FDA-iRISK® 4.0
Food Safety Modeling Tool

Quick Start

June 2017
Disclaimer
The U.S. Food and Drug Administration (FDA), the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and Risk Sciences International (RSI) have taken all reasonable precautions in creating the FDA-iRISK® quantitative risk assessment system (version 2.0) and the documentation accompanying it. FDA, JIFSAN and RSI are not responsible for errors, omissions or deficiencies regarding the system and the accompanying documentation. The FDA-iRISK system and the accompanying documentation are being made available “as is” and without warranties of any kind, either expressed or implied, including, but not limited to, warranties of performance, merchantability, and fitness for a particular purpose. FDA, JIFSAN and RSI are not making a commitment in any way to regularly update the system and the accompanying documentation.

Responsibility for the interpretation and use of the system and of the accompanying documentation lies solely with the user. Risk scenarios and data provided in the FDA-iRISK system are for illustration purposes only; they do not represent endorsements by FDA, JIFSAN, or RSI. In no event shall FDA, JIFSAN or RSI be liable for direct, indirect, special, incidental, or consequential damages resulting from the use, misuse, or inability to use the system and the accompanying documentation.

Third parties’ use of or acknowledgment of the system and its accompanying documentation, including through the suggested citation, does not in any way represent that FDA, JIFSAN or RSI endorses such third parties or expresses any opinion with respect to their statements.

June 2017
CONTENTS

Preface .............................................................................................................................................................................. 1
About this Guide ................................................................................................................................................................. 1
FDA-iRISK Support .......................................................................................................................................................... 1

Chapter 1: Introduction ...................................................................................................................................................... 2
FDA-iRISK Home Page ....................................................................................................................................................... 3
Logging in to FDA-iRISK .................................................................................................................................................. 4
Navigating FDA-iRISK ...................................................................................................................................................... 5
About the Example Risk Scenarios in this Guide ............................................................................................................. 6

Chapter 2: Examples of Computed Risk Scenarios for Acute Microbial Hazard .......................................................... 7
Scenario 1 - A single food-hazard pair in one population group ..................................................................................... 7
  Step 1: Create the Hazard ............................................................................................................................................... 7
  Step 2: Add Notes for the Hazard ................................................................................................................................ 9
  Step 3: Add a Dose Response Model .......................................................................................................................... 11
  Step 4: Add a Health Metric ......................................................................................................................................... 15
  Step 5: Create the Food ............................................................................................................................................... 16
  Step 6: Add a Consumption Model ............................................................................................................................ 17
  Step 7: Add a Process Model ....................................................................................................................................... 20
  Step 8: Add Process Stages ....................................................................................................................................... 22
  Step 9: Create the Risk Scenario ................................................................................................................................ 25
  Step 10: Generate the Risk Estimates and Scenario Ranking Report .......................................................................... 27
  Step 11: Interpreting the Report .................................................................................................................................. 30

Scenario 2 - A single food-hazard pair in three population groups .................................................................................. 33
  Step 1: Create the Hazard ............................................................................................................................................... 33
  Step 2: Add Dose Response Models .............................................................................................................................. 33
  Step 3: Add Health Metrics .......................................................................................................................................... 34
  Step 4: Create the Food ............................................................................................................................................... 34
  Step 5: Add a Consumption Model ............................................................................................................................. 34
  Step 6: Add Population Groups .................................................................................................................................. 35
  Step 7: Add a Process Model ....................................................................................................................................... 36
  Step 8: Add Process Stages ....................................................................................................................................... 37
  Step 9: Create the Risk Scenario ................................................................................................................................ 38
  Step 10: Generate the Ranking Report .......................................................................................................................... 38
  Step 11: Interpreting the Report .................................................................................................................................. 39

Chapter 3: Example of a Specified Risk Scenario for an Acute Microbial Hazard ......................................................... 41

FDA-iRISK® 4.0 Quick Start  i  June 2017
Chapter 4: Examples of Computed Risk Scenarios for a Chemical Hazard ............... 44
Scenario 1 - A single food-hazard pair involving an acute chemical hazard ................................................................. 44
  Step 1: Create the Hazard ................................................................................................................................................. 44
  Step 2: Add Notes for the Hazard ................................................................................................................................. 46
  Step 3: Add a Dose Response Model ............................................................................................................................ 47
  Step 4: Add a Health Metric ............................................................................................................................................. 50
  Step 5: Create the Food ..................................................................................................................................................... 50
  Step 6: Add a Consumption Model ............................................................................................................................... 51
  Step 7: Add a Process Model ........................................................................................................................................... 53
  Step 8: Add Process Stages .............................................................................................................................................. 55
  Step 9: Create the Risk Scenario ................................................................................................................................. 56
  Step 10: Generate the Risk Estimates and Scenario Ranking Report .................................................................. 58
  Step 11: Interpreting the Report ................................................................................................................................. 59
Scenario 2 - A single food-hazard pair involving a chronic chemical hazard ......................................................... 60
  Step 1: Create the Hazard ................................................................................................................................................. 60
  Step 2: Add a Dose Response Model ............................................................................................................................ 60
  Step 3: Add a Health Metric Computed from Health Endpoints ............................................................................... 61
  Step 4: Create the Food ..................................................................................................................................................... 64
  Step 5: Add a Consumption Model ............................................................................................................................... 65
  Step 6: Add a Process Model ........................................................................................................................................... 68
  Step 7: Create the Risk Scenario ................................................................................................................................. 69
  Step 8: Generate the Ranking Report ........................................................................................................................... 70
  Step 9: Interpreting the Report ....................................................................................................................................... 71

Chapter 5: What’s Next? .................................................................................................................................................... 73
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® 4.0 User Guide and the FDA-iRISK® 4.0 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


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.

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.

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.

<table>
<thead>
<tr>
<th>Area</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Logged In As</strong> Displays the email address of the user who is currently logged in. <strong>My Account</strong> Use the My Account link to edit your account settings, including changing your password. <strong>Logout</strong> Exits FDA-iRISK.</td>
</tr>
<tr>
<td>2</td>
<td><strong>Main Tab Bar</strong> Consists of the tabs to navigate to the Home, Models, Reports, Repositories, and Help pages.</td>
</tr>
<tr>
<td>3</td>
<td><strong>Breadcrumbs</strong> The breadcrumb string indicates the location in the site hierarchy of the page presently visible. You can navigate back up the hierarchy by clicking the appropriate breadcrumb link.</td>
</tr>
<tr>
<td>4</td>
<td><strong>Page Title</strong> Identifies the current page.</td>
</tr>
</tbody>
</table>

---

*FDA-iRISK*® 4.0 Quick Start 5 June 2017
### 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

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.
Chapter 2: Examples of Computed Risk Scenarios for Acute Microbial Hazard

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).”

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:


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.
Chapter 2: Examples of Computed Risk Scenarios for Acute Microbial Hazard

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.

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


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.

**Step 6: Add a Consumption Model**

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

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

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.

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

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.
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.

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.

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.

The scenario is now 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. On the Risk Estimates and Scenario Ranking Report page, change the report title to “FDA-iRISK Ranking for Salmonella in Peanut Butter”. Optionally add an abstract.

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, “Salmonella in Peanut Butter”. The Group 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. Click Generate Report for Checked.

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.
Chapter 2: Examples of Computed Risk Scenarios for Acute Microbial Hazard

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

Click the Refresh 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. 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:

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.

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.
Chapter 2: Examples of Computed Risk Scenarios for Acute Microbial Hazard

- **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

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Results Computed</td>
</tr>
<tr>
<td>Hazard</td>
<td>Salmonella (Microbial Pathogen)</td>
</tr>
<tr>
<td>Food</td>
<td>Peanut Butter</td>
</tr>
<tr>
<td>Process Model</td>
<td>Salmonella in Peanut Butter</td>
</tr>
<tr>
<td>Consumption Model</td>
<td>Peanut Butter Annual Consumption</td>
</tr>
<tr>
<td>Metric Type</td>
<td>DALY</td>
</tr>
<tr>
<td>Exposure Type</td>
<td>Acute</td>
</tr>
<tr>
<td>Converged</td>
<td>Yes (by 9000 samples)</td>
</tr>
<tr>
<td>Scenario Weight</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Initial Conditions</th>
<th>Model Outputs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence: 5.5E-6</td>
<td>4.19E-6</td>
</tr>
<tr>
<td>Concentration: Uniform (Units: log10 cfu/g)</td>
<td>0.371 log10 cfu/g</td>
</tr>
<tr>
<td>Minimum: -1.52</td>
<td></td>
</tr>
<tr>
<td>Maximum: 2.55</td>
<td></td>
</tr>
<tr>
<td>Mean: 1.58</td>
<td></td>
</tr>
<tr>
<td>Unit Mass: 6.85E3 kg</td>
<td>250 g</td>
</tr>
</tbody>
</table>

* Final prevalence and Prevalence-Weighted mean concentration

<table>
<thead>
<tr>
<th>Process Stages for Salmonella in Peanut Butter:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Stage</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Packaging</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Result Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean Exposure:</strong> See population groups</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population Group Definitions:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population Group</strong></td>
</tr>
<tr>
<td>General Population</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population Group Results:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population Group</strong></td>
</tr>
<tr>
<td>General Population</td>
</tr>
<tr>
<td>* Mean dose per Contaminated serving</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Response Type</th>
<th>r-Value</th>
<th>Probability of Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 60+ DR</td>
<td>Exponential</td>
<td>8.39E-12</td>
<td>100</td>
</tr>
<tr>
<td>Intermediate Aged (5-59) DR</td>
<td>Exponential</td>
<td>5.34E-14</td>
<td>100</td>
</tr>
<tr>
<td>Perinatal DR</td>
<td>Exponential</td>
<td>4.51E-11</td>
<td>100</td>
</tr>
</tbody>
</table>

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

![Dose Response Models in FDA-iRISK](image)

Quick Links: [Hazards]
Chapter 2: Examples of Computed Risk Scenarios for Acute Microbial Hazard

Step 3: Add Health Metrics

Add the following health metrics to the hazard:

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 60+ DALY</td>
<td>DALY</td>
<td>2.6</td>
</tr>
<tr>
<td>Intermediate Aged (5-59)</td>
<td>DALY</td>
<td>5.0</td>
</tr>
<tr>
<td>Perinatal DALY</td>
<td>DALY</td>
<td>14</td>
</tr>
</tbody>
</table>

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

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:

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

When complete, the population group list should display as:

![Edit Acute Consumption Model](image)

Quick Links: [Soft Ripened Cheese](#)
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.
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:

- **Stage Name:** Consumer Storage
- **Process Model:** L. monocytogenes in soft ripened cheese
- **Process Type:** Increase by Growth

### Increase in Microbial Population (log10 scale):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Uncertainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variability Distribution:</td>
<td>Triangular</td>
<td>N/A</td>
</tr>
<tr>
<td>Minimum:</td>
<td>0</td>
<td>Add</td>
</tr>
<tr>
<td>Mode:</td>
<td>0.03</td>
<td>Add</td>
</tr>
<tr>
<td>Maximum:</td>
<td>5.79</td>
<td>Add</td>
</tr>
</tbody>
</table>

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.
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.

![Edit Risk Scenario](image)

Step 10: Generate the Ranking Report

On the Reports tab, create a new Risk Estimates and Scenario Ranking report. Enter “Ranking Report for Salmonella and L. monocytogenes” as the report title and select the My Primary Repository check box. Click Update Selections and then click Load Risk Scenarios. Select the Run check boxes for both available scenarios. Click Generate Report for Checked.

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

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

<table>
<thead>
<tr>
<th>Scenario or Scenario Group</th>
<th>Total DALYs per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella in Peanut Butter</td>
<td>63.4</td>
</tr>
<tr>
<td>L. monocytogenes in soft ripened cheese</td>
<td>19.2</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Population Group</th>
<th>Consumption</th>
<th>Dose Response</th>
<th>Health Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 60+</td>
<td>Eating Occasions: 1.8E+08 ed/yr</td>
<td>Adults 60+ DR</td>
<td>Adults 60+ DALY (2.6 DALYs)</td>
</tr>
<tr>
<td></td>
<td>Per Eating Occasion: Triangular (Units: g/ed)</td>
<td>Exponential (Dose unit: cfu)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Minimum: 10</td>
<td>r: 8.39E-12</td>
<td>Probability of adverse effect: 100%</td>
</tr>
<tr>
<td></td>
<td>Mode: 28</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum: 85</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Chapter 2: Examples of Computed Risk Scenarios for Acute Microbial Hazard

<table>
<thead>
<tr>
<th>Population Group</th>
<th>Eating Occasions (eo/yr)</th>
<th>Per Eating Occasion (Units: g/eo)</th>
<th>Intermediate Aged (5-59) DR Exponential (Dose unit: cfu)</th>
<th>Intermediate Aged (5-59) DALY (5.0 DALYs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediate Aged (5-59)</td>
<td>1.7E+09</td>
<td>Per Eating Occasion: Triangular (Units: g/yo)</td>
<td>r: 5.34E-14</td>
<td>Probability of adverse effect: 100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum: 10</td>
<td>Mode: 28</td>
<td>Maximum: 168</td>
</tr>
<tr>
<td>Perinatal</td>
<td>1.2E+07</td>
<td>Perinatal DR Exponential (Dose unit: cfu)</td>
<td>r: 4.51E-11</td>
<td>Probability of adverse effect: 100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum: 10</td>
<td>Mode: 28</td>
<td>Maximum: 85</td>
</tr>
</tbody>
</table>

### Population Group Results:

<table>
<thead>
<tr>
<th>Population Group</th>
<th>Mean Dose* (units)</th>
<th>Mean** Prevalence in Servings</th>
<th>Mean Probability of Illness</th>
<th>Number of Illnesses per year</th>
<th>Total Metric Per Year (DALYs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 60+</td>
<td>1.43E+5</td>
<td>0.0104</td>
<td>1.25E-8</td>
<td>2.25</td>
<td>5.84</td>
</tr>
<tr>
<td>Intermediate Aged (5-59)</td>
<td>2.55E+5</td>
<td>0.0104</td>
<td>1.41E-10</td>
<td>0.240</td>
<td>1.20</td>
</tr>
<tr>
<td>Perinatal</td>
<td>1.55E+5</td>
<td>0.0104</td>
<td>7.26E-8</td>
<td>0.871</td>
<td>12.2</td>
</tr>
</tbody>
</table>

* 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.

Select “Peanut Butter” as the food and “Salmonella” as the hazard. Click Next.
Finally, select “DALY” as the health metric type. Click Add.

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.
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.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Lifecourse Duration</th>
<th>Eating Occasions or Consumers</th>
<th>Total Illnesses</th>
<th>Mean Risk of Illness</th>
<th>Total DALYs per Year</th>
<th>DALYs Per EO or Consumer</th>
<th>Total DALYs per Year (Weighted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella in Peanut Butter - Specified</td>
<td>N/A</td>
<td>N/A</td>
<td>3400</td>
<td>N/A</td>
<td>64.6</td>
<td>N/A</td>
<td>64.6</td>
</tr>
</tbody>
</table>

### Scenario Details for: Salmonella in Peanut Butter - Specified

- **Type:** Results Specified
- **Hazard:** Salmonella (Microbial Pathogen)
- **Food:** Peanut Butter
- **Number Of Cases:** 3400
- **Health Metric:** 0.019 DALY per case
- **Scenario Weight:** N/A
- **Metric Type:** DALY
- **Exposure Type:** Acute
- **Total DALY/Year:** 64.6
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

In this example, you will 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 the counts displayed on the tabs reflect the number of definitions that have been created for each element.
Chapter 4: Examples of Computed Risk Scenarios for a Chemical Hazard

Click the Add Hazard link.

Create a new hazard with the name “Ammonia” 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.
Add a second note. Enter “References” as the heading and add the following text:


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.

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

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.


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.

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

**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.

**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.

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

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.

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.

![Add Process Model](image)

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.
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.
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.

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.
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.

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

The scenario is ready to run.

**Step 10: Generate the Risk Estimates and Scenario Ranking Report**

On the Reports tab in the main tab bar, create a new Risk Estimates and Scenario Ranking report.
While this report only contains one scenario, it uses the generic ranking system to present results based on annual burden. On the Risk Estimates and Scenario Ranking page, change the report title to “FDA-iRISK Scenario Report for Ammonia in Frozen Pizza”. Optionally add an abstract.

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.


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](image)

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

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.

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 “Aflatoxin B1 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%”.

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.

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.

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.

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.

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.

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.

**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.

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

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.
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.
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:
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.
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.

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.

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.

**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 the five scenarios ranked in order of annual burden:

### Ranking Summary

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

<table>
<thead>
<tr>
<th>Scenario or Scenario Group</th>
<th>Total DALYs per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella in Peanut Butter - Specified</td>
<td>64.6</td>
</tr>
<tr>
<td>Salmonella in Peanut Butter</td>
<td>63.4</td>
</tr>
<tr>
<td>L. monocytogenes in soft ripened cheese</td>
<td>19.2</td>
</tr>
<tr>
<td>Aflatoxin B1 in Tortilla Chips</td>
<td>15.7</td>
</tr>
<tr>
<td>Ammonia in Frozen Pizza in Children</td>
<td>0.262</td>
</tr>
</tbody>
</table>

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

### Ranking Summary for Risk Scenarios (Ungrouped)

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

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Lifecourse Duration</th>
<th>Eating Occasions or Consumers</th>
<th>Total Illnesses</th>
<th>Mean Risk of Illness</th>
<th>Total DALYs per Year</th>
<th>DALYs Per EO or Consumer</th>
<th>Total DALYs per Year (Weighted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella in Peanut Butter - Specified</td>
<td>N/A</td>
<td>N/A</td>
<td>3400</td>
<td>N/A</td>
<td>64.6</td>
<td>N/A</td>
<td>64.6</td>
</tr>
<tr>
<td>Salmonella in Peanut Butter</td>
<td>N/A</td>
<td>1.70E+10</td>
<td>3340</td>
<td>1.96E-7</td>
<td>63.4</td>
<td>3.73E-9</td>
<td>63.4</td>
</tr>
<tr>
<td>L. monocytogenes in soft ripened cheese</td>
<td>N/A</td>
<td>1.89E+9</td>
<td>33.6</td>
<td>1.77E-9</td>
<td>19.2</td>
<td>1.02E-8</td>
<td>19.2</td>
</tr>
<tr>
<td>Aflatoxin B1 in Tortilla Chips</td>
<td>77</td>
<td>2.50E+7</td>
<td>0.811</td>
<td>3.24E-8</td>
<td>15.7</td>
<td>6.30E-7</td>
<td>15.7</td>
</tr>
<tr>
<td>Ammonia in Frozen Pizza in Children</td>
<td>N/A</td>
<td>1.30E+9</td>
<td>262</td>
<td>2.02E-7</td>
<td>0.262</td>
<td>2.02E-10</td>
<td>0.262</td>
</tr>
</tbody>
</table>

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

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

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® 4.0 User Guide, and the FDA-iRISK® 4.0 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.