Food Defense Plans and Vulnerability Assessments (VA's)
Session Overview

Purpose:
• To thoroughly understand the Food Defense capabilities of SF360
• To build an example VA and Food Defense Audit in SF360

Session Leader:
• George Howlett, CEO, Safefood 360

Timing:
• 90 Minutes

Agenda:
• Useful Supporting Information
• What is a Food Defense Plan?
• Three Building Blocks of a Food Defense Plan
  • Vulnerability Assessment (VA)
  • Food Defense Audit
  • Actions Plan
• Practical Exercises
Useful Supporting Information

Safefood 360 reference sources of information for Food Defense and Vulnerability Assessments.

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation</td>
<td>Food Defense and VA’s with Safefood 360°</td>
<td>URL available after conference</td>
</tr>
<tr>
<td>Website</td>
<td>FDA - Food Defense</td>
<td><a href="https://www.fda.gov/food/fooddefense/">https://www.fda.gov/food/fooddefense/</a></td>
</tr>
<tr>
<td>Website</td>
<td>FDA - Mitigation Strategies Database</td>
<td><a href="https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295898.htm">https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295898.htm</a></td>
</tr>
<tr>
<td>Legislation</td>
<td>FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration</td>
<td><a href="https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm">https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm</a></td>
</tr>
</tbody>
</table>
Objectives of Today's Session

FSMA Mitigation Strategies to Protect Against IA Requirements

Safefood 360 Solution Practical Exercises
Food Defense Plans and VA’s with Safefood 360°

FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

Objective
- The FDA Food Safety Modernization Act (FSMA) final rule is aimed at preventing intentional adulteration.

Requirements
- Rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities.

Application
- Rule applies to both domestic and foreign companies that are required to register with the FDA.
- Exceptions provided in the final rule.

Approach
- FDA has taken an approach similar to Hazard Analysis Critical Control Point (HACCP) system.
- This written plan must identify vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions and verification.
Intentional Adulteration

- Accidental Contamination
- Disgruntled Employee / Sabotage
- Economic Adulteration
- Counterfeit / Tampering
- Intentional Contamination
Elements of a Food Defense Plan

There are two main elements of a food defense plan. An **Audit** to identify broad mitigation strategies and **Risk Assessment** to identify focused mitigation strategies.

- **Broad Mitigation Strategies**
  - Audit

- **Focused Mitigation Strategies**
  - Risk Assessment

**Action Plan (CAPA)**

**Food Defense Plan**
Food Defense Plans and VA’s with Safefood 360°

Broad Mitigation Strategy - Example

What is it?
• A strategy designed to mitigate risks relating to the general operation.
• Identified in an audit.
• Broad mitigation strategies include security and screening procedures for the facility, materials, and people.

Example
• SECTION :: Outside Security - 1. Property Perimeter.
• MEASURE :: 1a. Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?
• RESPONSE :: Gap.
• PLAN CONTENT :: A fence secures the property perimeter against unauthorized entry. No trespassing signs are posted. The perimeter of the property is patrolled on a regular basis, at least every 30 minutes.
• ACTION STEP :: Install a new fence around facility.

Focused Mitigation Strategy - Example

What is it?
• Focused Mitigation Strategies are science-based procedures, practices, or processes to minimize the vulnerabilities.
• Identified in the vulnerability assessment.
• Focused Mitigation Strategies are applied at a specific process step.

Example
• PROCESS NAME :: Cooked Meat
• PROCESS STEP :: Cooking
• ACCESSIBILITY :: 8
• VULNERABILITY :: 10
• TOTAL :: 18
• MITIGATION STRATEGY :: Restrict access to location to authorized personnel.
Food Defense Plan Builder

The FDA provides a downloadable tool for assist in building Food Defense Plans.

https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm
What Else is Required in a Food Defense Plan?

The Final Rule calls for a number of other elements.

| RECORDS – Records for monitoring, actions and verification required. |
| ACTIONS – Actionable process steps to be identified and actions taken. |
| MONITOR – Establish and implement procedures, including the frequency with which they are to be performed, for monitoring mitigation strategies. |
| CORRECTIVE ACTION – Using corrective actions if mitigation strategies are not properly implemented. |
| VERIFICATION - Verification activities required to ensure that monitoring is being conducted and appropriate decisions about corrective actions are being made. |
| TRAINING – Personnel and supervisors assigned to the actionable process steps to be trained in food defense awareness and in their responsibilities for implementing focused mitigation strategies. |
How Does SF360 Build a Food Safety Plan?

Safefood 360 uses three main modules to build a Food Defense Plan. 1) Risk Module 2) Auditing Module 3) Corrective Action. These are combined to give the FDP.

- **RISK MODULE**
  - Vulnerability Assessment (VA)

- **AUDITING MODULE**
  - Food Defense Systems

- **CORRECTIVE ACTIONS MODULE (Action Plan)**

- **REPORT (Food Defense Plan) Under Development**
Three Steps to Creating a Food Defense Plan in SF360

The are three key steps in building a full food defense plan in SF360. Conduct Food Defense Audit, Conduct Vulnerability Assessment (VA) and Action Plan Development.
Three Steps to Creating a Food Defense Plan in SF360

The are three key steps in building a full food defense plan in SF360. Conduct Food Defense Audit, Conduct Vulnerability Assessment (VA) and Action Plan Development.

<table>
<thead>
<tr>
<th>Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Corrective Action Module</strong></td>
</tr>
<tr>
<td>• From the previous two activities a full Action Plan will arise.</td>
</tr>
<tr>
<td>• This is managed in the Corrective Actions module.</td>
</tr>
<tr>
<td>• SF360 is currently developing a full integrated report which will pull together all these elements into one FDA format Food Defense Plan.</td>
</tr>
</tbody>
</table>

| Conduct Vulnerability Assessment (VA) |
| **Risk - Food Safety Plan Module** |
| • The second step is to conduct a full Vulnerability Assessment (VI) using the Food Safety Plan module. |
| • This is a similar process to conducting a HACCP or PCP study except vulnerabilities are assessed. |
| • This will lead to specific monitoring measures and actions as required. |

| Conduct Food Defense Audit |
| **Auditing Module** |
| • The first step is to conduct a food defense audit to identify board mitigation strategies that are required. |
| • SF360 has the FDA audit checklist already built into the software for easy set-up. |
| • Once conducted the audit results will allow for the generation of Actions where required. |
Food Defense Plans and VA’s with Safefood 360°

Conducting a Food Defense (FD) Audit

Food Defense Audits are developed and managed in the Management centre under the Auditing module.

- **Add Program**: Used to create a new FD Audit Program.
- **Food Defense Audits**: Used to access / view / edit / copy / delete existing FD audits.
- **Add Audit**: Used to manually complete a FD audit record.
Checklists for Food Defense Audits

**Food Defense Audit Checklist**

- The FDA in their Food Defense Plan Builder have defined a checklist of items to be audited.
- The checks cover a wide range of general management procedures and controls which address the facility and its operation.
- These have been built into the standard library of checklists in Safefood 360 and can be selected when building your FD Audit Program.
- The Checklist covers all the elements of the audit and there is no requirement to build your own or modify it.
Checklists for Food Defense Audits

Below is the FDA defined checklists in Safefood 360.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Response</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside Security</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property Perimeter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a. Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?</td>
<td>1 - Currently Doing</td>
<td>A fence secures the property perimeter against unauthorized entry. “No trespassing” signs are posted. The perimeter of the property is patrolled on a regular basis, at least every 20 minutes.</td>
</tr>
<tr>
<td>1b. Is there adequate lighting around the property perimeter?</td>
<td>0 - GAP</td>
<td>Exterior lights are installed around the property perimeter; however, these lights are not adequate to illuminate the property perimeter to deter and aid in the detection of suspicious or unusual activities.</td>
</tr>
<tr>
<td>Building Perimeter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2a. Is there adequate lighting outside each building and in between buildings?</td>
<td>1 - Currently Doing</td>
<td>Exterior lights are installed outside and in between all buildings.</td>
</tr>
<tr>
<td>2b. Are primary entrances to the buildings and operating areas monitored and secured?</td>
<td>1 - Currently Doing</td>
<td>All primary entrances to the areas are secured. All doors have property functioning locks or alarms that are checked on a regular basis.</td>
</tr>
<tr>
<td>2c. Are emergency exit doors self-locking from the outside, with alarms that activate when the doors are opened?</td>
<td>1 - Currently Doing</td>
<td>Emergency exits are installed with self-locking doors and alarms that will sound when emergency exit doors are opened.</td>
</tr>
<tr>
<td>2d. Are operational entrances, such as the loading dock doors, secured when not in use?</td>
<td>1 - Currently Doing</td>
<td>The loading dock is regularly monitored and doors are secured when not in use.</td>
</tr>
</tbody>
</table>
Ratings for Food Defense Audits

**Master Data > Categories > Ratings**

### Food Defense Audit Rating Model

- The FDA in their Food Defense Plan Builder have defined how each checklist is recorded. The Options are:
  - **1 – Currently Doing** – this means the facility already has the control in place.
  - **0 - Gap** – this means the facility does not have a control in place to mitigate the vulnerability.
  - During the Audit the PCQI will record the status and the value 0 or 1 will be assigned to the check.
  - If 0 – Gap then this will not increase the Defense Score.
  - If 1 – Currently Doing this will increase the Defense Score by one.
  - The values or ratings at the end of the audit are added to give a final Defense Score and Rating e.g. Excellent or Poor Defense.
Ratings for Food Defense Audits

Below is how ratings are summarized in the Food Defense Report.

<table>
<thead>
<tr>
<th>Section</th>
<th>Score</th>
<th>Result</th>
<th>Rating</th>
<th>Non-conformances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>89/92</td>
<td>Pass</td>
<td>Excellent Defense</td>
<td>3 (1 Critical, 1 Major, 1 Minor, 0 Recommendation)</td>
</tr>
<tr>
<td>OUTSIDE SECURITY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Property Perimeter</td>
<td>1/2 (50%)</td>
<td>Fail</td>
<td>Poor Defense</td>
<td>1 (0 Critical, 0 Major, 1 Minor, 0 Recommendation)</td>
</tr>
<tr>
<td>2 Building Perimeter</td>
<td>6/6 (100%)</td>
<td>Pass</td>
<td>Excellent Defense</td>
<td>0 (0 Critical, 0 Major, 0 Minor, 0 Recommendation)</td>
</tr>
<tr>
<td>3 Vehicles</td>
<td>2/3 (67%)</td>
<td>Pass</td>
<td>Adequate Defense</td>
<td>1 (1 Critical, 0 Major, 0 Minor, 0 Recommendation)</td>
</tr>
</tbody>
</table>
Practical Exercise – Create Food Defense Audit Record

Task
Create Food Defense Audit Record

5 minutes

Instructions
- Click Management > Auditing > Add Audit > Internal Audit
- Click [CONFERENCE SAMPLE] FDA – FOOD DEFENSE :: Plan
- Click Create
- Click Save & Submit
- Click Actions > Rename
- In the Rename field enter your name
- Click Save
Conducting a Food Defense Audit – Details Section

**Details Section.** Complete high level details about the food defense audit.

- **Date**
  - Enter date FD audit record was created

- **Start / Finish Time**
  - Enter the start and finish time of the FD audit

- **Auditor**
  - Name of the person who conducted the FD audit

- **In Attendance**
  - Names of persons involved in the FD audit

**Example Details:****

- **Date:** 02/06/2017
- **Start Date / Time:** 02/06/2017 12:25
- **Finish Date / Time:** 02/06/2017 12:25
- **Auditor:** Silvia Riondino

*Note: The contact information is not shown in the example.*
**Conducting a Food Defense Audit – Audit Record Section**

**Audit Record Section.** Complete the audit checklist including responses and additional comments / observations. Actions can be created as required.

### Requirement
Read the checklist item and verify the requirement is in place.

### Response
Select the correct response e.g. Currently doing or Gap.

### Observations
Enter any supporting comments or details regarding the response including details of Gaps.

### File
Attach or upload any relevant documents of photos to support response.

### Corrective Actions
Check box is an Action is required.

<table>
<thead>
<tr>
<th>No.</th>
<th>Requirement</th>
<th>Response</th>
<th>Comments / Observations</th>
<th>File</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>OUTSIDE SECURITY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Property Perimeter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td>Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?</td>
<td>1: Currently Doing</td>
<td>A fence secures the property perimeter against unauthorized entry. &quot;No Trespassing&quot; signs are posted. The perimeter of the property is patrolled on a regular basis, at least every 30 minutes.</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>1b</td>
<td>Is there adequate lighting around the property perimeter?</td>
<td>0: GAP</td>
<td>Exterior lights are installed around the property perimeter. However, these lights are not adequate to illuminate the property perimeter to deter and aid in the detection of suspicious or unusual activities.</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>
Conducting a Food Defense Audit – Corrective Action Section

**Corrective Action Section.** Actions arising from the audit are carried over from the previous Audit Record section and can be managed and assigned for completion.

**Requirement**
From checklist item in the Record Section

**Observations**
Supporting comments or details regarding the response including details of Gaps from Record

**Category**
Select the category of the non-conformance

**Responsible**
Enter the name of the persons responsible for addressing the Action

**Due Date**
Enter the date by which the action needs to be completed

<table>
<thead>
<tr>
<th>No.</th>
<th>Requirement</th>
<th>Comments/Observations</th>
<th>Category</th>
<th>Responsible</th>
<th>Due Date</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1b</td>
<td>Is there adequate lighting around the property perimeter?</td>
<td>Exterior lights are installed around the property perimeter, however these lights are not adequate to illuminate the property perimeter to deter and aid in the detection of suspicious or unusual activities.</td>
<td>Minor</td>
<td>Silvia Riondina</td>
<td>02/10/2017</td>
<td>Awaiting Action Details</td>
</tr>
<tr>
<td>3b</td>
<td>Are all vehicles entering the property identified by decals or other form of company-issued visual identification? This may include forms of permanent identification for employee vehicles, and temporary identification for vehicles belonging to visitors, contract workers, suppliers, and customers.</td>
<td>Some authorized employee and business vehicles do not display a vehicle identification card provided by the company.</td>
<td>Critical</td>
<td>Silvia Riondina</td>
<td>02/10/2017</td>
<td>Completed</td>
</tr>
<tr>
<td>4j</td>
<td>Do you regularly take inventory of keys to secured/sensitive areas of the facility?</td>
<td>Physical keys are not issued under controlled conditions.</td>
<td>Major</td>
<td>Silvia Riondina</td>
<td>02/10/2017</td>
<td>Awaiting Investigation/Root Cause Analysis</td>
</tr>
</tbody>
</table>
Conducting a Food Defense Audit – Result Section

Result Section. Complete the final Food Defense audit result and ratings.

<table>
<thead>
<tr>
<th>Score</th>
<th>Calculated score for the audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Pass or Fail result selected by the PCQI</td>
</tr>
<tr>
<td>Rating</td>
<td>Select the appropriate rating for the audit</td>
</tr>
<tr>
<td>Summary</td>
<td>Enter any notes supporting result</td>
</tr>
</tbody>
</table>

Audit Result

<table>
<thead>
<tr>
<th>Score</th>
<th>Result</th>
<th>Rating</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>89/92 (97%)</td>
<td>Pass</td>
<td>Excellent Defense</td>
<td></td>
</tr>
</tbody>
</table>

- Poor Defense
- Adequate Defense
- Good Defense
- Excellent Defense
Practical Exercise – Complete Food Defense Audit

Task
Complete Food Defense Audit

20-25 minutes

Instructions
- Click Auditing > Actions [Your Audit] > Awaiting Audit Record
- Complete Audit Details
- Complete Actions
- Complete Audit Record
- Complete Corrective Actions
- Complete Result
- Click Save
Three Steps to Creating a Food Defense Plan in SF360

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Corrective Action Module
• From the previous two activities a full Action Plan will arise.
• This is managed in the Corrective Actions module.
• SF360 is currently developing a full integrated report which will pull together all these elements into one FDA format Food Defense Plan.

Risk - Food Safety Plan Module
• The second step is to conduct a full Vulnerability Assessment (VI) using the Food Safety Plan module.
• This is a similar process to conducting a HACCP or PCP study except vulnerabilities are assessed.
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Auditing Module
• The first step is to conduct a food defense audit to identify board mitigation strategies that are required.
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• Once conducted the audit results will allow for the generation of Actions where required.
Conducting a Vulnerability Assessment (VA)

Vulnerability Assessments are developed and managed in the Risk centre under the Food Safety Plans module.

Add Food Safety Plan
Used to create a new VA.

Vulnerability Assessments
Used to access/view/edit/copy/delete existing VA’s

Add Model
Used to access the options for creating a new model.

Add Model > Risk Assessment Model
Used to create a new risk assessment model.

Add Model > Decision Tree Model
Used to create a decision tree model.

Food Defense Plans and VA’s with Safefood 360°
**Risk Assessment Models for VA**

Risk > Food Safety Plans > Add Model > Risk Assessment Model

**Risk Assessment Model in Vulnerability Assessment**

- The FDA have pre-defined a risk assessment model to be used for VA's.
- Safefood 360 have built this into the software for each set up of your VA.
- It is a 5 x 5 matrix model. In this model ratings are added to calculate the final risk score.
- It uses two factors: **Accessibility** (Easy of access to the process step) and **Vulnerability** (Potential for doing damage if access is achieved).

![Risk Assessment Model Table](image)

**Vulnerability**

<table>
<thead>
<tr>
<th>Accessibility</th>
<th>Not Vulnerable (2)</th>
<th>Barely Vulnerable (4)</th>
<th>Somewhat Vulnerable (6)</th>
<th>Vulnerable (8)</th>
<th>Highly Vulnerable (10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Accessible (2)</td>
<td>4</td>
<td>6</td>
<td>8</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Hardly Accessible (4)</td>
<td>6</td>
<td>8</td>
<td>10</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Partially Accessible (6)</td>
<td>8</td>
<td>10</td>
<td>12</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td>Accessible (8)</td>
<td>10</td>
<td>12</td>
<td>14</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Easily Accessible (10)</td>
<td>12</td>
<td>15</td>
<td>16</td>
<td>18</td>
<td>20</td>
</tr>
</tbody>
</table>
Decision Tree Models for VA

**Risk > Food Safety Plans > Add Model > Decision Tree Model**

**Decision Tree Model in Vulnerability Assessment**

- The VA Decision Tree is designed to confirm that a focused mitigation strategy is required.
- Its use follows the identification of a significant vulnerability for a specific process step.
- Two simple questions are used in the standard SF360 model however more complex models can be developed.
- The result will indicate if a Focused Mitigation Strategy is required.

<table>
<thead>
<tr>
<th>Decision Tree</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Result**

Focus Mitigation Strategies

**Decision Report**

This is an actionable process step, food defense measures can be applied and are essential to prevent or eliminate a significant vulnerability or reduce such vulnerability to an acceptable level.
Vulnerability Assessments (VA’s)

Food Safety Plans

- Vulnerability Assessments are created and located in the Risk centre under the Food Safety Plan module.
- PCQI’s can build any number of VA’s.
- They contain a standard workflow to assist the PCQI in preparing VA’s in a structured and systematic way.
- VA’s are usually focused on a specific process steps.
- Workflow covers all the requirements for FSMA and the Final Rule.
Practical Exercise – Copy Example VA

Task
Copy Example VA in Safefood 360

5 minutes

Instructions
• Click Risk > Food Safety Plan > Actions (Tab)
• Click [VA :: Cooked Meat] in the table
• In the VA control page click Actions > Copy
• In Product / Process field delete the current content an replace with your name e.g. George Howlett
• Scroll to the end of the page and click Save
Steps in Building a VA in Safefood 360

The following details the steps to be followed in the Safefood 360 workflow for developing VA’s.

**VA Details**
- Define the scope of your VA.
- Where it starts (e.g., incoming) and finishes (e.g., despatch).
- Define your team members including PCQI’s.
- Define process details.
- Select models to be used in the VA.

**Materials**
- This step is not applicable in the VA workflow.
- It has been included here to align with the actual workflow of the module.
- You do not need to enter any data in this step.

**Flow Diagrams**
- Draft you process flow diagrams with the in application flow charting tool.

**Process Steps**
- Describe each step in the process.

**Hazard Analysis**
- Identify all potential vulnerabilities at each step of the process.
- Determine the risk of each vulnerability (Accessibility x Vulnerability).
- Determine if mitigation strategy is required.
- Plan you mitigation activities.

**VA Plan**
- Automatic building of your final VA plans.
- Approval of VA plans by your PCQI’s.
Steps in Building a PCP plan in Safefood 360

The following details the steps to be following in the Safefood 360 workflow for developing PCP plans.

**STEP 1**

**VA Details**

- Define the scope of your VA.
- Where it starts (e.g. incoming) and finishes (e.g. despatch).
- Define your team members including PCQI’s.
- Define process details.
- Select models to be used in the VA.
**Scope**
Define the scope of the VA study. What it covers, where it starts and finishes and what is not included.

<table>
<thead>
<tr>
<th>Product / Process</th>
<th>Scope</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA : Cooked Meat</td>
<td>The VA plan covers cooked meat products produced by the company at its premises. Specifically, it covers fully cooked, not shelf stable meat product. The product is boneless and vacuum packed for shipment to the customer. The VA Plan study scope starts at the sourcing and receiving of raw materials and ingredients through processing and packing and finished at distribution and information provision to the consumer.</td>
<td>The VA plan has been developed in compliance with FDA Regulation.</td>
</tr>
</tbody>
</table>
STEP 1 :: Build VA – Model Details (Part 2)

Model Details Section: Select the required risk assessment and decision tree models which will be used in this VA. Also, select those team members responsible for the approval of the VA.

- **Risk Assessment Model**: Select the Risk Assessment Model you wish to use in the VA.
- **Decision Tree Model**: Select the Decision Tree Model you wish to use in the VA.
- **Assign Users to Approve**: Select those members of your team who will approve the VA.

---

**Model Details**

<table>
<thead>
<tr>
<th>Risk Assessment Model</th>
<th>Decision Tree Model</th>
<th>Assign Users to Approve</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA Risk Assessment model</td>
<td>VA Decision Tree</td>
<td>Silvia Riondino</td>
</tr>
</tbody>
</table>

**Enable Periodic Review**

Add Line
**STEP 1 :: Build VA – Food Safety Team (Part 3)**

**Food Safety Team.** List of food safety team members and their function. External experts details are also captured in this section.

<table>
<thead>
<tr>
<th>Team Member Name</th>
<th>Function</th>
<th>Expert Assistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Braden X</td>
<td>Team Leader</td>
<td></td>
</tr>
<tr>
<td>Barry X</td>
<td>Food Safety / Technology</td>
<td></td>
</tr>
<tr>
<td>Bernard X</td>
<td>Maintenance</td>
<td></td>
</tr>
<tr>
<td>Addison X</td>
<td>Engineering</td>
<td></td>
</tr>
</tbody>
</table>

*No external assistance was provided at this.*
STEP 1 :: Build VA – Process Data (Part 4)

**Process Data.** The PCQI can define important data about the process that may be relevant in the VA study.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>These are the process data items which the PCQI can define</td>
<td>Enter the a full description of the process data item</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Data</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Description</td>
</tr>
<tr>
<td>Product Data</td>
<td>Refer to PCP plan</td>
</tr>
</tbody>
</table>

[Add Line]
STEP 1 :: Build VA – Regulatory Information (Part 5)

**Regulatory Legislation.** In this section you provide clear reference to the legislation governing the VA.

- **Governing Legislation**
  Provide details of the legislation that is governing this VA

- **Relevant Documents**
  Attach copies of the legislation for full reference

**Regulatory Information**

- **Governing Legislation**
  FDA-2013-N-1425-0002

- **Relevant Documents**
  Title
  View

- Add Line
Food Defense Plans and VA's with Safefood 360°

Practical Exercise – Complete Study Details

Task
Complete the Study Details Section of your VA

10 minutes

Instructions

• Click Risk > Food Safety Plan > Actions
• Click the name of your VA in the table
• Click Actions > Edit
• Go to Model Details Section and select the Risk Assessment Model for conducting VA's
• Go to Model Details section and select the Decision Tree Model for conducting VA's
• Scroll to the end of the screen and click Save
Steps in Building a VA in Safefood 360

The following details the steps to be followed in the Safefood 360 workflow for developing VAs.

**STEP 1**

**VA Details**
- Define the scope of your VA.
- Where it starts (e.g. incoming) and finishes (e.g. despatch).
- Define your team members including PCQI’s.
- Define process details.
- Select models to be used in the VA.

**STEP 2**

**Materials**
- This step is not applicable in the VA workflow.
- It has been included here to align with the actual workflow of the module.
- You do not need to enter any data in this step.
Steps in Building a VA in Safefood 360

The following details the steps to be followed in the Safefood 360 workflow for developing VA's

**STEP 1**
- **VA Details**
  - Define the scope of your VA.
  - Where it starts (e.g., incoming) and finishes (e.g., despatch).
  - Define your team members including PCQI's.
  - Define process details.
  - Select models to be used in the VA.

**STEP 2**
- **Materials**
  - This step is not applicable in the VA workflow.
  - It has been included here to align with the actual workflow of the module.
  - You do not need to enter any data in this step.

**STEP 3**
- **Flow Diagrams**
  - Draft you process flow diagrams with the in application flow charting tool.
STEP 3 :: Build VA – Flow Diagram

**Flow Diagram.** In this section of the VA workflow you draft a process flow diagram.

**Title**
Enter the title of the process flow diagram

**Description**
Enter a description for the process flow

**Menus**
Charting Menus

**Tools**
Charting Tools

**Canvass**
Draft your process flow diagram in this area
Food Defense Plans and VA’s with Safefood 360°

Practical Exercise – View Process Flow Diagram

Task
View flow diagram

5 minutes

Instructions
• Click Risk > Food Safety Plan > Actions
• Click the name of your VA in the table
• Click Actions > Edit
• Click Flow Diagrams and select the flow diagram
• View flow diagram

Gluten Free Burger Process Flow

1. General: Hygiene Controls
2. General: Cross-Contamination Controls
3. General: Cleaning & Sanitation Controls
4. General: Supply Chain Controls
5. General: Recall - Plan
Steps in Building a VA in Safefood 360

The following details the steps to be followed in the Safefood 360 workflow for developing VA’s.

**STEP 1**
- VA Details
  - Define the scope of your VA.
  - Where it starts (e.g. incoming) and finishes (e.g. despatch).
  - Define your team members including PCQI’s.
  - Define process details.
  - Select models to be used in the VA.

**STEP 2**
- Materials
  - This step is not applicable in the VA workflow.
  - It has been included here to align with the actual workflow of the module.
  - You do not need to enter any data in this step.

**STEP 3**
- Flow Diagrams
  - Draft you process flow diagrams with the in application flow charting tool.

**STEP 4**
- Process Steps
  - Describe each step in the process.
**STEP 4 :: Build VA – Process Steps**

**Process Steps Section.** In this section of the VA workflow you can describe in detail each process step which will be risk assessed.

<table>
<thead>
<tr>
<th>No.</th>
<th>Process Steps</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Receiving (Packaging)</td>
<td>Packaging materials including vacuum pouches, cooking bags and labels are delivered and transferred to a dedicated packaging store.</td>
</tr>
<tr>
<td>2</td>
<td>Storage (Packaging)</td>
<td>Materials are stored on pallets and racking in cool dry conditions away from direct sunlight.</td>
</tr>
<tr>
<td>3</td>
<td>Receiving (Ingredients)</td>
<td>Ingredients are received at the plant in a variety of formats.</td>
</tr>
<tr>
<td>4</td>
<td>Storage (Ingredients)</td>
<td>Ingredients are stored in a dedicated storage facility of pallets and racks.</td>
</tr>
<tr>
<td>5</td>
<td>Receiving (Raw Meat)</td>
<td>Raw meat is received under chilled conditions. Meat is packed in blue PE bags of 10kg units in Dolav storage units.</td>
</tr>
<tr>
<td>6</td>
<td>Chill Storage (32 - 41 °F)</td>
<td>Meat is immediately transferred to a chilled raw meat store at maximum 41 °F.</td>
</tr>
</tbody>
</table>
Practical Exercise – Add a Process Step

Task
Add a process step

10 minutes

Instructions
• Click Risk > Food Safety Plan > Actions
• Click the name of your VA in the table
• Click Actions > Edit
• Click Process Steps
• Click Add Line to add a new process step
• Enter the Name of the process step
• Enter the Description of the process step
• Click Save
Steps in Building a VA in Safefood 360

The following details the steps to be followed in the Safefood 360 workflow for developing VA’s.

**VA Details**
- Define the scope of your VA.
- Where it starts (e.g. incoming) and finishes (e.g. despatch).
- Define your team members including PCQI’s.
- Define process details.
- Select models to be used in the VA.

**Materials**
- This step is not applicable in the VA workflow.
- It has been included here to align with the actual workflow of the module.
- You do not need to enter any data in this step.

**Flow Diagrams**
- Draft you process flow diagrams with the in application flow charting tool.

**Process Steps**
- Describe each step in the process.

**Hazard Analysis**
- Identify all potential vulnerabilities at each step of the process.
- Determine the risk of each vulnerability (Accessibility x Vulnerability).
- Determine if mitigation strategy is required.
- Plan you mitigation activities.
STEP 5 :: Build VA – Hazard Analysis – Hazard Details Section

Hazard Details Section. In this section of the VA workflow you can identify vulnerabilities which may exist in the process for each process step.

- **Process Step**: Displays name of the process step
- **Hazard / Issue Category**: Select the category of hazard e.g. quality / other
- **Nature**: Select the nature of the hazard e.g. adulteration / deliberate contamination
- **Details / Source**: Describe in more detail the hazard including the source of the hazard

**Description**
Details of the hazard selected

**Hazard / Issue**
Select the Hazard(s) identified. You can add one or more hazards by using the Add Line button

**Preventive Measures**
Enter details of existing preventive measures
## Risk Assessment Section

In this section the PCQI can risk assess the hazard at the specific step to determine if it is significant.

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Actions</th>
<th>Advanced Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used to conduct a simple risk assessment</td>
<td>Displays the required actions for the risk</td>
<td>Click to open the advance matrix risk assessment model</td>
</tr>
</tbody>
</table>

### Risk Assessment Details

- **Risk**: Medium
  - Undesirable risk - evaluation required, specific actions may be required

### Advanced Risk Determination

- **Probability**: 3 - A: Partially Accessible (e.g., inside building, but in a relatively unsecured, but busy, part)
- **Severity**: 4 - V: Vulnerable (e.g., product has some open exposure and there is sufficient time to take corrective action)

### Report

- **Report**: Marija Karsan, 02/10/2017 04:30

### Probability
- Select the probability ratings available

### Severity
- Select the severity ratings available

### Rating
- Select the appropriate rating for the hazard
STEP 5 :: Build VA – Hazard Analysis – Decision Tree Section

Decision Tree Section. In this section the PCQI can determine if mitigation strategies are required.

**Question**
Used to direct the PCQI is answer a question regarding the nature of the risk

**Answer**
PCQI selects Yes or No. Each answer will either direct the user to another question or produce a final Result

**Result**
Displayed result based on the decision tree model

**Decision Report**
Provide details support the final risk decision
STEP 5 :: Build VA – Hazard Analysis – Monitoring Details Section

Monitoring Details Section. In this section the PCQI can detail the mitigation strategies and monitoring details.

- **Control**
  - Enter the name of the mitigation measure

- **Control Limit**
  - Enter the control specification / limit

- **How**
  - Enter the method for monitoring

- **Responsible**
  - Enter the role responsible for the control

- **Frequency**
  - Enter the frequency at which check is conducted

- **Corrective Action**
  - Enter the corrective action to be taken if limits are exceeded

- **Record**
  - Select the record or SF360 program where monitoring data on the control is maintained

**Add Line**
Click to add an additional mitigation

**Add Control**
Click to add a standard mitigation strategy from the list of pre-built mitigations in the software.

**Verification**
Enter details of the verification activities regard this mitigation measure
Food Defense Plans and VA’s with Safefood 360°

Practical Exercise – Add New Hazard and Complete

**Task**
Add new hazard to the VA and complete details

**Instructions**
- Click **Risk > Food Safety Plan > Actions**
- Click the name of your VA plan in the table
- Click **Actions > Edit**
- Click **Hazard Analysis > 6- Chilled Storage > Add Hazard**
- Complete **Hazard Details**
- Complete **Risk Assessment**
- Complete **Decision Tree**
- Complete **Monitoring Details**
- Click **Save**
Steps in Building a VA in Safefood 360

The following details the steps to be followed in the Safefood 360 workflow for developing VA's.

**VA Details**
- Define the scope of your VA.
- Where it starts (e.g. incoming) and finishes (e.g. despatch).
- Define your team members including PCQI's.
- Define process details.
- Select models to be used in the VA.

**Materials**
- This step is not applicable in the VA workflow.
- It has been included here to align with the actual workflow of the module.
- You do not need to enter any data in this step.

**Flow Diagrams**
- Draft your process flow diagrams with the in application flow charting tool.

**Process Steps**
- Describe each step in the process.

**Hazard Analysis**
- Identify all potential vulnerabilities at each step of the process.
- Determine the risk of each vulnerability (Accessibility x Vulnerability).
- Determine if mitigation strategy is required.
- Plan your mitigation activities.

**VA Plan**
- Automatic building of your final VA plans.
- Approval of VA plans by your PCQI's.
STEP 6 :: Build VA – Plans

Plans Section. In this section the software pulls together all the relevant data from the previous steps to produce the VA. A PDF of the VA plan can also be generated using the Actions button.

<table>
<thead>
<tr>
<th>No.</th>
<th>Hazard</th>
<th>Control</th>
<th>Control Limit</th>
<th>How</th>
<th>Frequency</th>
<th>Responsible</th>
<th>Corrective Action</th>
<th>Record</th>
<th>Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality / Other. Adulteration / Deliberate Contamination</td>
<td>Ingredients</td>
<td>All ingredients are sealed no evidence of tampering</td>
<td>Visual check</td>
<td>At each delivery</td>
<td>Intake/ Despatch Manager</td>
<td>Reject delivery if any evidence of tampering</td>
<td>Sample Procedure</td>
<td>Audit</td>
</tr>
<tr>
<td>#1</td>
<td>(Intentional contamination/adulteration)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quality / Other. Adulteration / Deliberate Contamination</td>
<td>Drivers</td>
<td>All drivers need to check-in</td>
<td>Drivers identification</td>
<td>At each delivery</td>
<td>Intake/ Despatch Manager</td>
<td>Reject delivery if any evidence of tampering</td>
<td>Sample Procedure</td>
<td>Audit</td>
</tr>
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<td>#1</td>
<td>(Intentional contamination/adulteration)</td>
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<td></td>
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</tr>
<tr>
<td>#2</td>
<td>Storage restricted access</td>
<td>Authorized personnel only</td>
<td>Question people’s purpose in the warehouse. Make sure the workers know who has authorization and who doesn’t.</td>
<td>Use an alarm system to secure access to location.</td>
<td>At all times</td>
<td>Intake/ Despatch Manager</td>
<td>Remove unauthorized personnel. Review materials in the area for tampering.</td>
<td>Sample Procedure</td>
<td>Audits</td>
</tr>
<tr>
<td></td>
<td>(Storage (Ingredients))</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>#3</td>
<td>Drivers check-in &amp; Raw materials check - (5 / Receiving (Raw Meat))</td>
<td>Raw materials</td>
<td>All Raw Materials are covered no evidence of tampering</td>
<td>Visual check</td>
<td>At each delivery</td>
<td>Intake/ Despatch Manager</td>
<td>Reject delivery if any evidence of tampering</td>
<td>Sample Procedure</td>
<td>Audits</td>
</tr>
<tr>
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</tr>
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<td>#3</td>
<td>Drivers check-in &amp; Raw materials check - (5 / Receiving (Raw Meat))</td>
<td>Drivers</td>
<td>All drivers need to check-in</td>
<td>Drivers identification</td>
<td>At each delivery</td>
<td>Intake/ Despatch Manager</td>
<td>Reject delivery if any evidence of tampering</td>
<td>Sample Procedure</td>
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<tr>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Practical Exercise – View VA Plan

Task
View VA Plan

5 minutes

Instructions (VA Plan)

• Click Risk > Food Safety Plan > Actions
• Click the name of your VA in the table
• Click Actions > Edit
• Click Plans
• To get PDF copy
• Click Risk > Food Safety Plan > Actions
• Click the name of your VA plan in the table
• Click Actions > Get PDF
Three Steps to Creating a Food Defense Plan in SF360

There are three key steps in building a full food defense plan in SF360. Conduct Food Defense Audit, Conduct Vulnerability Assessment (VA) and Action Plan Development.

**Corrective Action Module**
- From the previous two activities a full Action Plan will arise.
- This is managed in the Corrective Actions module.
- SF360 is currently developing a full integrated report which will pull together all these elements into one FDA format Food Defense Plan.

**Risk - Food Safety Plan Module**
- The second step is to conduct a full Vulnerability Assessment (VI) using the Food Safety Plan module.
- This is a similar process to conducting a HACCP or PCP study except vulnerabilities are assessed.
- This will lead to specific monitoring measures and actions as required.

**Auditing Module**
- The first step is to conduct a food defense audit to identify board mitigation strategies that are required.
- SF360 has the FDA audit checklist already built in the software for easy set-up.
- Once conducted the audit results will allow for the generation of Actions where required.
Practical Exercise – View Corrective Action

Task
View Corrective Action

5 minutes

Instructions
- Click Risk > Food Safety Plan > Complete
- Click the name of your VA in the table
- Scroll to Corrective Actions section
- Click Completed hyperlink in the Corrective Action column
- View the Corrective Action record and workflow