User Conference

Food Defense Plans and Vulnerability Assessments (VA's)

Safefood 360°

connect 360°

Food Defense Plans and VA's with Safefood 360°

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.

Type	Name	Location
Presentation	Food Defense and VA's with Safefood 360°	URL available after conference
SF360 Article	New to Food Defense?	http://safefood360.com/2016/06/new-to-food-defense-heres-the-5-things-you-need-to-know/
Website	FDA - Food Defense	https://www.fda.gov/food/fooddefense/
Website	FDA - Food Defense Plan Builder	https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm
Website	FDA - Mitigation Strategies Database	https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295898.htm
Legislation	FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm

FSMA Supplier Verification with Safefood 360°

Objectives of Today's Session

FSMA Mitigation Strategies to Protect Against IA Requirements

Safefood 360 Solution

Practical Exercises

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

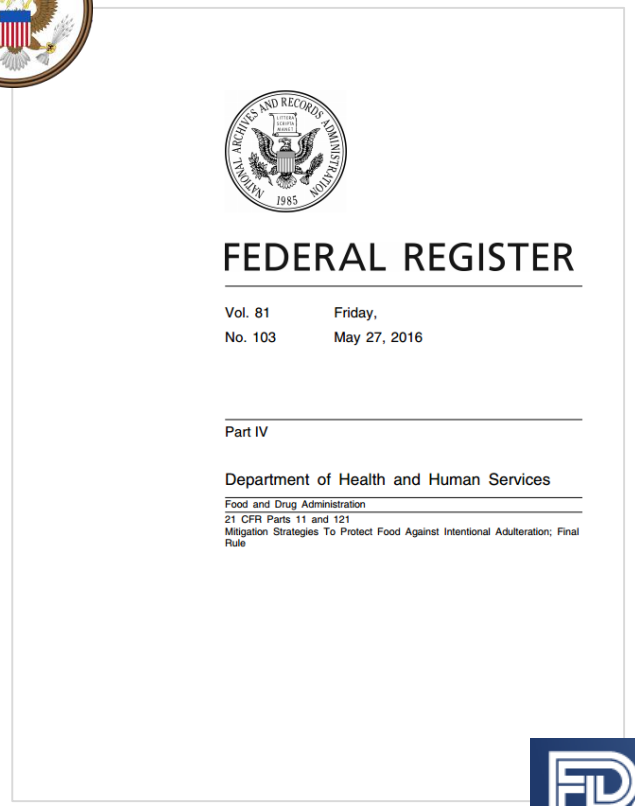
- Rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities.

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.


FEDERAL REGISTER

Vol. 81 Friday,
No. 103 May 27, 2016

Part IV

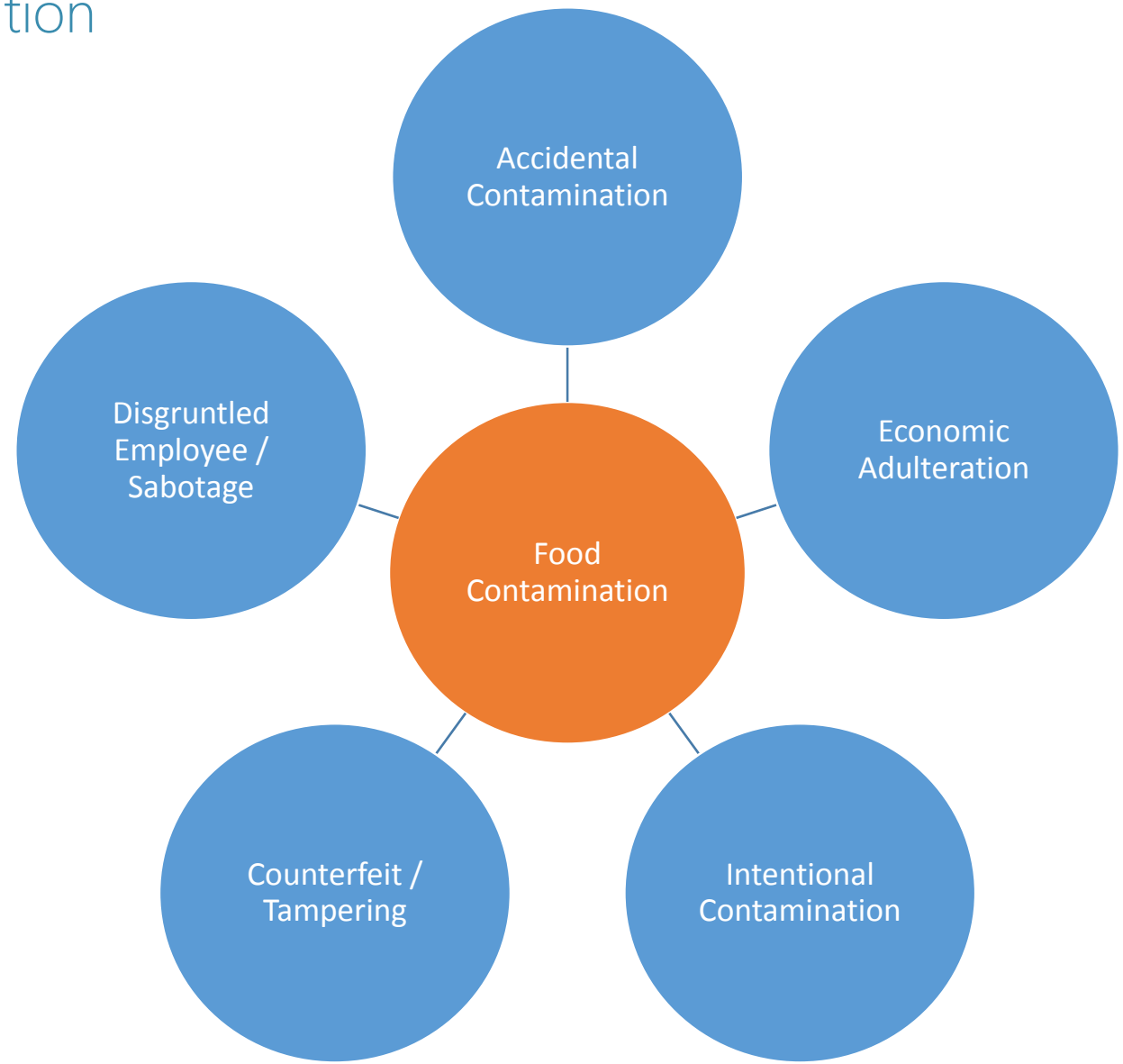
Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11 and 121
Mitigation Strategies To Protect Food Against Intentional Adulteration; Final Rule

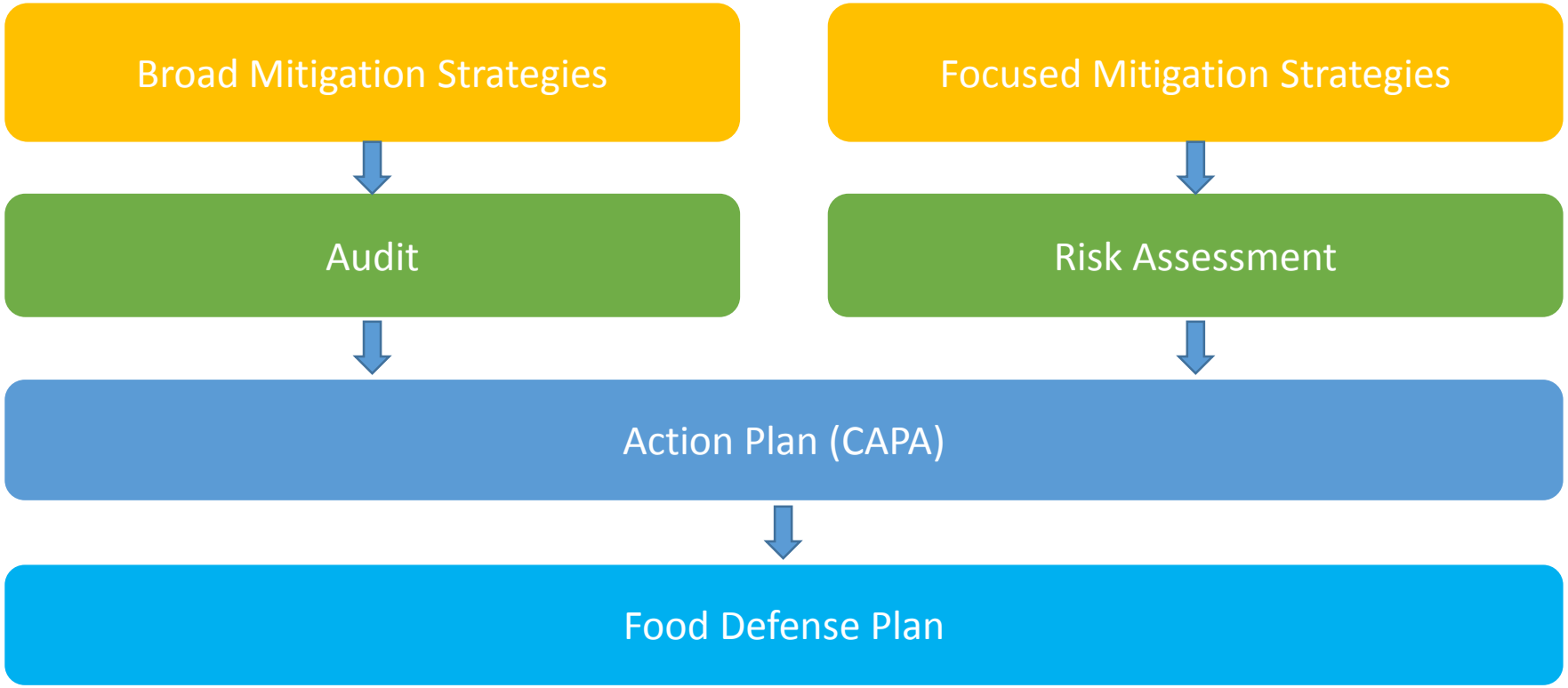
Food Defense Plans and VA's with Safefood 360°

Intentional Adulteration



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.



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.

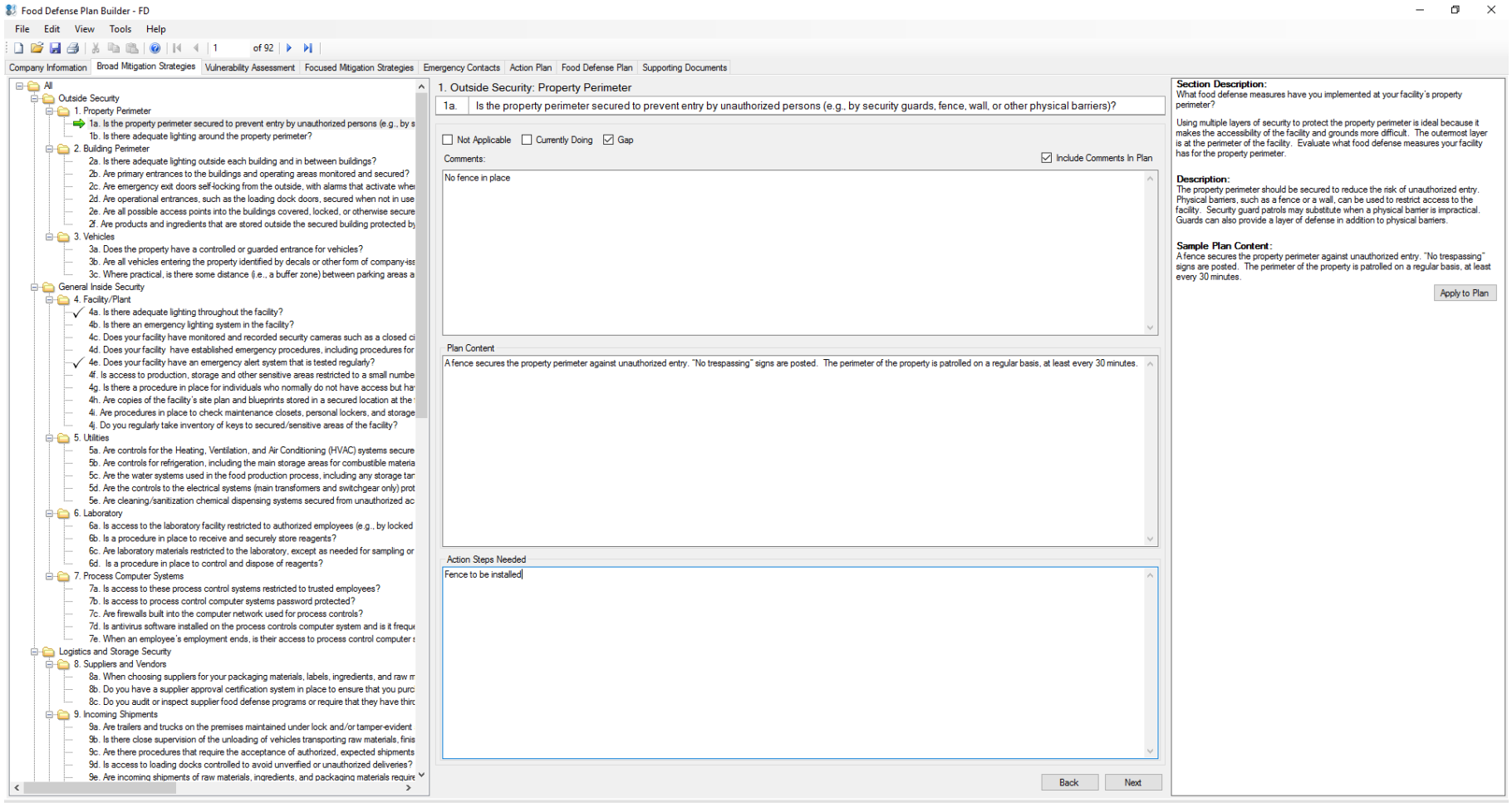
Example

- PROCESS NAME :: Cooked Meat
- PROCESS STEP :: Cooking
- ACCESSIBILIY :: 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?

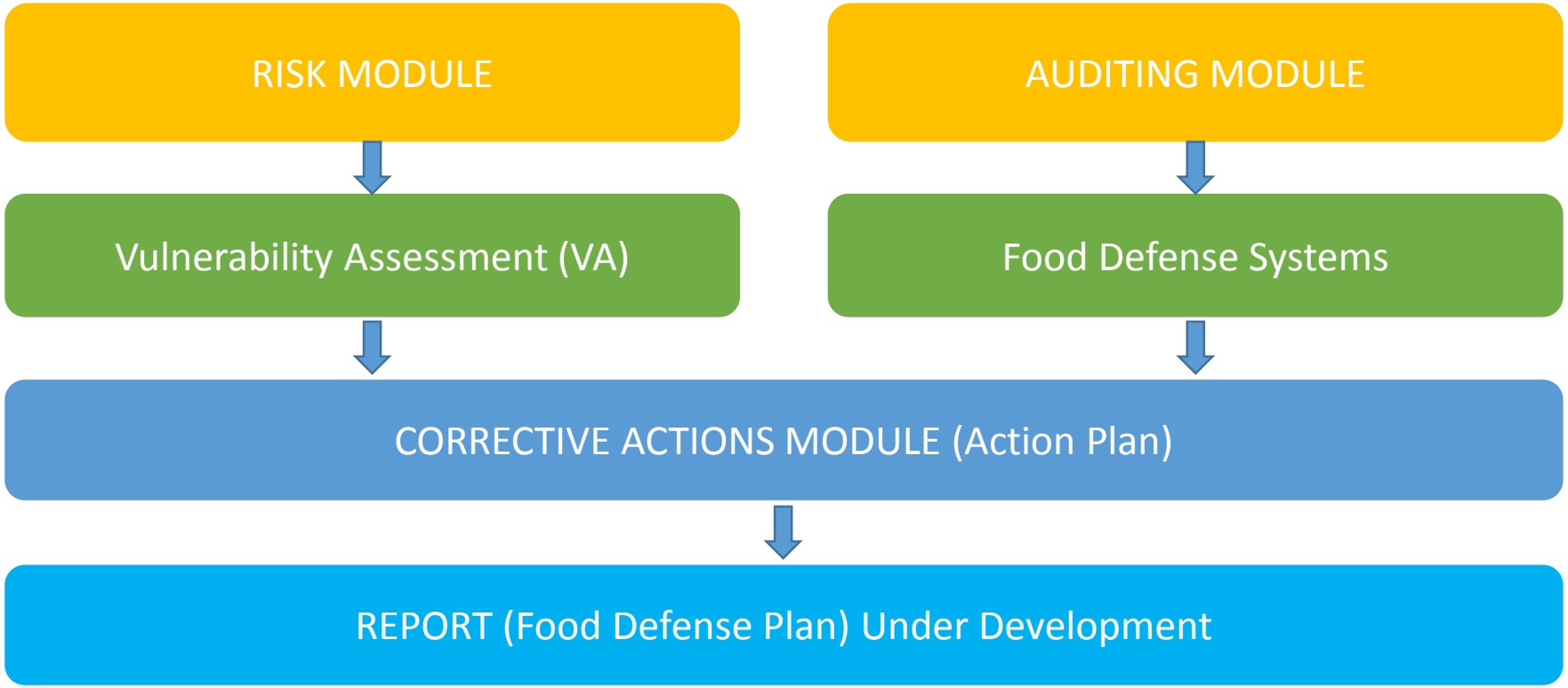
The Final Rule calls for a number of other elements.

- 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.

Food Defense Plans and VA's with Safefood 360°

How Does SF360 Build a Food Safety Plan?

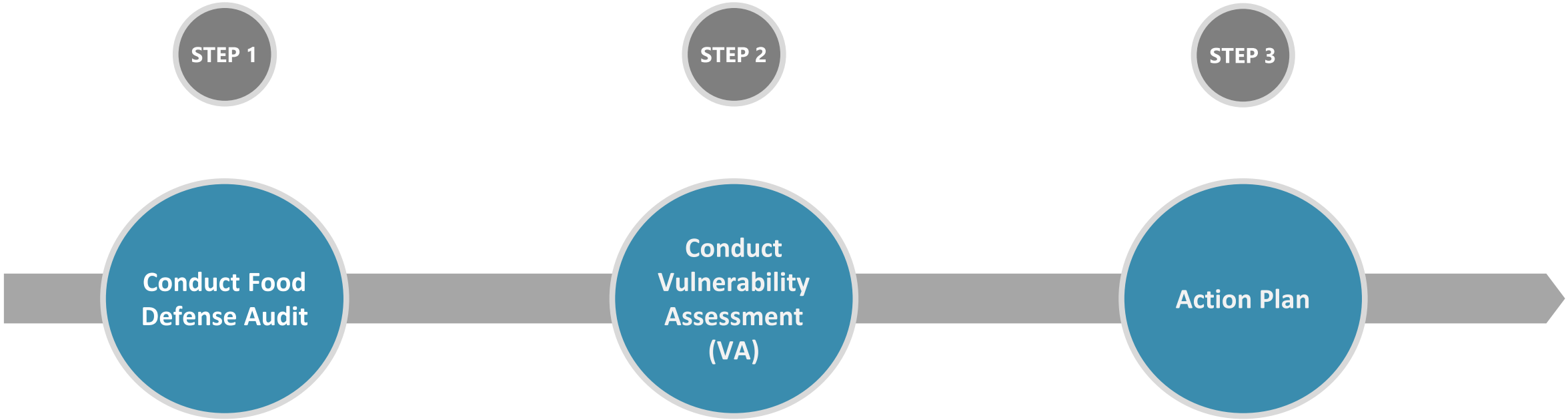
Safefood 360 uses three main modules to build a Food Defense Plan. 1) Risk Module 2) Auditing Module 3) Corrective Action. These are combined to give the FDP.



Food Defense Plans and VA's with Safefood 360°

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.



Food Defense Plans and VA's with Safefood 360°

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

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 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°

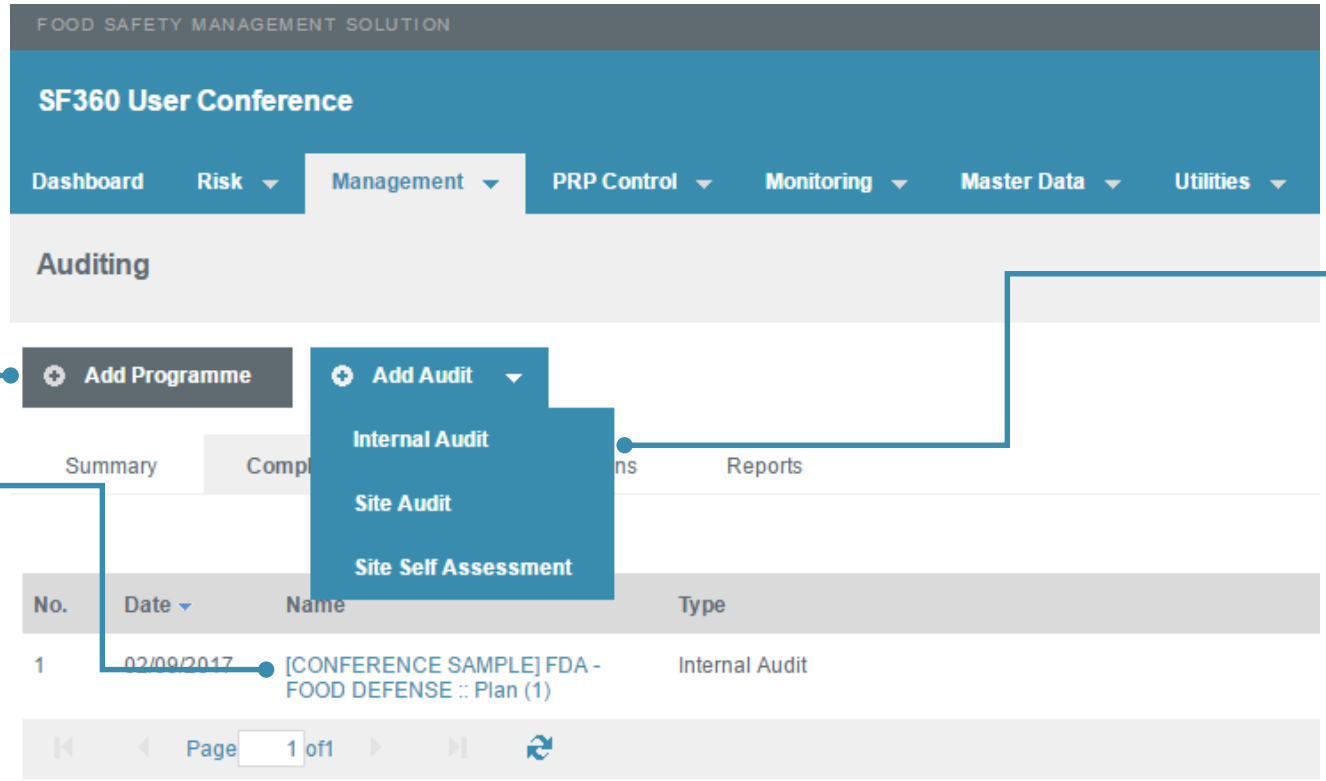
Conducting a Food Defense (FD) Audit

Conduct Food Defense 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

Master Data > Categories> Checklists

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.

Food Defense Plans and VA's with Safefood 360°

Checklists for Food Defense Audits

Below is the FDA defined checklists in Safefood 360.

Requirement
These are the FDA defined checks to be conducted

Response
Used to define your findings for the check. The responses are standard and defined by the FDA including 1- Currently Doing; 0-Gap

Observations
Used to record details of the response

No.	Requirement	Response	Comments / Observations
	OUTSIDE SECURITY		
1	**Property Perimeter**		
1a.	Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?	1 - Currently Doing	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.
1b.	Is there adequate lighting around the property perimeter?	0 - GAP	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.
2.	**Building Perimeter**		
2a.	Is there adequate lighting outside each building and in between buildings?	1 - Currently Doing	Exterior lights are installed outside and in between all buildings.
2b.	Are primary entrances to the buildings and operating areas monitored and secured?	1 - Currently Doing	All primary entrances to the areas are secured. All doors have properly functioning locks or alarms that are checked on a regular basis.
2c.	Are emergency exit doors self-locking from the outside, with alarms that activate when the doors are opened?	1 - Currently Doing	Emergency exits are installed with self-locking doors and alarms that will sound when emergency exit doors are opened.
2d.	Are operational entrances, such as the loading dock doors, secured when not in use?	1 - Currently Doing	The loading dock is regularly monitored and doors are secured when not in use.

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.

Food Defense Plans and VA's with Safefood 360°

Ratings for Food Defense Audits

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

Overall Rating
The total Score of the audit is indicated

Section Score
The individual section scores are also indicated

Result
The result is also expressed as Pass or Fail

Rating
The rating is expressed as level of defense

Non-conformances
Indicates the number of non-conformances arising from the audit

Section	Score	Result	Rating	Nonconformances
Overall	89/92 (97%)	Pass	Excellent Defense	3 (1 Critical,1 Major,1 Minor,0 Recommendation)
OUTSIDE SECURITY	9/11 (82%)	Pass	Excellent Defense	2 (1 Critical,0 Major,1 Minor,0 Recommendation)
1 Property Perimeter	1/2 (50%)	Fail	Poor Defense	1 (0 Critical,0 Major,1 Minor,0 Recommendation)
2. Building Perimeter	6/6 (100%)	Pass	Excellent Defense	0 (0 Critical,0 Major,0 Minor,0 Recommendation)
3. Vehicles	2/3 (67%)	Pass	Adequate Defense	1 (1 Critical,0 Major,0 Minor,0 Recommendation)

Practical Exercise – Create Food Defense Audit Record

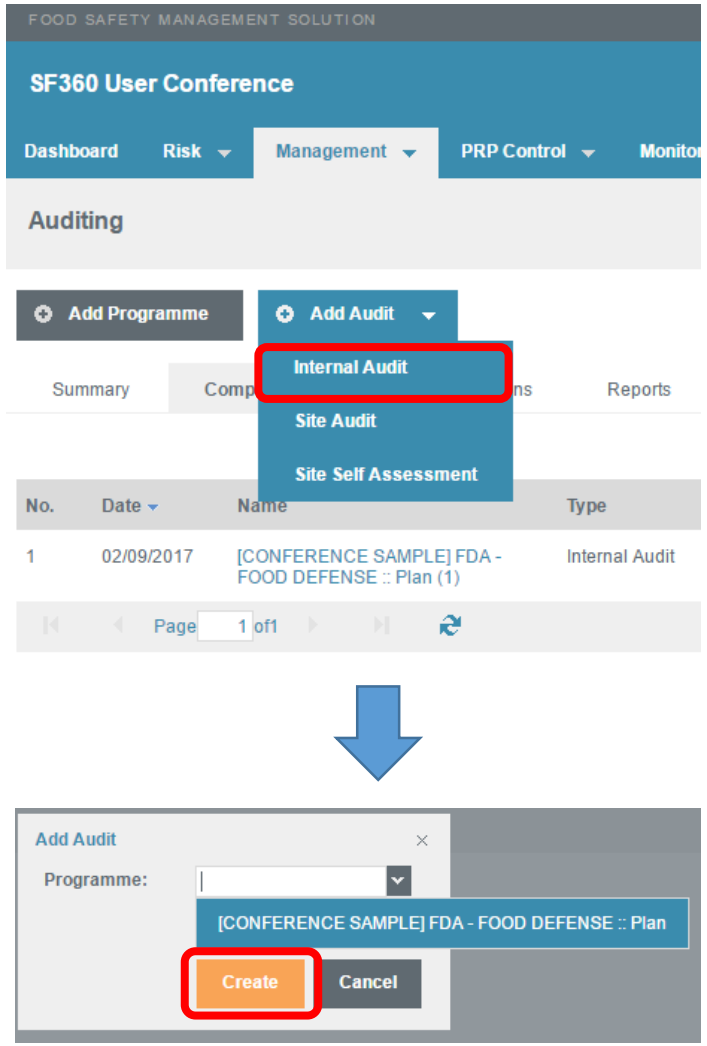
Task

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

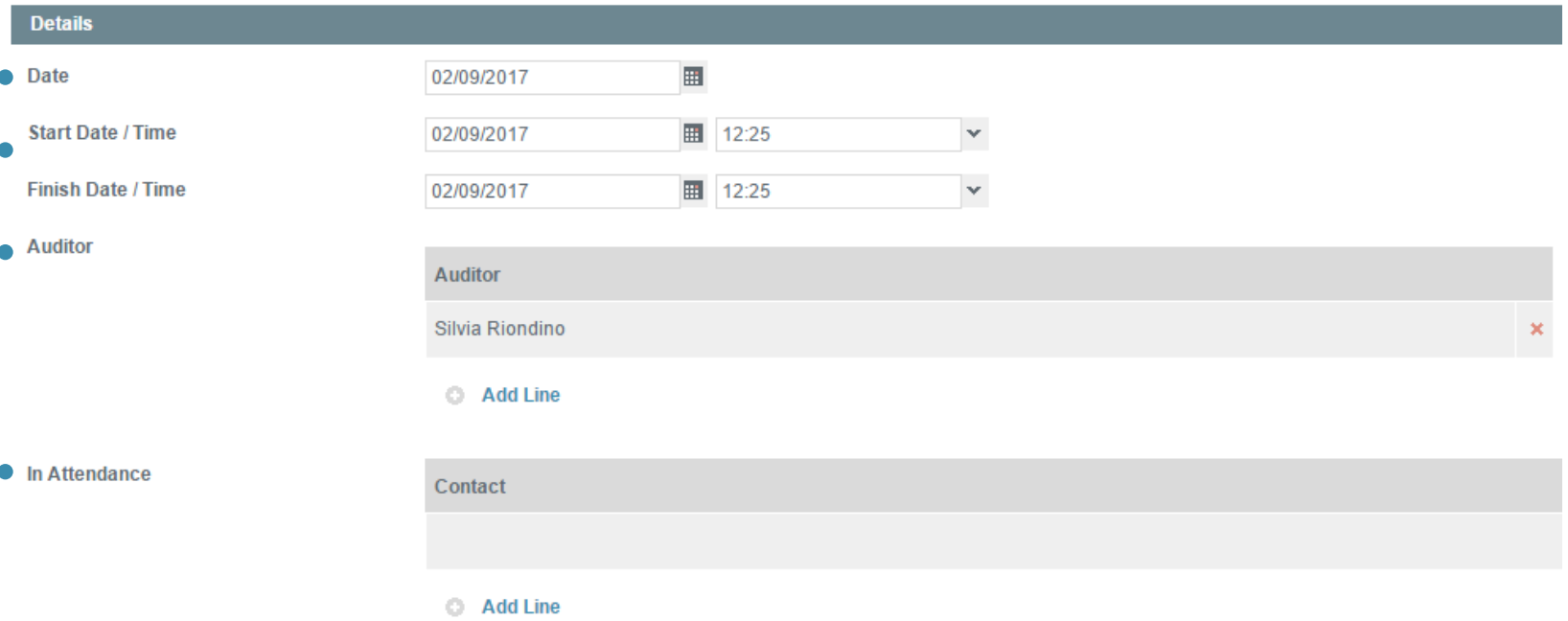
Details Section. Complete high level details about the food defense audit.

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



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

No.	Requirement	Response	Comments / Observations	File	Corrective Action
	OUTSIDE SECURITY				
1	Property Perimeter				
1a.	Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?	1 - Currently Doing	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.		No
1b.	Is there adequate lighting around the property perimeter?	0 - GAP	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.		Yes

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

No.	Requirement	Comments / Observations	Category	Responsible	Due Date	Corrective Action
1b.	Is there adequate lighting around the property perimeter?	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.	Minor	Silvia Riondino	02/10/2017	Awaiting Action Details
3b.	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.	Some authorized employee and business vehicles do not display a vehicle identification card provided by the company.	Critical	Silvia Riondino	02/10/2017	Completed
4j.	Do you regularly take inventory of keys to secured/sensitive areas of the facility?	Physical keys are not issued under controlled conditions	Major	Silvia Riondino	02/10/2017	Awaiting Investigation / Root Cause Analysis

Corrective Action
Hyperlink to the Corrective Action

Conducting a Food Defense Audit – Result Section

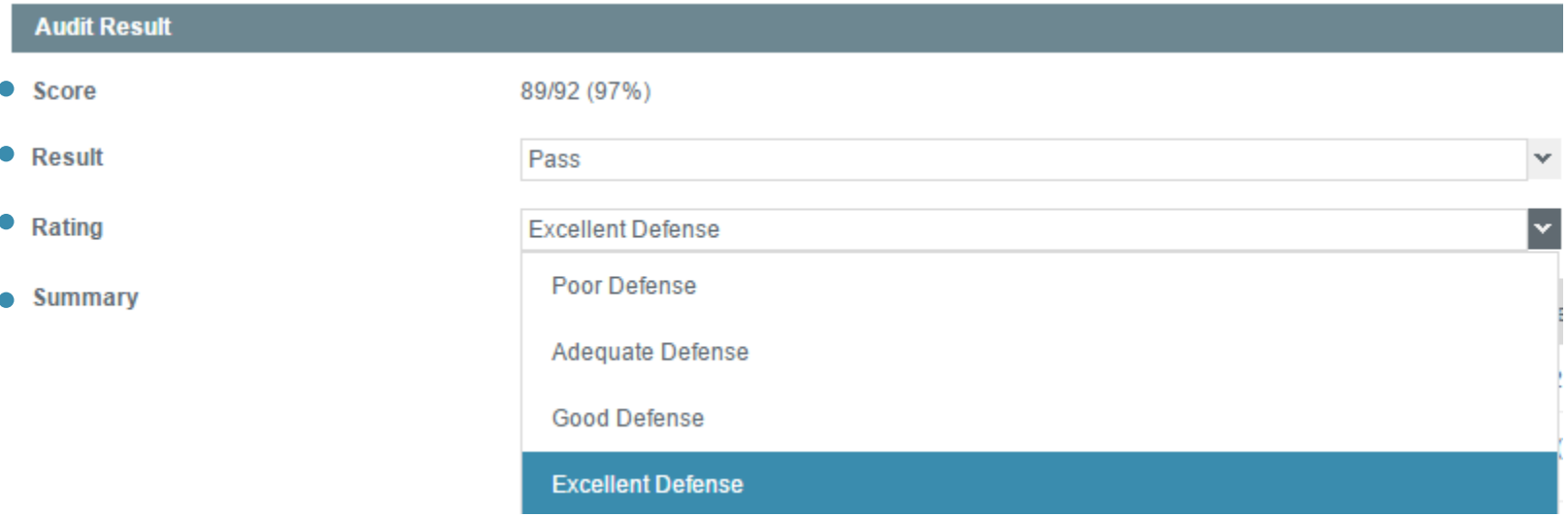
Result Section. Complete the final Food Defense audit result and ratings.

Score
Calculated score for the audit

Result
Pass or Fail result selected by the PCQI

Rating
Select the appropriate rating for the audit

Summary
Enter any notes supporting result



Food Defense Plans and VA's with Safefood 360°

Practical Exercise – Complete Food Defense Audit

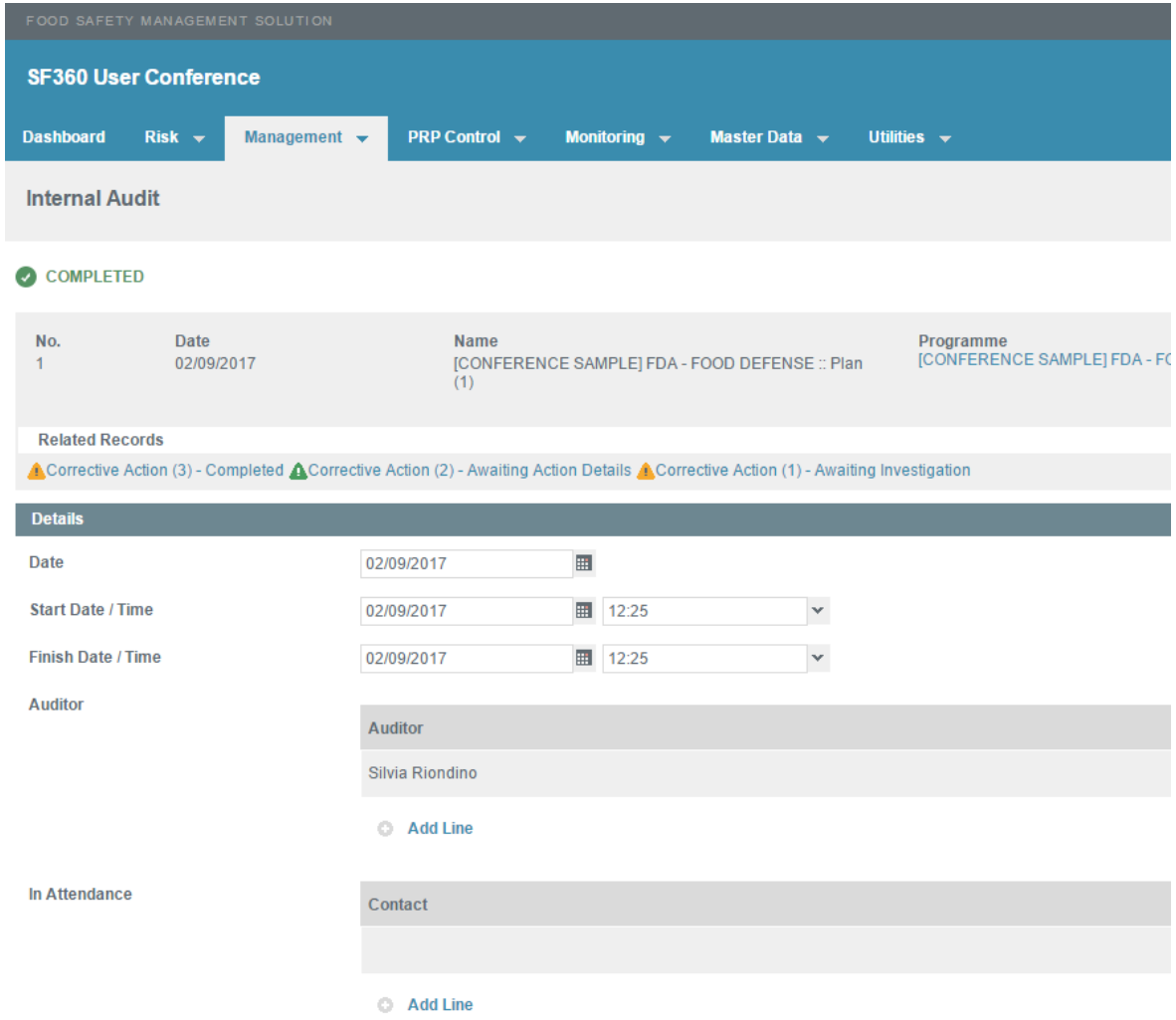
Task

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**



Food Defense Plans and VA's with Safefood 360°

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.

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.

Food Defense Plans and VA's with Safefood 360°

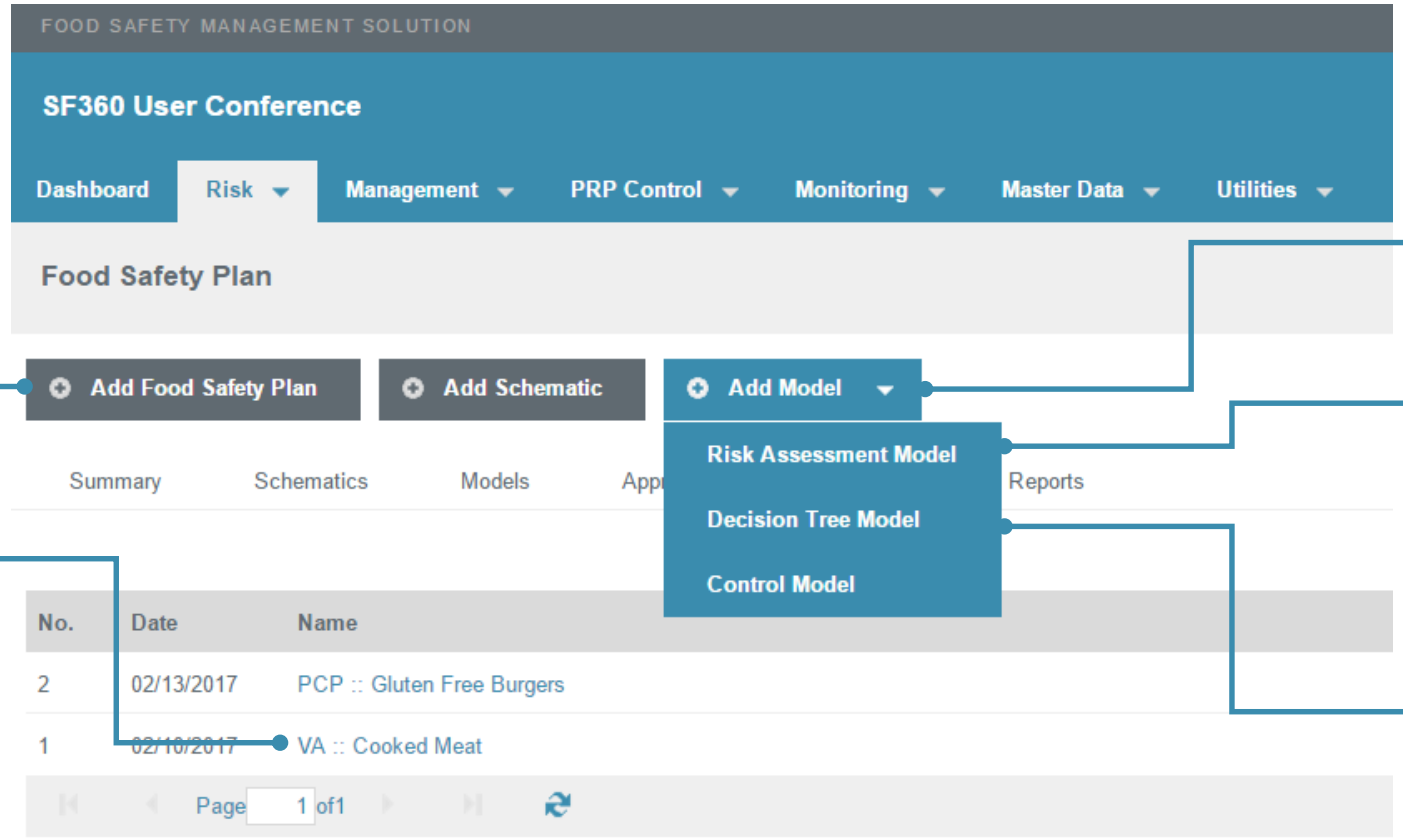
Conducting a Vulnerability Assessment (VA)

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

Conduct Vulnerability Assessment (VA)

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.

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).

		Vulnerability				
		Not Vulnerable (2)	Barely Vulnerable (4)	Somewhat Vulnerable (6)	Vulnerable (8)	Highly Vulnerable (10)
Accessibility	Not Accessible (2)	4	6	8	10	12
	Hardly Accessible (4)	6	8	10	12	14
	Partially Accessible (6)	8	10	12	14	16
	Accessible (8)	10	12	14	16	18
	Easily Accessible (10)	12	15	16	18	20

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.

Decision Tree

Decision Tree

No.	Question	Answer
1	Is there an opportunity to access the product at or just prior to the equipment?	Yes
2	A contaminant, if intentionally added, would be distributed into the food?	Yes

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.

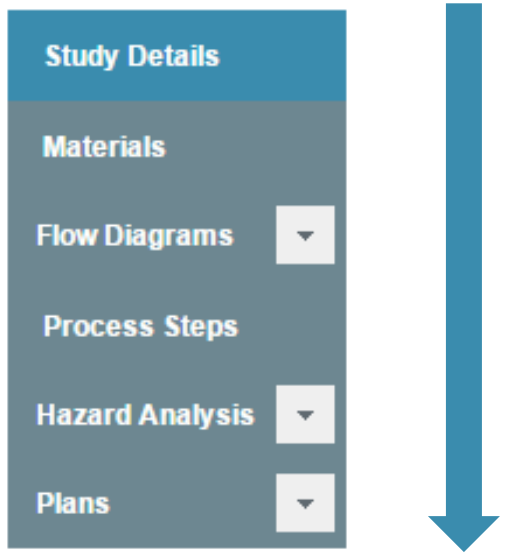
Food Defense Plans and VA's with Safefood 360°

Vulnerability Assessments (VA's)

Risk > Food Safety Plans > Add Food Safety Plan

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.



Food Defense Plans and VA's with Safefood 360°

Practical Exercise – Copy Example VA

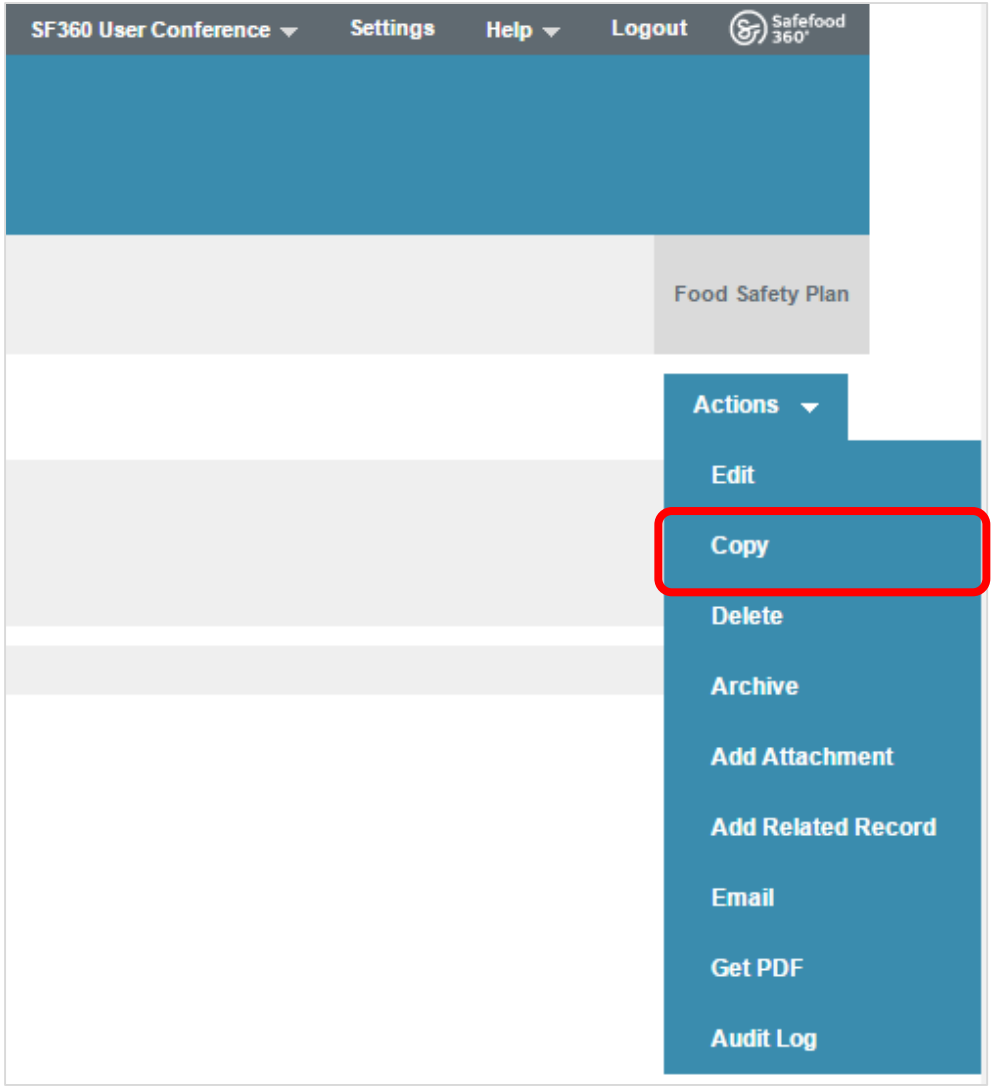
Task

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**



Food Defense Plans and VA's with Safefood 360°

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.

Food Defense Plans and VA's with Safefood 360°

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.

STEP 1 :: Build VA – Study Details (Part 1)

Study Details Section. General details of the VA including name.

Product / Process
Define the name of the process under study for VA development

Scope
Define the scope of the VA study. What it covers, where it starts and finishes and what is not included.

Notes
Enter any additional or relevant notes supporting the VA study.

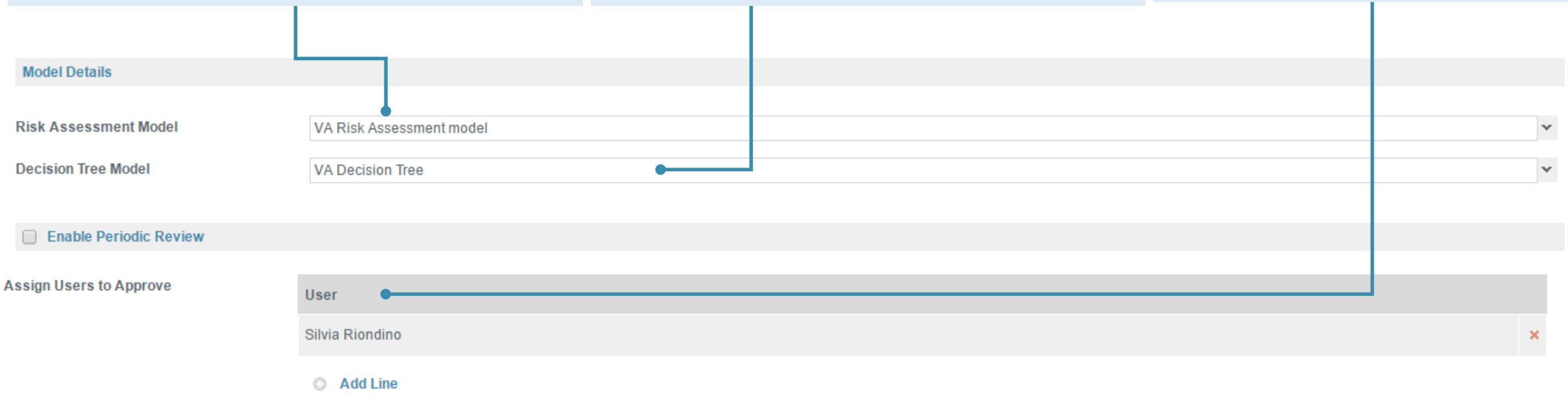
STEP 1 :: Build VA – Model Details (Part 2)

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



Food Defense Plans and VA's with Safefood 360°

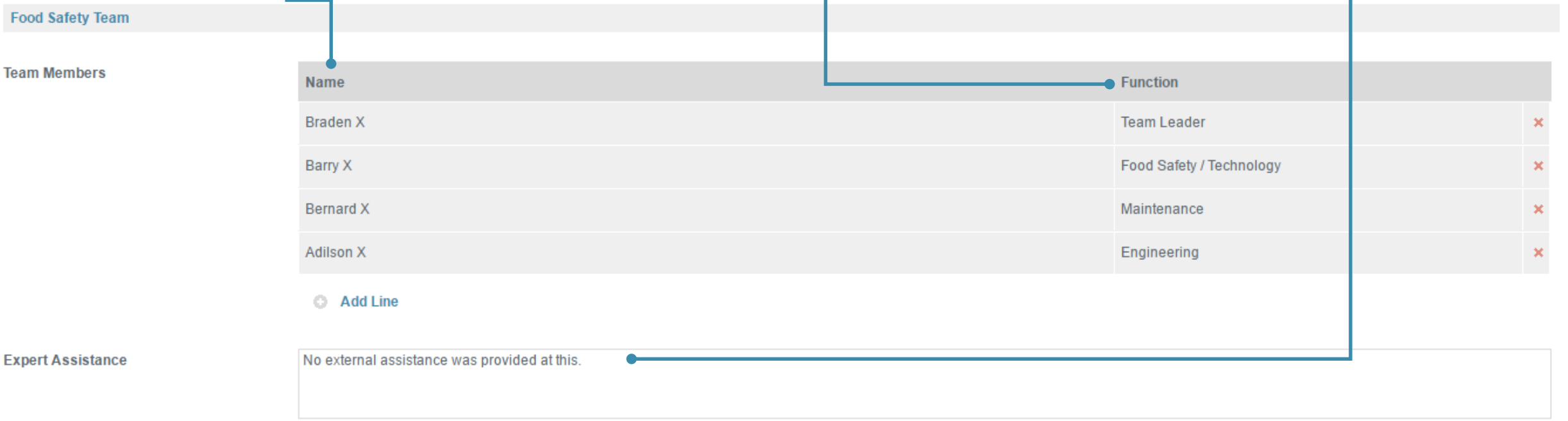
STEP 1 :: Build VA – Food Safety Team (Part 3)

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

Team Member Name
Select Employees who are involved in the development of the VA

Function
Select the function which the employee serves on the VA team

Expert Assistance
Enter details of any external experts used to assist in the development of the VA

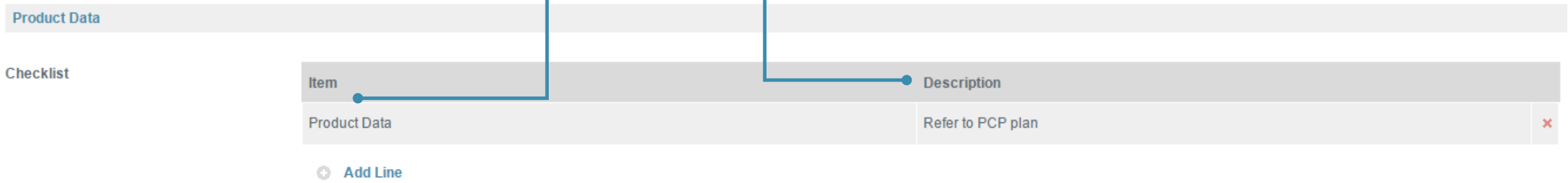


STEP 1 :: Build VA – Process Data (Part 4)

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

Item
These are the process data items which the PCQI can define

Description
Enter the a full description of the process data item

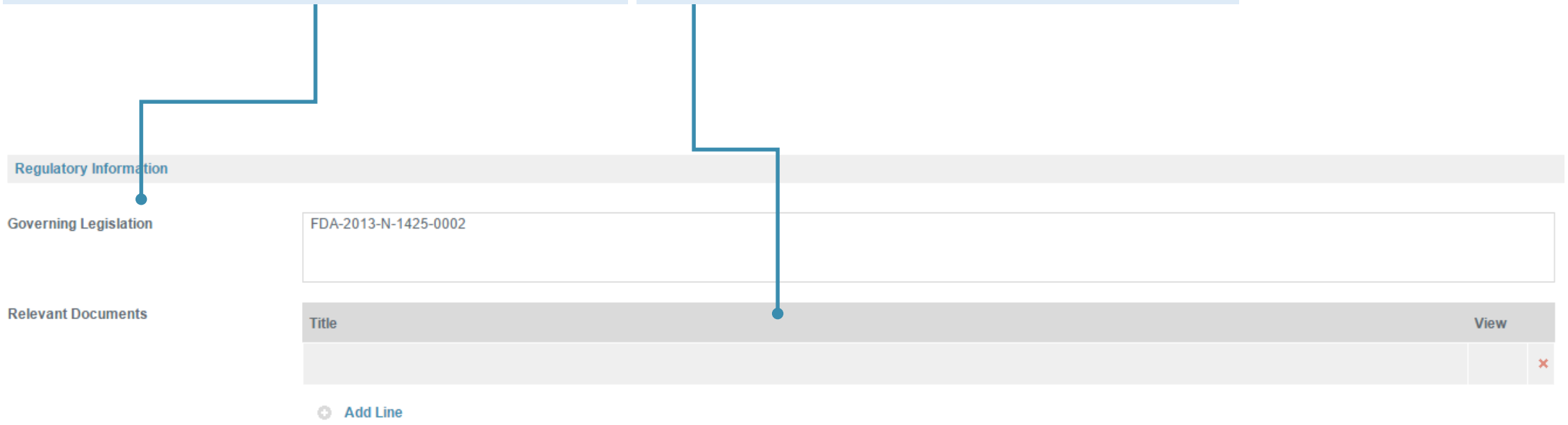


STEP 1 :: Build VA – Regulatory Information (Part 5)

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



Food Defense Plans and VA's with Safefood 360°

Practical Exercise – Complete Study Details

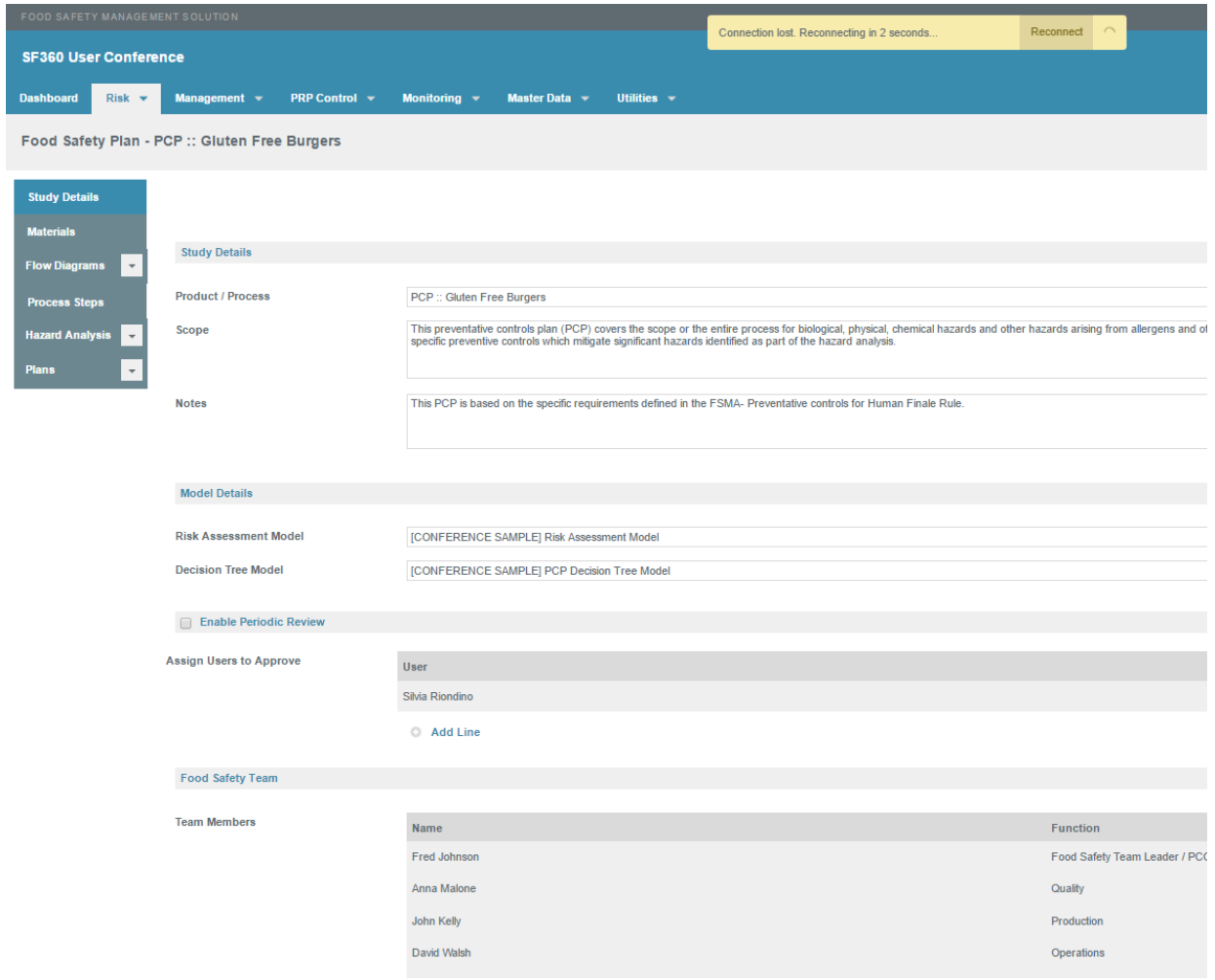
Task

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**



Food Defense Plans and VA's with Safefood 360°

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

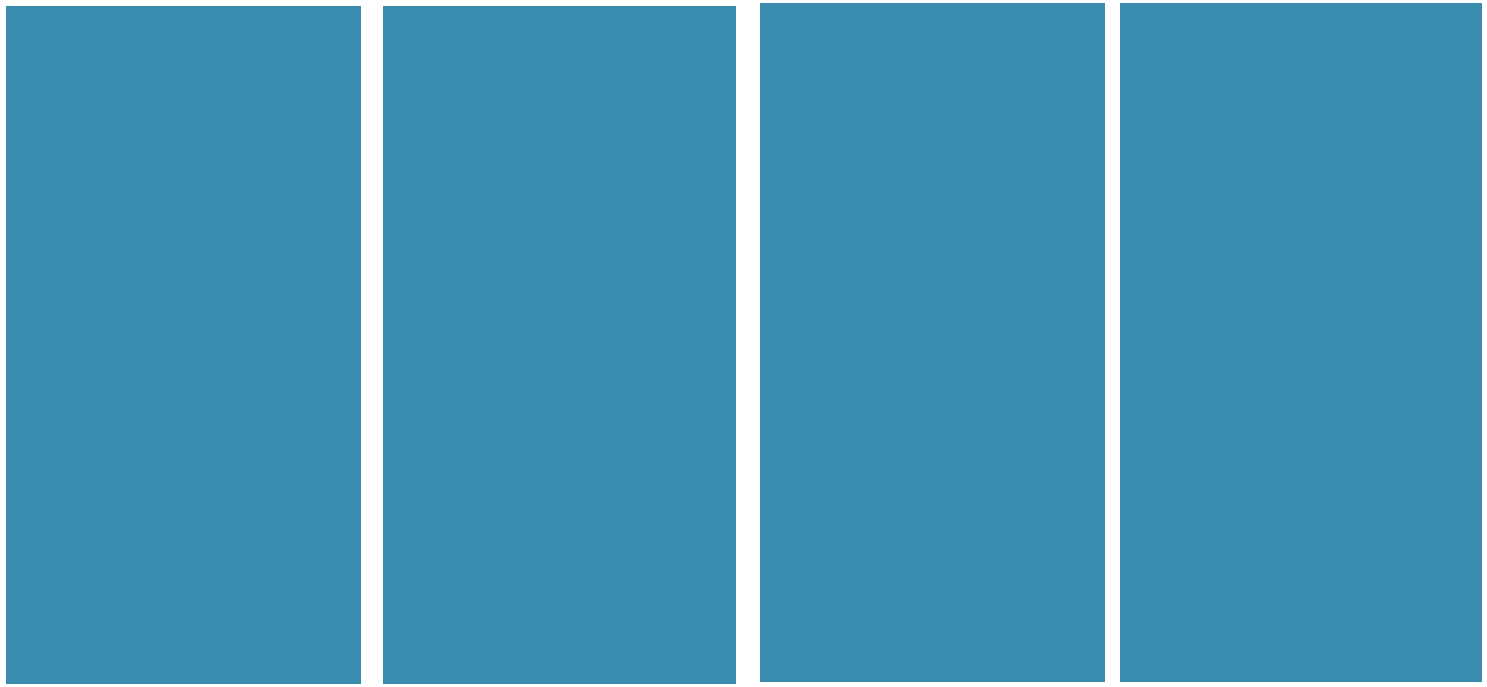
STEP 2

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.



Food Defense Plans and VA's with Safefood 360°

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.

STEP 3 :: Build VA – Flow Diagram

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

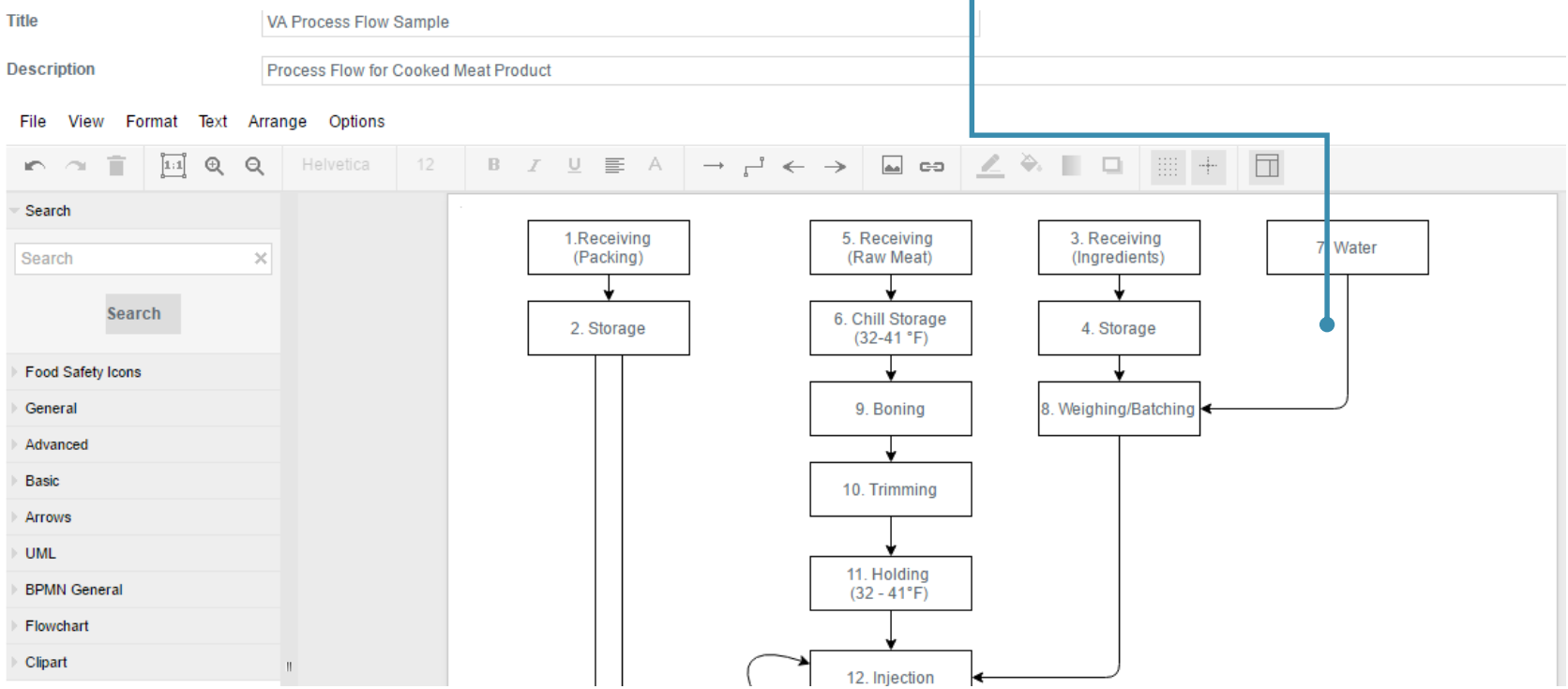
Title
Enter the title of the process flow diagram

Description
Enter a description for the process flow

Menus
Charting Menus

Tools
Charting Tools

Canvass
Draft your process flow diagram in this area



Practical Exercise – View Process Flow Diagram

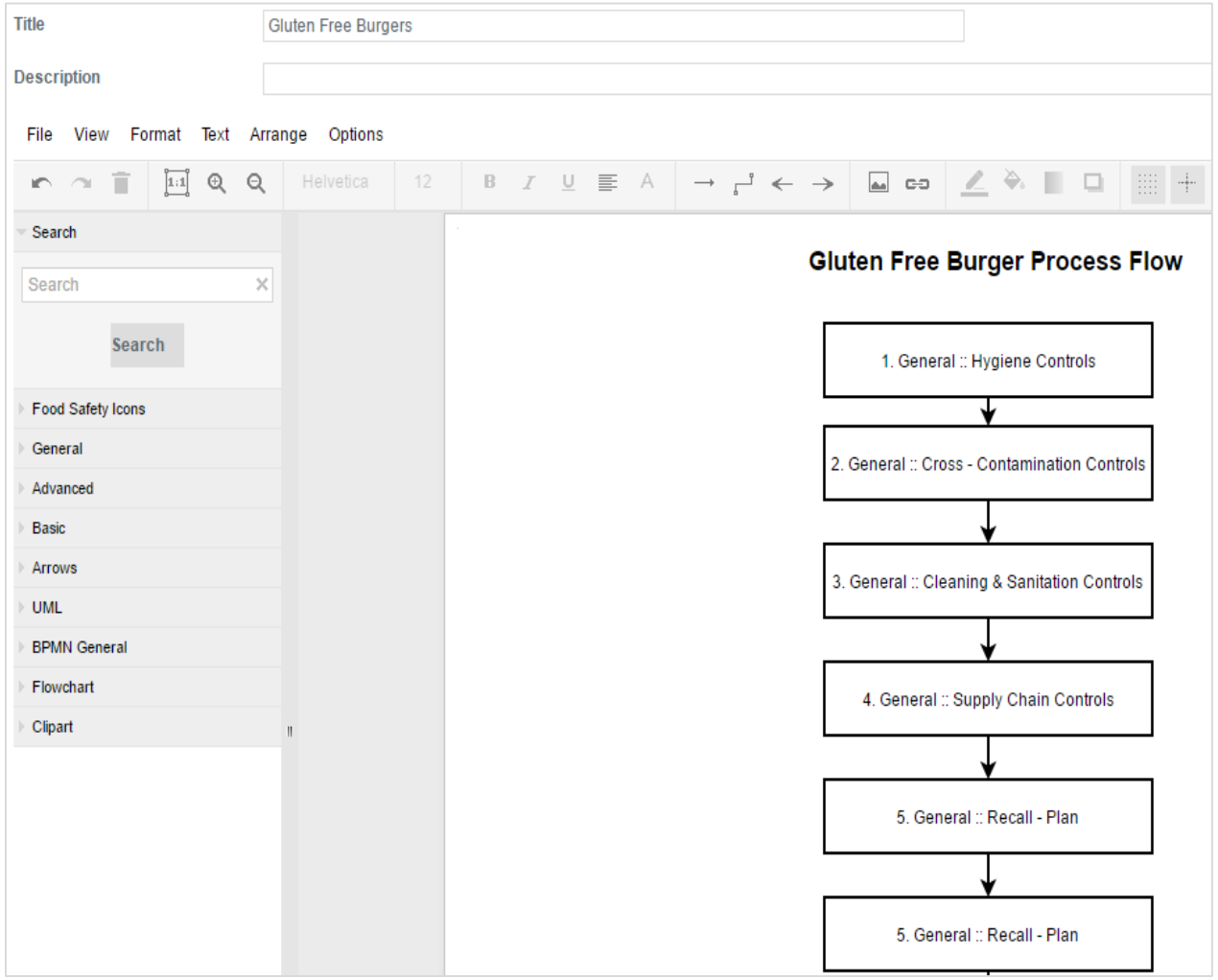
Task

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



Food Defense Plans and VA's with Safefood 360°

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 | STEP 2 | STEP 3 | STEP 4

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.

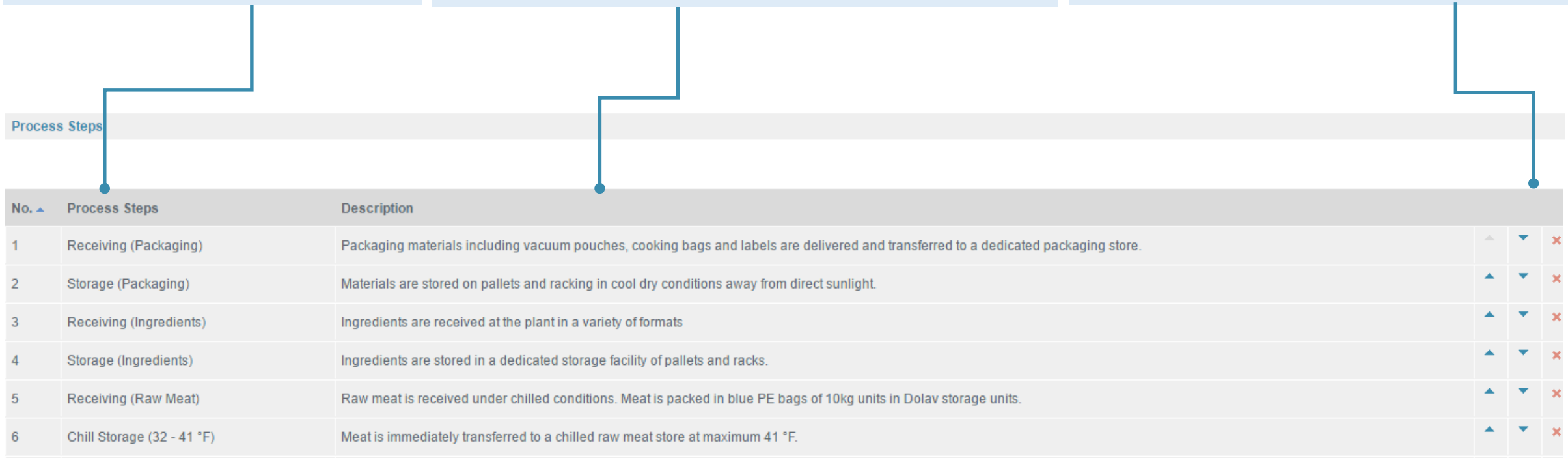
STEP 4 :: Build VA – Process Steps

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

Process Steps
Enter the name of the process step

Description
Provide a full description of the process step

Editing
Change the order of steps, add and remove steps



Food Defense Plans and VA's with Safefood 360°

Practical Exercise – Add a Process Step

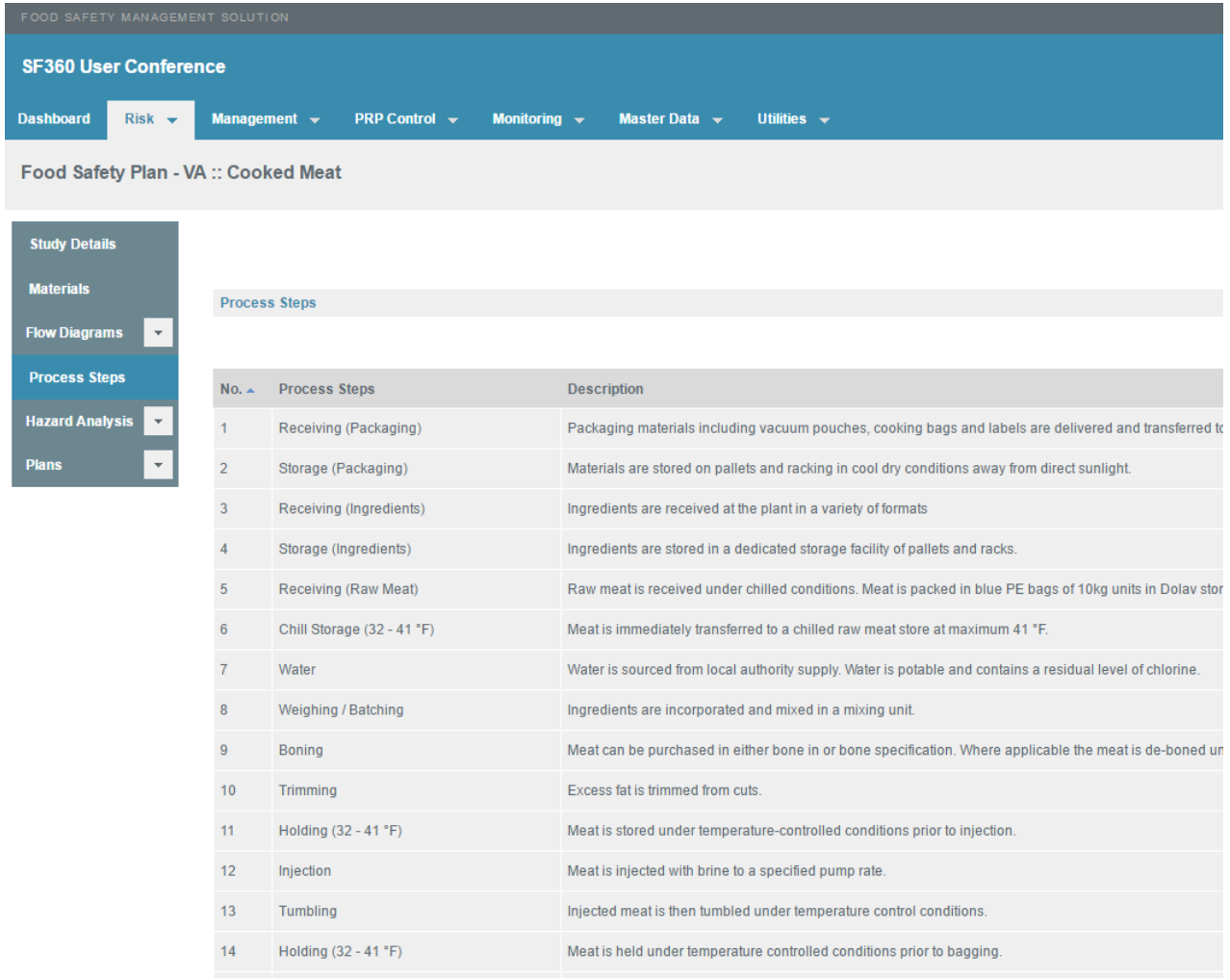
Task

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**



No.	Process Steps	Description
1	Receiving (Packaging)	Packaging materials including vacuum pouches, cooking bags and labels are delivered and transferred to
2	Storage (Packaging)	Materials are stored on pallets and racking in cool dry conditions away from direct sunlight.
3	Receiving (Ingredients)	Ingredients are received at the plant in a variety of formats
4	Storage (Ingredients)	Ingredients are stored in a dedicated storage facility of pallets and racks.
5	Receiving (Raw Meat)	Raw meat is received under chilled conditions. Meat is packed in blue PE bags of 10kg units in Dolav stor
6	Chill Storage (32 - 41 °F)	Meat is immediately transferred to a chilled raw meat store at maximum 41 °F.
7	Water	Water is sourced from local authority supply. Water is potable and contains a residual level of chlorine.
8	Weighing / Batching	Ingredients are incorporated and mixed in a mixing unit.
9	Boning	Meat can be purchased in either bone in or bone specification. Where applicable the meat is de-boned un
10	Trimming	Excess fat is trimmed from cuts.
11	Holding (32 - 41 °F)	Meat is stored under temperature-controlled conditions prior to injection.
12	Injection	Meat is injected with brine to a specified pump rate.
13	Tumbling	Injected meat is then tumbled under temperature control conditions.
14	Holding (32 - 41 °F)	Meat is held under temperature controlled conditions prior to bagging.

Food Defense Plans and VA's with Safefood 360°

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 5

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

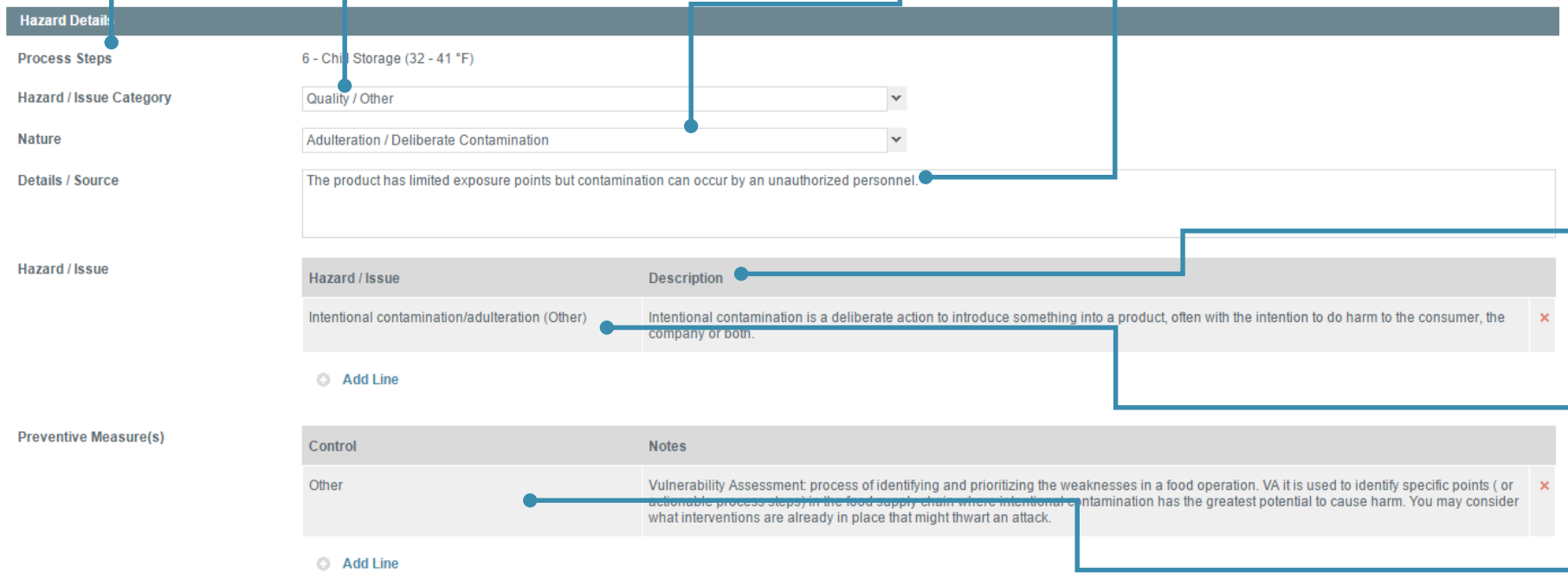
Hazard Details Section. In this section of the VA workflow you can identify vulnerabilities which may exist in the process for each process step.

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

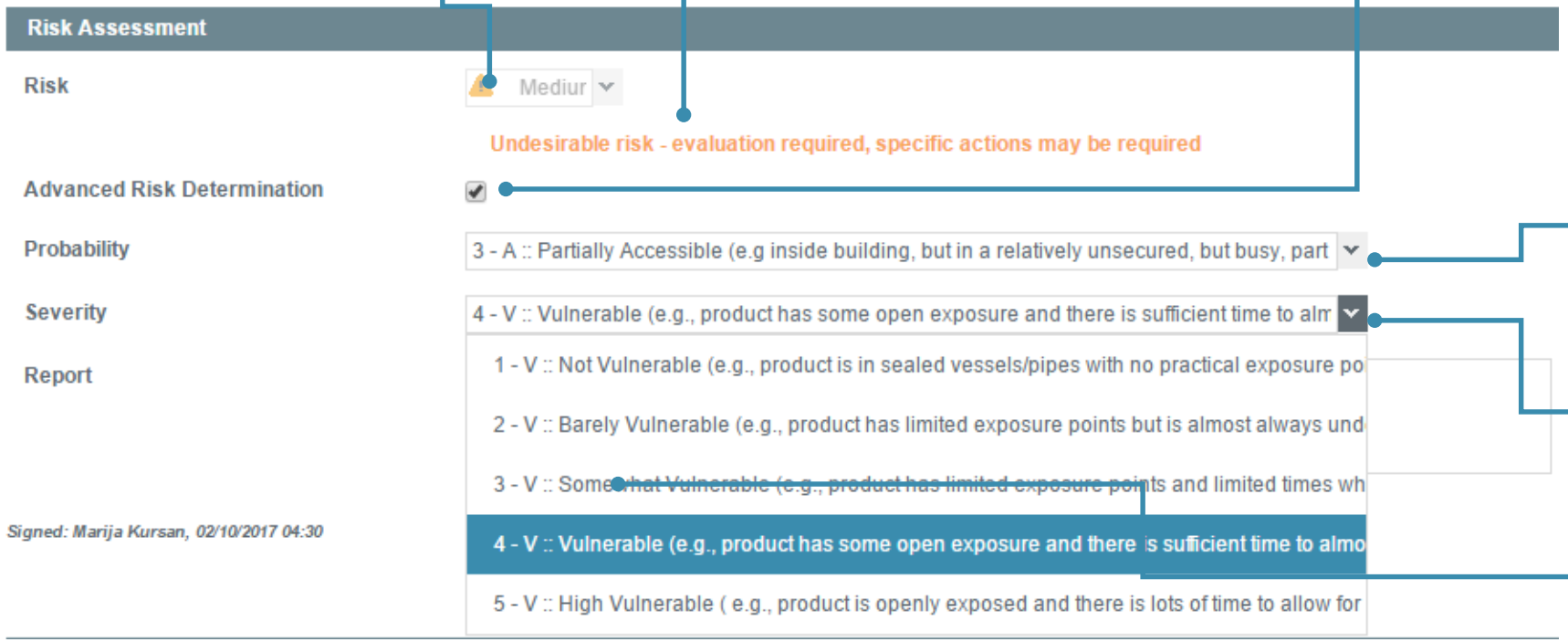
STEP 5 :: Build VA – Hazard Analysis – Risk Assessment Section

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

Risk
Used to conduct a simple risk assessment

Actions
Displays the required actions for the risk

Advanced Risk Assessment
Click to open the advance matrix risk assessment model



Probability
Select the probability ratings available

Severity
Select the severity ratings available

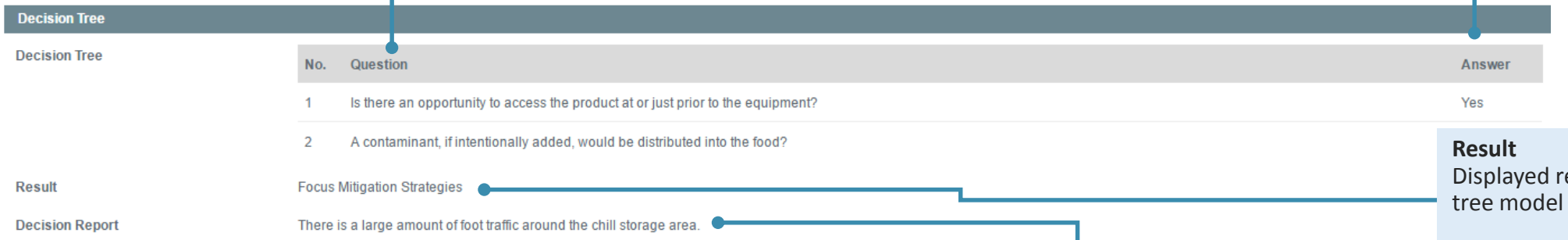
Rating
Select the appropriate rating for the hazard

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

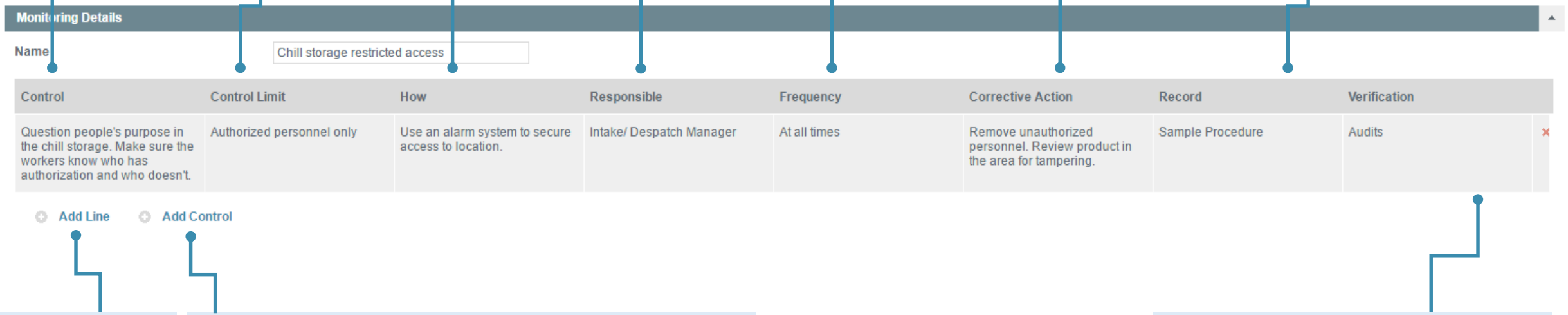
How
Enter the method for monitoring

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

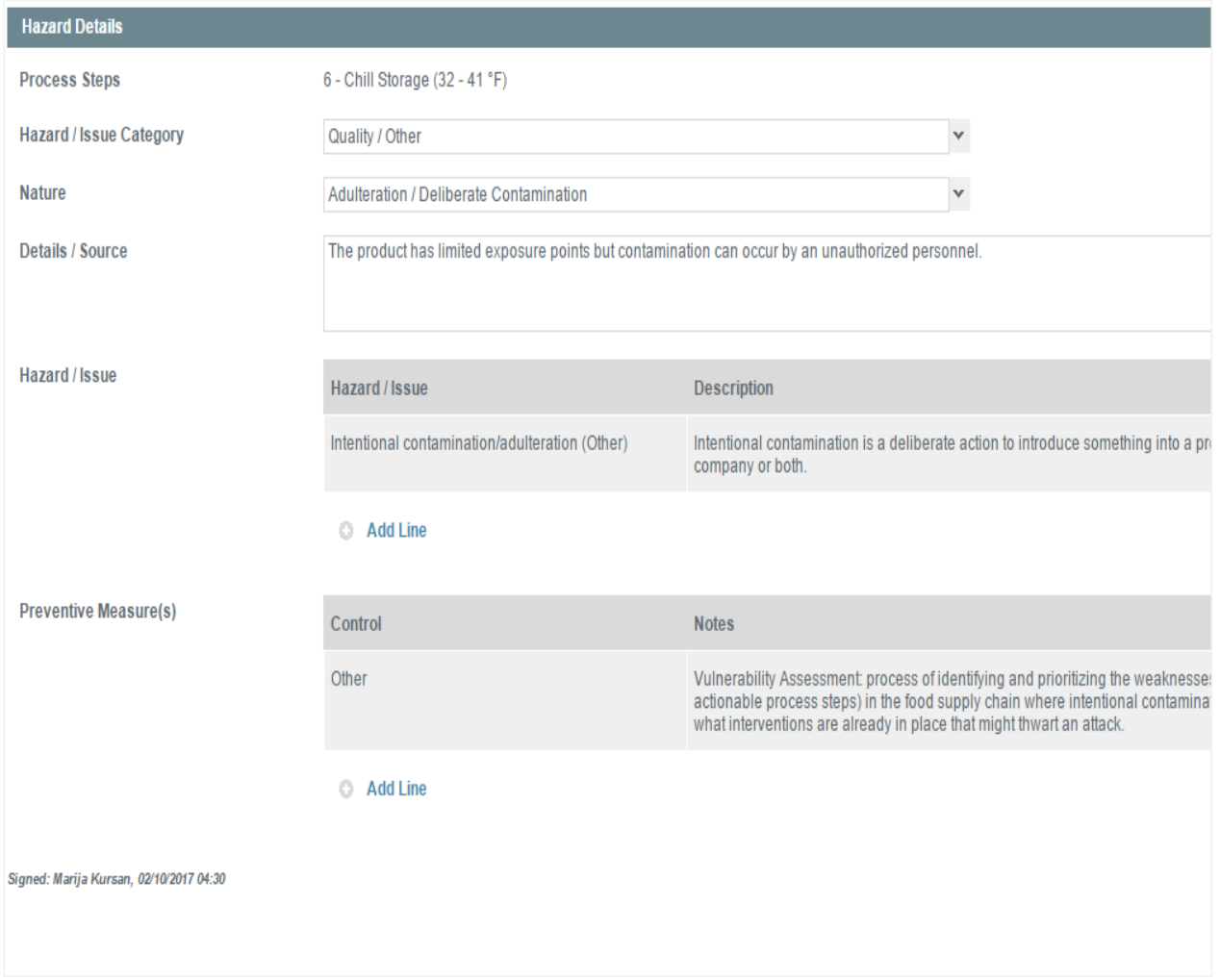
Task

Add new hazard to the VA and complete details

15 - 20 minutes

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**



Hazard Details

Process Steps	6 - Chill Storage (32 - 41 °F)
Hazard / Issue Category	Quality / Other
Nature	Adulteration / Deliberate Contamination
Details / Source	The product has limited exposure points but contamination can occur by an unauthorized personnel.

Hazard / Issue

Hazard / Issue	Description
Intentional contamination/adulteration (Other)	Intentional contamination is a deliberate action to introduce something into a pr company or both.

Add Line

Preventive Measure(s)

Control	Notes
Other	Vulnerability Assessment: process of identifying and prioritizing the weaknesse actionable process steps) in the food supply chain where intentional contamina what interventions are already in place that might thwart an attack.

Add Line

Signed: Marija Kursan, 02/10/2017 04:30

Food Defense Plans and VA's with Safefood 360°

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.

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.

Food Safety Plan - Focus Mitigation Strategies

No.	Hazard	Control	Control Limit	How	Frequency	Responsible	Corrective Action	Record	Verification
#1Drivers check-in & Ingredients check - (3 / Receiving (Ingredients))	Quality / Other: Adulteration / Deliberate Contamination (Intentional contamination/adulteration)	Ingredients	All ingredients are sealed no evidence of tampering	Visual check	At each delivery	Intake/ Despatch Manager	Reject delivery if any evidence of tampering	Sample Procedure	Audit
#1Drivers check-in & Ingredients check - (3 / Receiving (Ingredients))	Quality / Other: Adulteration / Deliberate Contamination (Intentional contamination/adulteration)	Drivers	All drivers need to check-in	Drivers identification	At each delivery	Intake/ Despatch Manager	Reject delivery if any evidence of tampering	Sample Procedure	Audit
#2Storage restricted access - (4 / Storage (Ingredients))	Quality / Other: Adulteration / Deliberate Contamination (Intentional contamination/adulteration)	Question people's purpose in the warehouse. Make sure the workers know who has authorization and who doesn't.	Authorized personnel only	Use an alarm system to secure access to location,	At all times	Intake/ Despatch Manager	Remove unauthorized personnel. Review materials in the area for tampering.	Sample Procedure	Audits
#3Drivers check-in & Raw materials check - (5 / Receiving (Raw Meat))	Quality / Other: Adulteration / Deliberate Contamination (Intentional contamination/adulteration)	Raw materials	All Raw Materials ar covered no evidence of tampering	Visual check	At each delivery	Intake/ Despatch Manager	Reject delivery if any evidence of tampering	Sample Procedure	Audits
#3Drivers check-in & Raw materials check - (5 / Receiving (Raw Meat))	Quality / Other: Adulteration / Deliberate Contamination (Intentional contamination/adulteration)	Drivers	All drivers need to check-in	Drivers identification	At each delivery	Intake/ Despatch Manager	Reject delivery if any evidence of tampering	Sample Procedure	Audits

Food Defense Plans and VA's with Safefood 360°

Practical Exercise – View VA Plan

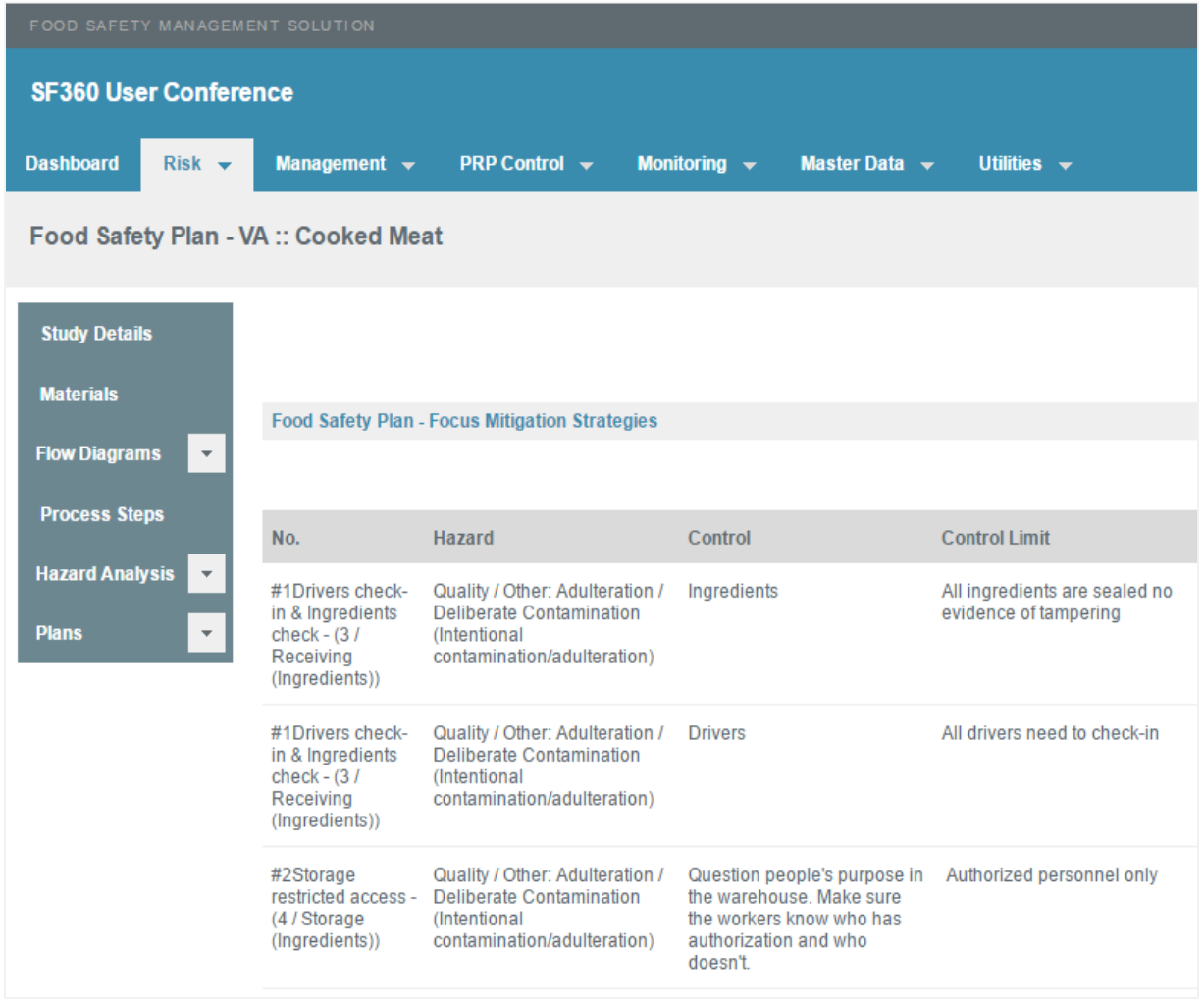
Task

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



Food Defense Plans and VA's with Safefood 360°

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

Action Plan

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.

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 in 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°

Practical Exercise – View Corrective Action

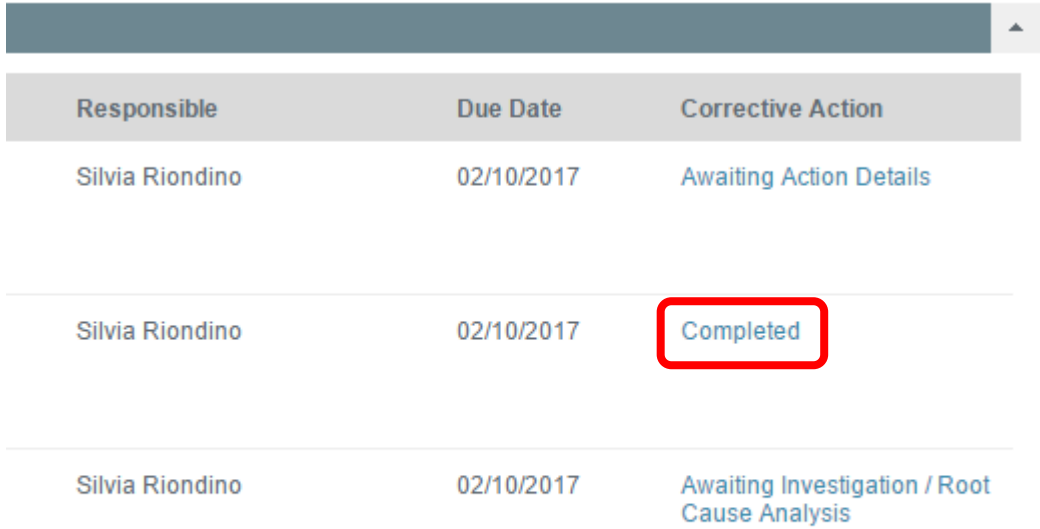
Task

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



Responsible	Due Date	Corrective Action
Silvia Riondino	02/10/2017	Awaiting Action Details
Silvia Riondino	02/10/2017	Completed
Silvia Riondino	02/10/2017	Awaiting Investigation / Root Cause Analysis