page, add one or more notes. Click the Add Note link.



On the Add Note for Ammonia page, enter “Description” as the heading, and then click Add. Add the following text:

“Ammonia is a corrosive alkaline gas at room temperature, with an acrid odor that can be detected at concentrations of 35 mg per cubic meter of air (IPCS, 1990). It is used industrially and is also associated with normal biological activity, and typical levels range from less than 25 to 200 µg per cubic meter (IPCS, 1990). If

exposure is brief, up to 100 mg per cubic meter is tolerated, but at higher exposures people experience irritation of the skin, eyes, and/or respiratory tract (IPCS, 1990)."

Click Save and Close. The text displays on the Note tab and can be edited or deleted at any time.

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

Edit Hazard

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

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

[Add Note](#)

Type	Heading	Text	Actions
Public	Description	Ammonia is a corrosive alkaline gas at room temperature, with an acrid odor that can be detected at concentrations of 35 mg per cubic metre of air (IPCS, 1990). It is used industrially and is also associated with normal biological activity, and typical levels range from less than 25	Edit Copy Delete ↑ ↓

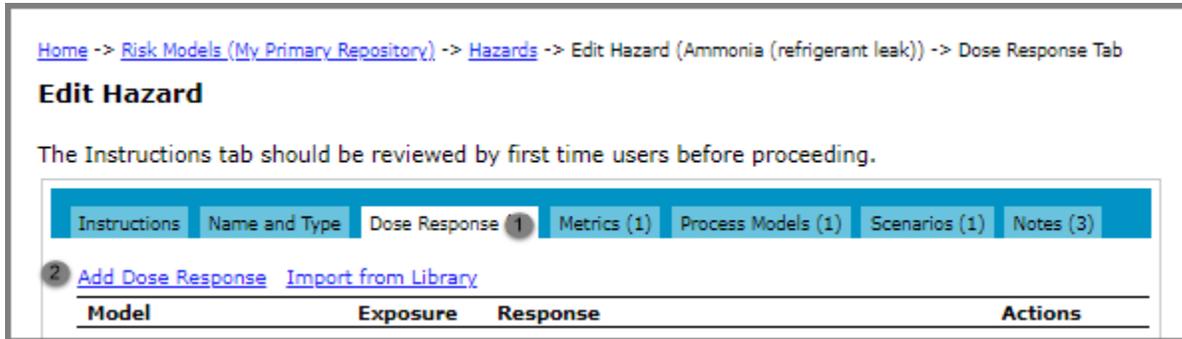
Add a second note. Enter "References" as the heading and add the following text:

"International Programme on Chemical Safety (IPCS). 1990. Ammonia Health and Safety Guide. Available at: <http://www.inchem.org/documents/hsg/hsg/hsg037.htm>. Accessed Dec. 17, 2013."

Click Save and Close.

Step 3: Add a Dose Response Model

Click the Dose Response tab on the Edit Hazard page and then click the Add Dose Response link.



The Add Dose Response Model page displays the options for model types according to exposure (i.e. acute or chronic). Enter "Ammonia Non-Threshold Linear" as the name for the dose response model and leave the exposure type as "Acute". Click Next.

Confirm the dose metric that will be used for the dose response model. In this example, “Mass” is appropriate. Click Next.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> [Hazard \(Ammonia \(refrigerant leak\)\)](#) -> Add Dose Response Model

Add Dose Response Model

Step 2: Select units for the dose

Name: Ammonia Non-Threshold Linear
Exposure Type: Acute
Dose Units: 1
 2

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)

Select “Non-Threshold Linear” as the response type to use for this dose response model. Click Add.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> [Hazard \(Ammonia \(refrigerant leak\)\)](#) -> Add Dose Response Model

Add Dose Response Model

Step 3: Select dose response type, then click Add

Name: Ammonia Non-Threshold Linear
Exposure Type: Acute
Dose Units: mass (e.g. mg)
Response Type: 1
 2

On the Edit Dose Response Model page, leave the dose unit as “mg”, and enter “0.21” for risk at reference point and “118 (mg)” for reference point. Leave the probability of adverse effect given response at 100%. Click Save.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Ammonia (refrigerant leak)) -> Edit Dose Response Model (Ammonia Non-Threshold Linear) -> Name and Parameters Tab

Edit Dose Response Model

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

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

Note: all fields are required

Model Name:

Parameter	Value	Uncertainty
Exposure Type:	Acute	N/A
Dose Unit :	<input type="text" value="mg"/> 1	N/A
Response Type:	Non-Threshold Linear	N/A
Risk at Reference Point: (No units; min > 0; max <= 1)	<input type="text" value="0.21"/> 2	Add
Reference Point: (mg; min > 0; no max)	<input type="text" value="118"/> 3	Add
Probability of adverse effect given response: (%; 100 when dose response is for adverse effect)	<input type="text" value="100"/> 4	Add

The chart below describes the probability of response for the dose response model specified above for a range of doses. The chart is only updated if the page is saved or the Refresh Chart button is clicked.

Dose Response Chart

Dose (mg)	Probability
0	0.00
118	0.21
312	0.55

Last Modified: 11-Dec-2013 12:55:31

Quick Links: [Ammonia \(refrigerant leak\)_\(H\)](#)

On the Notes tab, click the Add Note link. Enter "Rationale" as the heading and click Add. Add the following text to the Note text box:

"Acute poisonings from ammonia by oral exposures are rare, and no dose response model for this scenario was located in the literature. This dose response model is based on an outbreak of ammonia poisoning from oral exposure reported by Dworkin et al., (2004). Assuming that each chicken tender weighed 30 g, and that the average level of ammonia measured in the food post-outbreak represents the average level at the time of exposure, the dose associated with various reported attack rates can be calculated. Subtracting the reported attack rate at zero exposure from the remaining attack rates gives an attack rate (risk at reference point) of 21% at an exposure (reference point) of 118 mg ammonia. This dose response model also assumes that there is no threshold for effect.

Dworkin MS, Patel A, Fennell ME, Vollmer M, Bailey S, et al. 2004. An Outbreak of Ammonia Poisoning from Chicken Tenders Served in a School Lunch. Journal of Food Protection® 67(6):1299-1232."

Click Save and Close.

Step 4: Add a Health Metric

To add a health metric for Ammonia, click the Ammonia quick link or breadcrumb. Then, click the Metrics tab and the Add Health Metric link.

Enter "Ammonia (oral) DALY" as the name and leave the type as "DALY". Click Add.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> [Hazard \(Ammonia \(refrigerant leak\)\)](#) -> Add Health Metric

Add Health Metric

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

Note: all fields are required

Name: 1

Type: 2

3

On the Edit Health Metric page, enter "0.001" as the value. Save and close the page.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Ammonia (refrigerant leak)) -> Edit Health Metric (Ammonia (oral) DALY) -> Name and Parameters Tab

Edit Health Metric

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

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

Note: all fields are required

Name: Ammonia (oral) DALY

Type: DALY

Value: 0.001 [Compute from Health Endpoints](#)

Uncertainty: [Add](#)

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

Last Modified: 11-Dec-2013 12:56:45

Quick Links: [Ammonia \(refrigerant leak\)_\(H\)](#)

Step 5: Create the Food

On the FDA-iRISK window, click the Risk Models tab and then the Foods tab. Click the Add Food link.

Add a food with the name "Frozen Pizza" and leave "Mass" as the unit type for measuring food quantity. Click Add.

Confirm that the food definition is correct and then click Save.

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

Edit Food

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

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

Note: All fields are required

Name: Frozen Pizza 1

Quantity Measured In: Mass

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

Last Modified: 10-Dec-2013 11:01:39

Quick Links: [Foods](#)

Step 6: Add a Consumption Model

On Consumption Models tab, click the Add Consumption Model link.

Create a consumption model with the name "Frozen Pizza Consumption by Children," and leave exposure type as Acute. Click Add and then click Save.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Frozen Pizza) -> Add Consumption Model

Add Consumption Model

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

Note: all fields are required

Name: 1

Exposure Type: 2

On the Population Groups tab, click the Add Population Group link. Add the population group, "Children 6 to 12". Click Add.

Home -> Risk Models (My Primary Repository) -> Foods -> Consumption Model (Frozen Pizza Consumption by Children) -> Add Population Group

Add Population Group

Enter a population group name and click "Add".

Note: all fields are required

Population Group Name: 1

2

Enter the required information to define the consumption model. For this example, assume that there are 1.3E9 eating occasions per year across the population of children 6 to 12. During each eating occasion, the amount of the

food consumed can be described as a triangular distribution ranging from a minimum of 100 g to a maximum of 300 g with a mode of 150 g.

Home -> Risk Models (My Primary Beers) -> Foods -> Food (Frozen Pizza) -> Consumption Model (Frozen Pizza Consumption by Children) -> Edit Population Group and Consumption (Children 6 to 12) -> Name and Parameters Tab

Edit Population Group and Consumption

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

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

Note: All fields are required

Name:

Parameter	Value	Uncertainty
Eating occasions per year:	<input type="text" value="1.3E3"/>	Add

Amount per eating occasion:

Parameter	Value	Uncertainty
Unit:	<input type="text" value="g"/>	N/A
Variability Distribution:	<input type="text" value="Triangular"/>	N/A
Minimum:	<input type="text" value="100"/>	Add
Mode:	<input type="text" value="150"/>	Add
Maximum:	<input type="text" value="300"/>	Add

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

[Refresh Chart](#)

Body Weight (kg):

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

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

Number of servings per person:

Note: Assumptions necessary, e.g., mean risk per serving for the population applicable to the individual. Refer to the [Technical Documentation](#) section 4.2.3 for additional information before using this feature.

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

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

Spearman (Rank) Correlation:

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

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

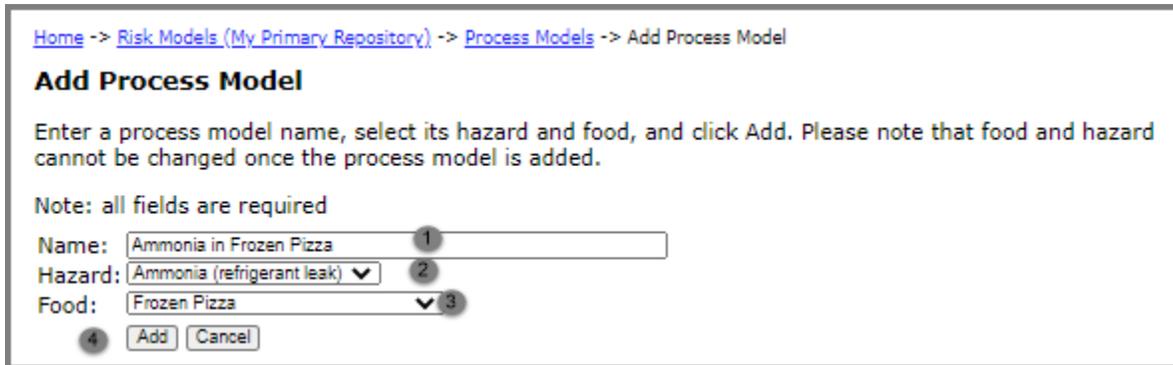
Last Modified: 02-Sep-2010 14:42:26

Quick Links: [Frozen Pizza \(F\)](#) | [Frozen Pizza Consumption by Children \(CN\)](#)

The body weight is not required unless dose response models are used that have doses expressed per kg body weight. Click Save and Close.

Step 7: Add a Process Model

Click the My Primary Repository breadcrumb, or the Risk Models tab on the main tab bar, to return to the Risk Models page. On the Process Models tab, click the Add Process Model link. Create a process model with the name "Ammonia in Frozen Pizza" and select the appropriate food and hazard from the drop-down lists. Click Add.



Home -> Risk Models (My Primary Repository) -> Process Models -> Add Process Model

Add Process Model

Enter a process model name, select its hazard and food, and click Add. Please note that food and hazard cannot be changed once the process model is added.

Note: all fields are required

Name: 1

Hazard: 2

Food: 3

4

On the Edit Process Model page, specify the initial unit mass, initial prevalence and initial concentration values for the process model. If the Process Model begins after the food has become contaminated, the initial level (concentration) and prevalence of the hazard in the food must be defined. You can see the appropriate parameter boxes appear as you select different options for distribution of initial concentration.

In this example, an accident of this type is assumed to be a one-in-a-million occurrence, so enter "1E-6" as the initial prevalence. The units are individual pizzas each weighing 150 g, so select "g" as the unit and enter "150" as the initial unit mass.

This Process Model describes a situation in which a refrigerant line has ruptured, contaminating the product. Therefore, select the Initial Units are Contaminated check box.

Assume that the level of contamination is represented by a triangular distribution with minimum concentration being 0.7 mg/g, the mode being 1.3 mg/g, and the maximum concentration being 2 mg/g.

Save the changes.

Home -> Risk Models (1) -> Primary Receptor -> Process Models -> Edit Process Model (Ammonia in Frozen Pizza) -> Name and Initial Conditions Tab

Edit Process Model

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

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

Note: All fields are required

Model Name:

Define Initial Conditions Using:

Single Set of Parameters
 Upstream Process Model

Initial Contamination, Unit Size and Prevalence:

Parameter	Value	Uncertainty
Hazard:	Ammonia (refrigerant leak)	N/A
Food:	Frozen Pizza	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/>	N/A
Initial Prevalence:	<input type="text" value="1E-8"/> <input type="button" value="Add"/>	
Select Mass Units:	<input type="text" value="g"/>	N/A

Initial Unit Mass:

Distribution Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="1E0"/> <input type="button" value="Add"/>	

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

Initial Concentration:

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

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

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

Quick Links: [Process Stages \(2\)](#) | [Ammonia \(refrigerant leak\) \(1\)](#)

Step 8: Add Process Stages

On the Process Stages tab, click the Add Process Stage link. Create a process stage with the name "Storage" and process type "Decrease". Click Add.

Set its variability distribution to “Uniform” with a minimum and maximum of “0.05” and “0.1”, respectively. This will apply a proportional reduction of that amount to the concentration at the beginning of the stage. Click Save and Close.

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

Edit Process Stage

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

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

Note: All fields are required

Stage Name:

Process Model: Ammonia in Frozen Pizza

Process Type: Decrease

Proportion Removed:

Parameter	Value		Uncertainty
Variability Distribution:	<input type="text" value="Uniform"/>	1	N/A
Minimum:	<input type="text" value="0.05"/>	2	Add
Maximum:	<input type="text" value="0.1"/>	3	Add

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

Last Modified: 03-Sep-2019 11:01:38

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

Create a second process stage called “Cooking” and process type “Decrease” that results in a decrease that reduces the concentration of the hazard in the food by 50% (i.e. “0.5”). Click Save and Close.

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

Edit Process Stage

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

Instructions | Name and Parameters | Notes (0)

Note: All fields are required

Stage Name:

Process Model: Ammonia in Frozen Pizza

Process Type: Decrease

Proportion Removed:

Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="0.5"/> ¹	Add

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

Last Modified: 03-Sep-2019 11:01:38

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

Step 9: Create the Risk Scenario

You have now defined the process model up to the point of consumption and the Risk Scenario can be compiled. On the Edit Process Model page showing the list of Process Stages, click the Scenarios tab. Click the Add Risk Scenario link.

On the Add Risk Scenario page, create a risk scenario with the name “Ammonia in Frozen Pizza in Children” and leave the type as “Computed using FDA-iRISK model for a single hazard and single food”. Click Next.

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

Add Risk Scenario

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

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

Note: all fields are required

Name:

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

Exposure only

Select “Ammonia in Frozen Pizza” as the process model. The appropriate food and hazard are automatically selected. As a chemical hazard can have acute or chronic effects, you need to specify the aspect to model in this scenario. Leave the exposure type as “Acute” and the metric type as “DALY”.

This page also provides a summary of model elements associated with the selected process model (and its food and hazard) for review.

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

Add Risk Scenario

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

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

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

Name: Ammonia in Frozen Pizza in Children
 Type: Results Computed for Single Food

Filter Process Models by:

Process Model: 1
 Food: Frozen Pizza, Hazard: Ammonia (refrigerant leak)

Exposure Type: 2
 Metric Type: 3

Available Models:

Health Metrics	for Acute Exposure	for Chronic Exposure
DALY <ul style="list-style-type: none"> Ammonia (oral) DALY Cost Per Illness No Models* QALY No Models*	Consumption Models <ul style="list-style-type: none"> Frozen Pizza Consumption by Children Dose Response Models <ul style="list-style-type: none"> Ammonia Non-Threshold Linear 	Consumption Models No Models* Dose Response Models No Models*

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

For the purpose of this scenario, leave the consumption model selected as “Frozen Pizza Consumption by Children.” Click Add.

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

Add Risk Scenario

Step 3: Select consumption model.

Name: Ammonia in Frozen Pizza in Children
 Type: Results Computed For Single Food
 Process Model: Ammonia in Frozen Pizza
 Food: Frozen Pizza
 Hazard: Ammonia (refrigerant leak)
 Exposure Type: Acute
 Health Metric Type: DALY

Consumption Model: Frozen Pizza Consumption by Children 1

Previous Add Cancel

All required elements are now added to the scenario. Next, you must select the population group(s) from the consumption model to include in the scenario. These are not assigned by default as you must confirm the dose response model and the health metric to use for each population group in the consumption model. In this scenario, there is only one option for each.

Note: It is required that population groups be selected. Otherwise, you will be unable to run the scenario.

On the Edit Risk Scenario page, click the Population Groups tab. This tab also shows the number of population groups currently assigned out the total available (i.e. 0/1).

Select the Include in Analysis check box beside the population group and leave the selected dose response model and health metric as “Ammonia Non-Threshold Linear” and “Ammonia (oral) DALY (0.001)”, respectively. Click Save and Close.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Process Models](#) -> [Process Model \(Ammonia in Frozen Pizza\)](#) -> Edit Risk Scenario (Ammonia in Frozen Pizza in Children) -> Population Groups Tab

Edit Risk Scenario

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

Population Group	Consumption	Dose Response & Health Metric Model	Include in Analysis
Children 6 to 12	Triangular (Minimum: 100, Mode: 150, Maximum: 300) g/ea; 1.3E9 ea/yr	Dose Response: Ammonia Non-Threshold Linear Health Metric: Ammonia (oral) DALY (0.001) 2	<input checked="" type="checkbox"/> 1

Save Save and Close Close 3

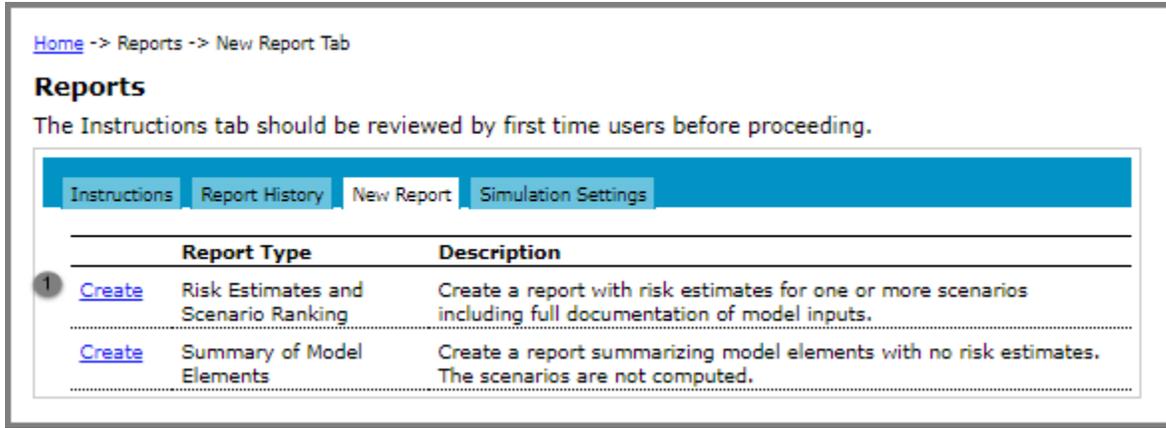
Last Modified: 27-Sep-2014 09:22:51

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

The scenario is ready to run.

Step 10: Generate the Risk Estimates and Scenario Ranking Report

Click the Reports tab in the main tab bar, and then click the Create link beside the Risk Estimates and Scenario Ranking report type in the list of options.



While this report only contains one scenario, it uses the generic ranking system to present results based on annual burden.

Under List scenarios for: select the check box beside My Primary Repository, and then click the Update Selections button. Click the Load Risk Scenarios button.

Under Risk Scenarios Available for Ranking, select the Run check box for the scenario, "Ammonia in Frozen Pizza in Children".

Change the report title to "FDA-iRISK Scenario Report for Ammonia in Frozen Pizza". Optionally add an abstract.

Click Generate Report for Checked.

Next, click the Report History link to open the Reports page, which lists and shows the status of all reports. Alternatively you can click the Report History tab on the Reports page.

Click the Refresh Lists button to update the status. Once the report is complete, view it in PDF format. You can optionally include details and notes by selecting the appropriate box(es) prior to clicking the View PDF.

Step 11: Interpreting the Report

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

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
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.

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)
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.

The ungrouped summary shows the number of eating occasions that were input for the scenario, and the resulting estimate for the number of illnesses, the mean risk of illness per eating occasion, the population burden in DALYs, and the burden per eating occasion. Notice that multiplying the number of eating occasions by the burden per eating occasion gives the DALY value.

Ensuing pages reproduce the input values (and notes if selected) for the other model elements (i.e. the process model, population group(s), consumption, dose response and Health Metric).

Scenario 2 - A single food-hazard pair involving a chronic chemical hazard

This section describes how to create an FDA-iRISK scenario for chronic exposure to Aflatoxin B1 in corn tortilla chips. Most of the steps are similar to the previous scenario. However, this one includes 5 life stages differing in age and body weight, that collectively define the population exposed to this chronic hazard.

Step 1: Create the Hazard

Create a new hazard with the name "Aflatoxin B1". Select "Chemical" as the hazard type, and click Add. Select "ng" as the default unit. Click Save.

Step 2: Add a Dose Response Model

The dose response describes the probability of developing liver cancer over a lifetime of exposure to Aflatoxin B1 in the food. Create a dose response model.

Enter "Linear by Slope Factor" as the name and select "Chronic" as the exposure type. Select "Linear by Slope Factor" as the response type. Enter a slope of "7.7E-6" and specify the dose units as "ng"/kg-day. The probability of adverse effect given response is kept as "100%".

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

Edit Hazard

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

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

[Add Dose Response](#) | [Import from Library](#)

Model	Exposure	Response	Actions
Linear by Slope Factor	Chronic	Linear by Slope Factor Dose unit: ng/kg-day (Slope:7.7E-6; 100%)	Edit Copy Delete

u: Uncertainty distribution defined for this parameter

Quick Links: [Hazards](#)

Step 3: Add a Health Metric Computed from Health Endpoints

Define a health metric for the hazard. Chronic exposure to Aflatoxin B1 may result in liver cancer. In this scenario, the metric representing liver cancer is computed rather than input directly. Click the Compute from Health Endpoints link.

Home -> Risk Models (My Primary Repository) -> Hazards -> Hazard (Aflatoxin B1) -> Edit Health Metric (Liver Cancer) -> Name and Parameters Tab

Edit Health Metric

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

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

Note: all fields are required

Name:

Type: DALY

Value: [Compute from Health Endpoints](#) 1

Uncertainty: [Add](#)

Last Modified: 12-Dec-2013 10:26:33

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

The health end-points associated with liver cancer are non-fatal liver cancer, fatal liver cancer (being the disability or “morbidity” associated with a case that becomes fatal), and the fatality itself.

First, enter the duration (specify units) and severity of fatal liver cancer, as well as the fraction of cases expected to experience this outcome. In this scenario, these values are 0.4, Years, 0.56, and 0.95 respectively. Click Add.

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

Compute DALY

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

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

Note: all fields are required

Health Endpoint	Duration	Unit	Severity	DALY	Fraction of Cases	Weighted DALY	Actions
<input type="text" value="Morbidity: Fatal Liver Cancer"/> 1	<input type="text" value="0.4"/> 2	<input type="text" value="Y"/> 3	<input type="text" value="0.56"/> 4		<input type="text" value="0.95"/> 5		<input type="button" value="Add"/> 6
Totals:						0.000000 (< 1)	0.00

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

FDA-iRISK automatically computes the burden associated with the first health endpoint.

Next, enter the values for duration, severity, and fraction of cases for non-fatal liver cancer. In this scenario, non-fatal liver cancer is assumed to comprise 5% of all liver cancer cases, and last 15.1 years with a severity weight of 0.2. Click Add.

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

Compute DALY

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

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

Note: all fields are required

Health Endpoint	Duration	Unit	Severity	DALY	Fraction of Cases	Weighted DALY	Actions
Morbidity: Fatal Liver Cancer	<input type="text" value="0.4"/>	<input type="text" value="Y"/>	<input type="text" value="0.56"/>	0.22400	<input type="text" value="0.95"/>	0.21280	Delete
Morbidity: Non-fatal Liver Cancer	<input type="text" value="15.1"/>	<input type="text" value="Y"/>	<input type="text" value="0.2"/>		<input type="text" value="0.05"/>		Add
Totals:					0.9500000	0.213	
					(< 1)		

Last Modified: 16-Aug-2020 08:28:52

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

FDA-iRISK calculates the weighted DALY as each endpoint is added.

Finally, enter the values associated with the fatalities, that is, the years of life lost as a result of premature death. The life expectancy associated with different ages can be obtained from life tables. The median age at death from liver cancer is 62 years, so the duration of the fatality is considered to be 20 years (life expectancy at age 62). The severity weight assigned to death is 1. As mentioned, fatal cases are assumed to comprise 95% of all liver cancer cases. Click Add.

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

Compute DALY

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

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

Note: all fields are required

Health Endpoint	Duration	Unit	Severity	DALY	Fraction of Cases	Weighted DALY	Actions
Morbidity: Fatal Liver Cancer	<input type="text" value="0.4"/>	<input type="text" value="Y"/>	<input type="text" value="0.56"/>	0.22400	<input type="text" value="0.95"/>	0.21280	Delete
Morbidity: Non-fatal Liver Cancer	<input type="text" value="15.1"/>	<input type="text" value="Y"/>	<input type="text" value="0.2"/>	3.0200	<input type="text" value="0.05"/>	0.15100	Delete
Mortality: Fatal Liver Cancer	<input type="text" value="20"/>	<input type="text" value="Y"/>	<input type="text" value="1"/>		<input type="text" value="0.95"/>		Add
Totals:					1.0000000	0.364	

Last Modified: 16-Aug-2020 08:31:11

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

Notice that FDA-iRISK alerts you whenever the fraction of cases adds up to a value other than 1. Values less than 1 imply that health endpoints are being ignored. In this case, the value greater than 1 reflects the fact that some cases experience more than one health endpoint sequentially. Click Save and Close until you are returned to the Edit Hazard page.

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

Edit Hazard

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

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

[Add Health Metric](#)

Name	Type	Value	Actions
Liver Cancer (computed)	DALY	19.4	Edit Copy Delete

u: Uncertainty distribution defined for this parameter

Quick Links: [Hazards](#)

FDA-iRISK assigns this health metric to each case of illness predicted.

To improve transparency, you are encouraged to document the rationale applied on the Notes tab.

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> [Hazard \(Aflatoxin B1\)](#) -> [Edit Health Metric \(Liver Cancer \(computed\)\)](#) -> [Name and Parameters Tab](#)

Edit Health Metric

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

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

Note: all fields are required

Name:

Type: DALY

Value: [Compute from Health Endpoints](#)

Uncertainty: [Add](#)

Last Modified: 12-Dec-2013 10:27:26

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

[Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Hazards](#) -> [Hazard \(Aflatoxin B1\)](#) -> [Hazard Metric \(Liver Cancer \(computed\)\)](#) -> [Edit Note \(Rationale for computed liver cancer DALY\)](#)

Edit Note

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

Note: all fields are required

Private:

Heading:

Note:

Liver cancer was assumed to be experienced as either diagnosis and primary therapy, state after intentionally curative primary cancer, and rest of live for survivors, or diagnosis and primary therapy, remission, disseminated cancer and terminal cancer for non-survivors. In addition, non-surviving cases incurred a YLL (Years of life lost) corresponding to the standard life expectancy of their age at death.

For the morbidity endpoints, severity was calculated as the weighted average of disability weights of the states involved (colorectal cancer was used as a proxy for liver cancer). Duration is the sum of the durations for these states.

Values for fraction of cases experiencing each endpoint were based on 5-year survival rates for liver cancer, weighted by incidence-by-age.

The above calculations used data from the Australian Institute of Health and Welfare, 1999. Since survival time is brief in fatal cases, life expectancy was based on the median age at diagnosis (63; NCI, 2010)

Australian Instituted of Health and Welfare. 1999 YLD by disease. 1996 Australian Burden of Disease Study. Available at: <http://www.aihw.gov.au/body-yld-disease/#F>

National Cancer Institute. 2010. SEER Stat Fact Sheets. Liver and Intraheptic Bile Duct. Available at: <http://seer.cancer.gov/statfacts/html/livibd.html>

Last Modified: 16-Aug-2020 08:42:48

Step 4: Create the Food

This scenario assumes that Aflatoxin B1 is contaminating corn tortilla chips; therefore, define a food named "Tortilla Chips", measured by Mass. Click Add and then Save.

Step 5: Add a Consumption Model

Because this is a chronic exposure scenario and the dose is calculated as a fraction of body weight, it is advisable to specify a consumption model for different ages. This allows FDA-iRISK to calculate a weighted average daily dose over the lifetime (the Lifetime Average Daily Dose or LADD) that takes into account potentially higher “per kg” doses during childhood.

On the Consumption Models tab, start by adding a consumption model named “Tortilla Chip Consumption”, with a chronic exposure type. Click Add.

Home -> Risk Models (My Primary Repository) -> Foods -> Food (Tortilla Chips) -> Add Consumption Model

Add Consumption Model

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

Note: all fields are required

Name: 1

Exposure Type: 2

3

Next, enter the number of lifelong consumers. For this scenario, assume 25 million people or “25E6”. Click Save.

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

Edit Chronic Consumption Model

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

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

Note: All fields are required

Model Name:

Exposure Type:

Annual Consumers: 1

Uncertainty: [Add](#) 2

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

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

Each life stage must be defined individually in terms of the body weight and average daily consumption of tortilla chips. On the Life Stages tab, add the life stages. Name the first group "Children 1 to 5", and then click Add.

The screenshot shows a web-based form titled "Add Life Stage". At the top, there is a breadcrumb trail: [Home](#) -> [Risk Models \(My Primary Repository\)](#) -> [Foods](#) -> [Consumption Model \(Tortilla Chip Consumption\)](#) -> [Add Life Stage](#). Below the breadcrumb is the heading "Add Life Stage". The instructions read: "Enter a life stage name and click 'Add'." A note states: "Note: all fields are required". The form contains a text input field labeled "Life Stage Name:" with the text "Children 1 to 5" entered. There are two buttons below the input field: "Add" and "Cancel". A small circled "1" is positioned at the end of the input field, and a small circled "2" is positioned above the "Add" button.

This group spans 5 years of a lifetime. For this scenario, assume that they consume an average of 6 grams of tortilla chips daily. Define the body weight as a uniform distribution ranging from 10 kg to 30 kg.

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

Edit Life Stage and Consumption

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

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

Note: All fields are required

Name:

Span in years: ①

Average Daily Consumption:

Parameter	Value	Uncertainty
Units:	<input type="text" value="g"/> per day	N/A
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="6"/> ②	Add

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

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

Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Uniform"/> ③	N/A
Minimum:	<input type="text" value="10"/> ④	Add
Maximum:	<input type="text" value="30"/> ⑤	Add

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

Refresh Chart

Spearman (Rank) Correlation:

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

⑥

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

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

Save and close the page.

Continue adding life stages until the entire lifespan (exposure period) is accounted for. In this scenario, those aged 6 to 10 are assumed to eat 9 g of tortilla chips on average each day, those 11 to 15: 13 g, those 16 to 20: 18 g, and those 20 and over: 15 grams. The body weights for these groups are defined as:

- Children 6 to 10: Uniform(20,60); Span (Years) 5
- Children 11 to 15: Uniform(30,70); Span (Years) 5
- Youth 16 to 20: Uniform(60,90); Span (Years) 5
- Adults 20 and over: Normal(80,16); Span (Years) 57

The definitions you have provided are displayed on the Edit Chronic Consumption Model page:

[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 \(F\)](#)

Step 6: Add a Process Model

In this scenario, assume that the tortilla chips have already been contaminated and that the level and prevalence are known. The mass of each package of tortilla chips is 270 g. The prevalence is defined as 0.01 and the level (in

contaminated units) is defined as a normal distribution having a mean of 150 µg/kg and a standard deviation of 30 µg/kg. No more stages are required as the chips are ready to be consumed.

Home -> Risk Models (My Primary Repository) -> Process Models -> Edit Process Model (Aflatoxin B1 in Tortilla Chips) -> Name and Initial Conditions Tab

Edit Process Model

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

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

Note: All fields are required

Model Name:

Define Initial Conditions Using:

Single Set of Parameters
 Upstream Process Model

Initial Contamination, Unit Size and Prevalence:

Parameter	Value	Uncertainty
Hazard:	Aflatoxin B1	N/A
Food:	Tortilla Chips	N/A
Initial Units are Contaminated:	<input checked="" type="checkbox"/>	N/A
Initial Prevalence:	<input type="text" value="0.01"/>	Add
Select Mass Units:	<input type="text" value="g"/>	N/A

Initial Unit Mass:

Distribution Parameter	Value	Uncertainty
Variability Distribution:	<input type="text" value="Fixed Value"/>	N/A
Value:	<input type="text" value="275"/>	Add

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

Initial Concentration:

Parameter	Value	Uncertainty
Units:	<input type="text" value="µg"/> / <input type="text" value="g"/> Update	N/A
Variability Distribution:	<input type="text" value="Normal"/>	N/A
Mean:	<input type="text" value="150"/>	Add
Standard deviation:	<input type="text" value="30"/>	Add

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

Last Modified: 26-Sep-2010 10:44:17

Step 7: Create the Risk Scenario

Add a risk scenario named, "Aflatoxin B1 in Tortilla Chips" and specify that the results are computed using the FDA-iRISK model for a single hazard and single food.

Next, select the appropriate process model, exposure type ("Chronic" for this scenario) and metric type ("DALY" for this scenario). Click Next.

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

Add Risk Scenario

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

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

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

Name: Aflatoxin B1 in Tortilla Chips
 Type: Results Computed for Single Food

Filter Process Models by:

Process Model: 1
 Food: Tortilla Chips, Hazard: Aflatoxin B1

Exposure Type: 2
 Metric Type: 3

Available Models:

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

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

Select the desired consumption model from the drop-down list. Click Add and then click Save.

On the Life Stages tab, select all of the defined life stages to include. Click Save to confirm the total exposure span and save the settings.

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

Edit Risk Scenario

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

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

Annual Consumers: 25E6

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

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

On the Dose Responses tab, select the dose response models to include and the associated health metric to use for the dose response model (from the drop-down menu). Click Save and Close.

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

Edit Risk Scenario

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

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

Dose Response	Health Metric	Include
Linear by Slope Factor	Liver Cancer (computed) (19.4)	<input checked="" type="checkbox"/>

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

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

Step 8: Generate the Ranking Report

If you have created more than one of the scenarios presented in this Quick Start Guide, you can rank them in a report in which the risk is calculated for each and the scenarios are listed in descending order of annual burden.

Click the Reports tab in the main tab bar, and then click the Create link beside the Risk Estimates and Scenario Ranking report type in the list of options.

On the Risk Estimates and Scenario Ranking page, type a report abstract if desired, and click the Generate Report for All Listed button to include all available scenarios.

Click the Report History link to open the Reports page. Once the report is complete, view it in PDF format.

Step 9: Interpreting the Report

The PDF report shows all the scenarios ranked in order of annual burden:

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 population groups included in the scenario.

Scenario or Scenario Group	Total DALYs per Year
Salmonella in Peanut Butter - Specified	64.6
Salmonella in Peanut Butter	63.4
L. monocytogenes in soft ripened cheese	19.2
Aflatoxin B1 in Tortilla Chips	15.7
Ammonia in Frozen Pizza in Children	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.

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 - Specified	N/A	N/A	3400	N/A	64.6	N/A	64.6
Salmonella in Peanut Butter	N/A	1.70E+10	3340	1.96E-7	63.4	3.73E-9	63.4
L. monocytogenes in soft ripened cheese	N/A	1.89E+9	3.36	1.77E-9	19.2	1.02E-8	19.2
Aflatoxin B1 in Tortilla Chips	77	2.50E+7	0.811	3.24E-8	15.7	6.30E-7	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.

For the chronic exposure to Aflatoxin B1 scenario the lifecourse duration provides the length of exposure in years, and the number of consumers exposed is shown next to it. The predicted values for total illnesses, mean risk of illness (per consumer), and burden in DALYs are all given on an annualized basis, by dividing the model results by the value for lifecourse duration.

The value for total illnesses can be obtained by multiplying the number of consumers by the mean risk of illness per consumer, while the burden per consumer is obtained by dividing the annual DALY value by the number of consumers. The results for other scenarios are explained in previous sections of this guide. Ensuing pages display the inputs for the remaining model elements.

CHAPTER 5

Example of Sensitivity Analysis for a Single Food-Hazard Pair

This chapter describes using sensitivity analysis to explore the impact of two alternative dose response parameters on risk estimates for a single food-hazard pair.

Step 1: Create the Sensitivity Analysis Sets

On the FDA-iRISK window, click the Risk Models tab and then click the Risk Scenarios tab. On the Risk Models page, verify that My Primary Repository is selected in the Show Models For drop-down list.

Click the Edit link to the right of the Salmonella in Peanut Butter that was created in "Scenario 1 - A single food-hazard pair in one population group" on page 8.

Click the Sensitivity Analysis tab, and then click the Add Sensitivity Analysis Set link.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (Salmonella in peanut butter) -> Sensitivity Analysis Tab

Edit Risk Scenario

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

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

Define Sensitivity Analysis Parameter Sets

2 [Add Sensitivity Analysis Set](#)

Scenario Model Element	Parameter	Current Definition
------------------------	-----------	--------------------

On the Add Sensitivity Analysis Set page, enter "Dose-response parameters lower uncertainty bound" as the Set Name. Click Add.

Home -> Risk Models (My Primary Repository) -> Risk Scenario (Aflatoxin B1 in Tortilla Chips) -> Add Sensitivity Analysis Set

Add Sensitivity Analysis Set

Enter a set name, and click "Add".

Note: all fields are required

Set Name: 1

2

A column for the parameter set is added to the Sensitivity Analysis tab. To customize the alpha value for the dose response model, click Add to the right of Dose Response - Salmonella Beta-Poisson DR/alpha value (No units).

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (Salmonella in peanut butter)

Edit Risk Scenario

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

Instructions | Name and Parameters | Population Groups (1/1) | Notes (0) | Sensitivity Analysis | Report

Run Sensitivity Analysis Report

Sensitivity Analysis Set	Include in Report
Dose-response parameters lower uncertainty bound	<input type="checkbox"/>

Send Email Notifications:

Define Sensitivity Analysis Parameter Sets

[Add Sensitivity Analysis Set](#)

Scenario Model Element	Parameter	Current Definition	Set: Dose-response parameters lower uncertainty bound Edit Delete
Salmonella in Peanut Butter - Initial Conditions	Initial Prevalence	5.5E-6 Edit	Add
	Initial Concentration	Uniform (Minimum:-1.52, Maximum:2.55) Edit	Add
	Initial Unit Mass	Fixed Value (Value:6.85E3) Edit	Add
	Maximum Population Density	9 Edit	Add
Process Stage - Packaging	New Size	Fixed Value (Value:250) Edit	Add
Process Stage - Storage	Amount of Decrease	Uniform (Minimum:0.49, Maximum:3.47) Edit	Add
Consumption Population Group - General Population	Eating Occasions Per Year	1.7E10 Edit	Add
	Amount Per Eating Occasion	Fixed Value (Value:30) Edit	Add
	Body Weight	Fixed Value (Value:0) Edit	Add
	Number of Servings per Day	Fixed Value (Value:0) Edit	Add
Health Metric - Salmonella DALY	Metric	0.019 Edit	Add
Dose Response - Salmonella Beta-Poisson DR	alpha value (No units)	0.1324 Edit	Add ⓘ
	beta value (No units)	51.45 Edit	Add
	Probability of Illness (%)	100 Edit	Add

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

Type 0.094 and then click Save and Close.

Edit Sensitivity Analysis Set Parameter

Note: all fields are required

Model Element: Dose Response - Salmonella Beta-Poisson DR

Parameter: alpha value (No units)

Scenario Current Value: 0.1324

Sensitivity Analysis Value: Dose Unit: cfu
Value: (No units; min > 0; no max)

Last Modified: 16-Aug-2020 09:54:07

Click Add to the right of Dose Response - Salmonella Beta-Poisson DR/beta value (No units). Change value to 43.75 and then click Save and Close.

Add a second sensitivity set called “Dose response parameters upper uncertainty bound” and define the value for the Dose Response - Salmonella Beta-Poisson DR/alpha value (No units) to be 0.1817 and the beta value to be 56.39.

Home -> Risk Models / My Primary Repository -> Risk Scenarios -> Edit Risk Scenario (Salmonella in peanut butter) -> Sensitivity Analysis Tab

Edit Risk Scenario

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

Instructions | Name and Parameters | Population Groups (1/1) | Notes (0) | Sensitivity Analysis | Report

Run Sensitivity Analysis Report

Sensitivity Analysis Set	Include in Report
Dose-response parameters lower uncertainty bound	<input type="checkbox"/>
Dose response parameters upper uncertainty bound	<input type="checkbox"/>

Send Email Notifications:

[Run Selected Sets](#) [Run All Sets](#)

Define Sensitivity Analysis Parameter Sets

[Add Sensitivity Analysis Set](#)

Scenario Model Element	Parameter	Current Definition	Set: Dose-response parameters lower uncertainty bound Edit Delete	Set: Dose response parameters upper uncertainty bound Edit Delete
Salmonella in Peanut Butter - Initial Conditions	Initial Prevalence	5.5E-6 Edit	Add	Add
	Initial Concentration	Uniform (Minimum:1.52, Maximum:2.55) Edit	Add	Add
	Initial Unit Mass	Fixed Value (Value:6.85E3) Edit	Add	Add
	Maximum Population Density	9 Edit	Add	Add
Process Stage - Packaging	New Size	Fixed Value (Value:250) Edit	Add	Add
Process Stage - Storage	Amount of Decrease	Uniform (Minimum:0.49, Maximum:3.47) Edit	Add	Add
Consumption Population Group - General Population	Eating Occasions Per Year	1.7E10 Edit	Add	Add
	Amount Per Eating Occasion	Fixed Value (Value:30) Edit	Add	Add
	Body Weight	Fixed Value (Value:0) Edit	Add	Add
	Number of Servings per Day	Fixed Value (Value:0) Edit	Add	Add
Health Metric - Salmonella DALY	Metric	0.019 Edit	Add	Add
Dose Response - Salmonella Beta-Poisson DR	alpha value (No units)	0.1324 Edit	0.094 Edit Delete	0.1817 Edit Delete
	beta value (No units)	51.45 Edit	43.75 Edit Delete	56.39 Edit Delete
	Probability of Illness (%)	100 Edit	Add	Add

Quick Links: [Dose-Response](#) / (1) | [Salmonella](#) / (1) | [Salmonella in Peanut Butter](#) / (1)

Step 2: Run Sensitivity Analysis

Under Run Sensitivity Analysis Report, click Run All Sets. The report request is submitted and a link to the Report History page is provided.

Click the Report History link.

Home -> Risk Models (My Primary Repository) -> Risk Scenarios -> Edit Risk Scenario (Salmonella in peanut butter) -> Sensitivity Analysis Tab

Edit Risk Scenario

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

Instructions | Name and Parameters | Population Groups (1/1) | Notes (0) | Sensitivity Analysis | Report

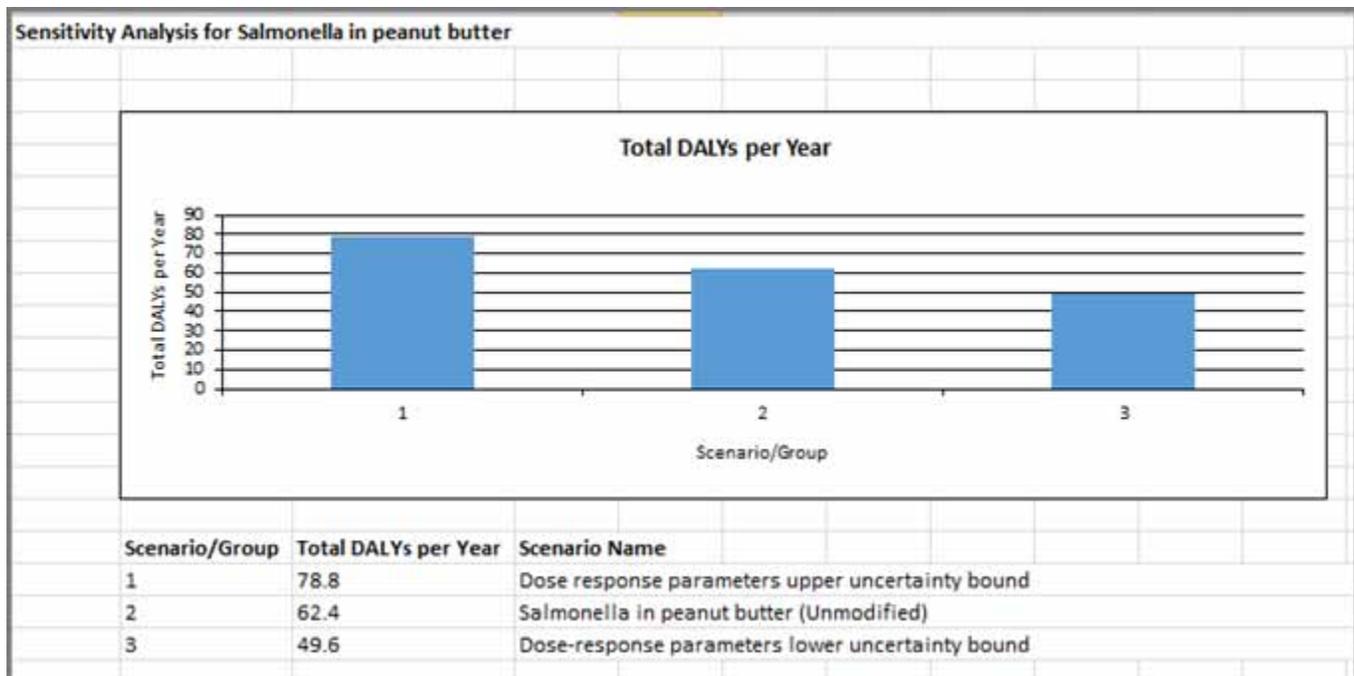
The job is submitted. Use the [Report History](#) tab to check the report status.

Run Sensitivity Analysis Report

Sensitivity Analysis Set	Include in Report
Dose-response parameters lower uncertainty bound	<input checked="" type="checkbox"/>
Dose response parameters upper uncertainty bound	<input checked="" type="checkbox"/>

Send Email Notifications:

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.



CHAPTER 6

What's Next?

This completes the quick start scenarios.

You will find more information on the Help page in FDA-iRISK, including links to the more extensive *FDA-iRISK® User Guide*, and the *FDA-iRISK® Technical Document* that describes the underlying mathematical architecture and equations used for risk calculations.

You can also review and explore examples of different elements in the Sample Models repository that is available with your account.