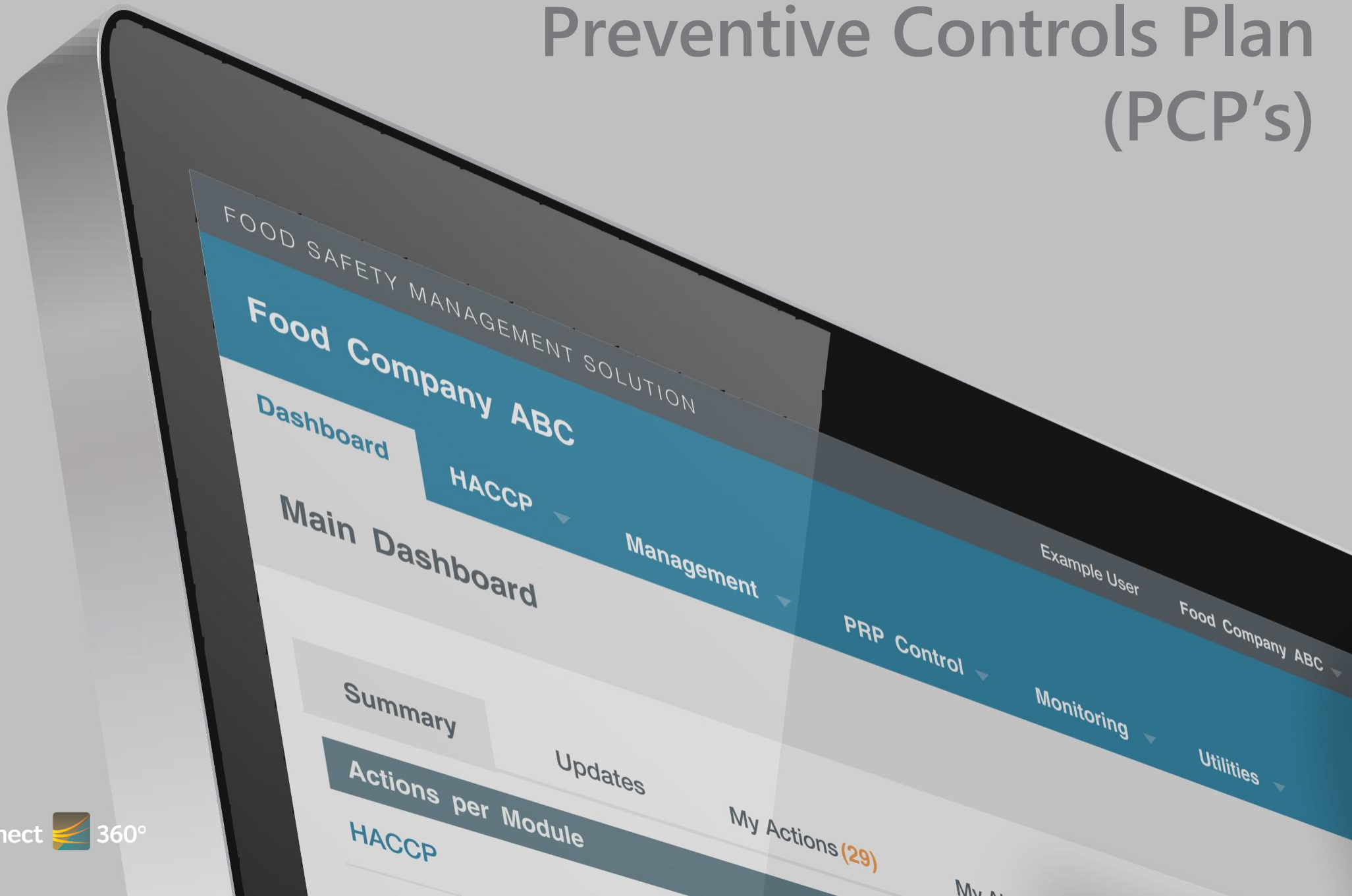
User Conference

Preventive Controls Plan (PCP's)



Safefood 360°

connect 360°

Preventive Control Plans (PCP's) with Safefood 360°

Session Overview

Purpose:
- To review the FSMA requirements for preventive controls.
- To thoroughly understand the PCP capabilities of the Risk Module.
- To build an example PCP plan in the SF360 software

Session Leader:
- George Howlett, CEO, Safefood 360

Timing:
- 105 Minutes

Agenda:
- Some Interesting Fact about FSMA and PCP's
- Useful Supporting Information
- What is a Preventive Controls Plan (PCP)
- Three Building Blocks of a PCP Plan
  - Risk Assessment Model
  - Decision Tree Model
  - Complete a PCP Plan
- Practical Exercises

Preventive Control Plans (PCP's) with Safefood 360°

Some Interesting Facts about Preventive Controls

All FSMA Final Rules Call for PC's	**225,000** Domestic Food Businesses	**300,000 +** Foreign Business
PCQI Must Develop PCP Plan	**PCP Plans** Complex in Nature	**PCP Plans** Are Not the Same as HACCP

Preventive Control Plans (PCP's) with Safefood 360°

Useful Supporting Information

Safefood 360 reference sources of information for building PCP Plans Safefood 360.

Type	Name	Location
Blog	The difference between HACCP and HARPC. A case of the Emperor's New Clothes?	http://safefood360.com/2016/05/the-difference-between-haccp-and-harpc/
Web Site	FSMA Final Rule for Preventive Controls for Human Food	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm
Web Site	FSMA Final Rule for Preventive Controls for Animal Food	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm
Website	FSMA Final Rule on Sanitary Transportation of Human and Animal Food	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm
Fact Sheet	FSMA Compliance Dates	http://www.gmaonline.org/file-manager/FSMA%20Compliance%20Dates(5).pdf

Preventive Control Plans (PCP's) with Safefood 360°

Deadlines

General Compliance Period

Proposed Rule	Final Rule	Requirement	Deadline
Preventive Controls for Human Food	8-30-15	1 year after final rule	8-30-16
Preventive Controls for Animal Feed	8-30-15	1 year after final rule	8-30-16
Produce Safety	10-31-15	2 years + 60 days from final rule*	12-31-17
Foreign Supplier Verification Program	10-31-15	18 months from final rule†	4-31-17
3rd Party Accreditation and Certification	10-31-15	After Model Accreditation Standards‡	-
Sanitary Transportation	3-31-16	1 year from final rule	3-31-16
Food Defense	5-31-16	1 year + 60 days from final rule	7-31-17

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Objectives of Today's Session

FSMA Preventive Controls Requirements

Safefood 360 Food Safety Plan Solution

Practical Exercises

Preventive Control Plans (PCP's) with Safefood 360°

FSMA and PCP Plans - FSMA Final Rule for Preventive Controls for Human Food

What does FSMA want in regard to PCP Plans?

→	HUMAN FOODS RULE :: Subpart C Hazard Analysis and Risk Based Preventive Controls. § *117.126 Food safety plan*
→	The food safety plan must be prepared by one or more preventive controls qualified individuals (PCQI) § *117.126 a2*
→	PCP plan must include written hazard analysis § *117.130(a)(2)*
→	PCP plan must include written preventive controls § *117.135(b)*
→	PCP plan must include written procedures for monitoring § *117.145(a)(1), corrective action § 117.150(a)(1) and verification § 117.165(b)*
→	Hazard analysis to identify and evaluate, based on experience and data, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at facility to determine whether there are any hazards requiring a preventive control. § *117.130(a1)*

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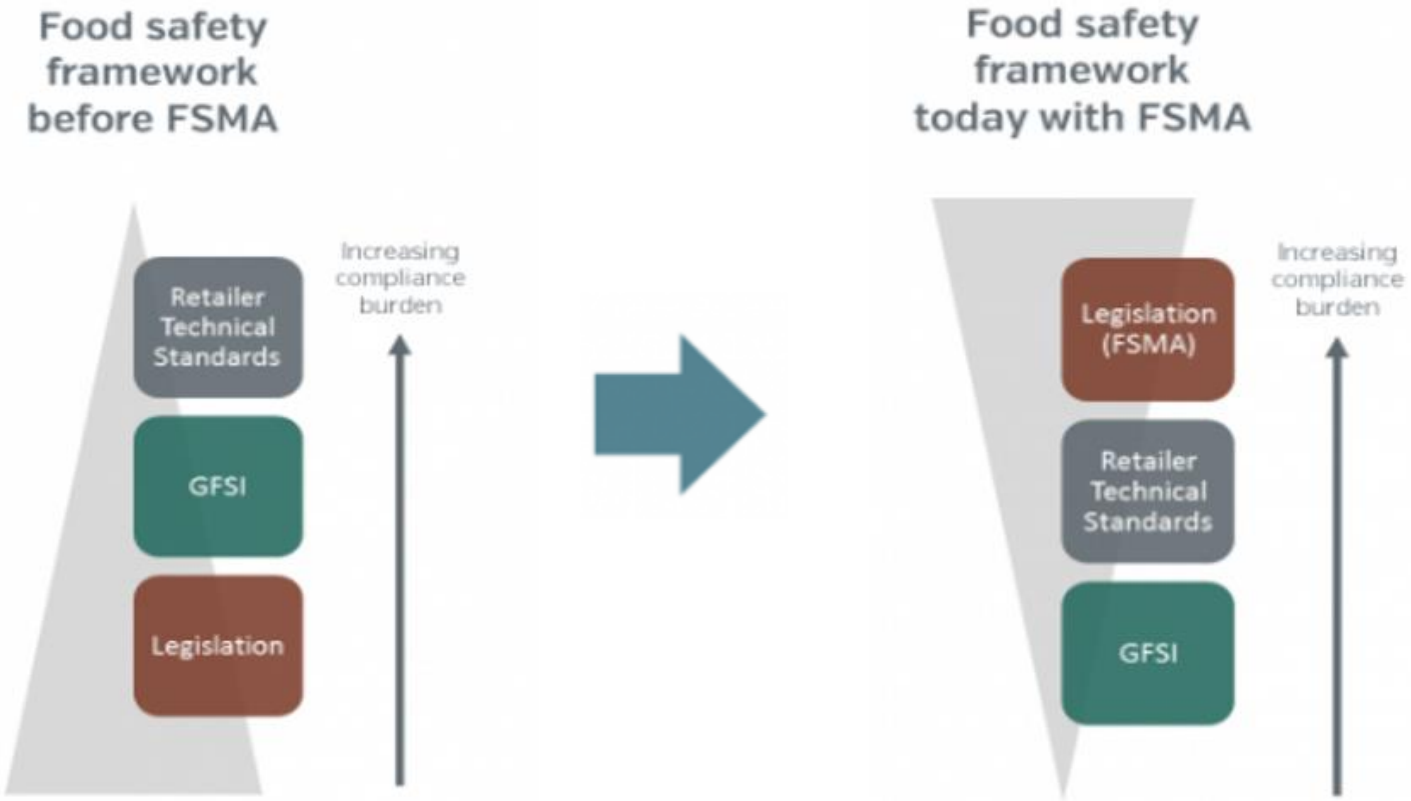
Changing Food Safety Management Framework

FSMA has changed the framework for food safety management by exceeding the requirements previously set down by GFSI standards. .



Preventive Control Plans (PCP's) with Safefood 360°

What is a PCP Plan?

A Preventive Control Plan (PCP) is a risk assessment and management system legally required under FSMA

- HAZARDS – Company must identified Hazards in the supply chain and process which may require a Preventive Control
- RISK ASSESSMENT – Company must analysis these hazard and determine which ones are significant
- PREVENTIVE CONTROLS – Company must put in place controls designed to reduce or control significant risks
- DOCUMENT – Company must document the above for inspection and audit
- RISK – PCP plans are essentially a Risk Management tool similar to HACCP
- SYSTEMATIC – Best practice dictates that a systematic and scientific approach should be adopted in preparing PCP plans

Preventive Control Plans (PCP's) with Safefood 360°

What is a PCP Plan?

PCP Plans require full planning for controls beyond the traditional CCP.

Preventive Control Plans (PCP's) with Safefood 360°

What are Preventive Control?

Critical Control Points (CCP's)
- Thermal Processing
- Freezing
- Chemical Preservation
- Other Lethal Processes

Operational Pre-requisites (oPRP's)
- Metal Detection
- Detection and Scanning
- Filtering and Sieving
- Chilling / Refrigeration

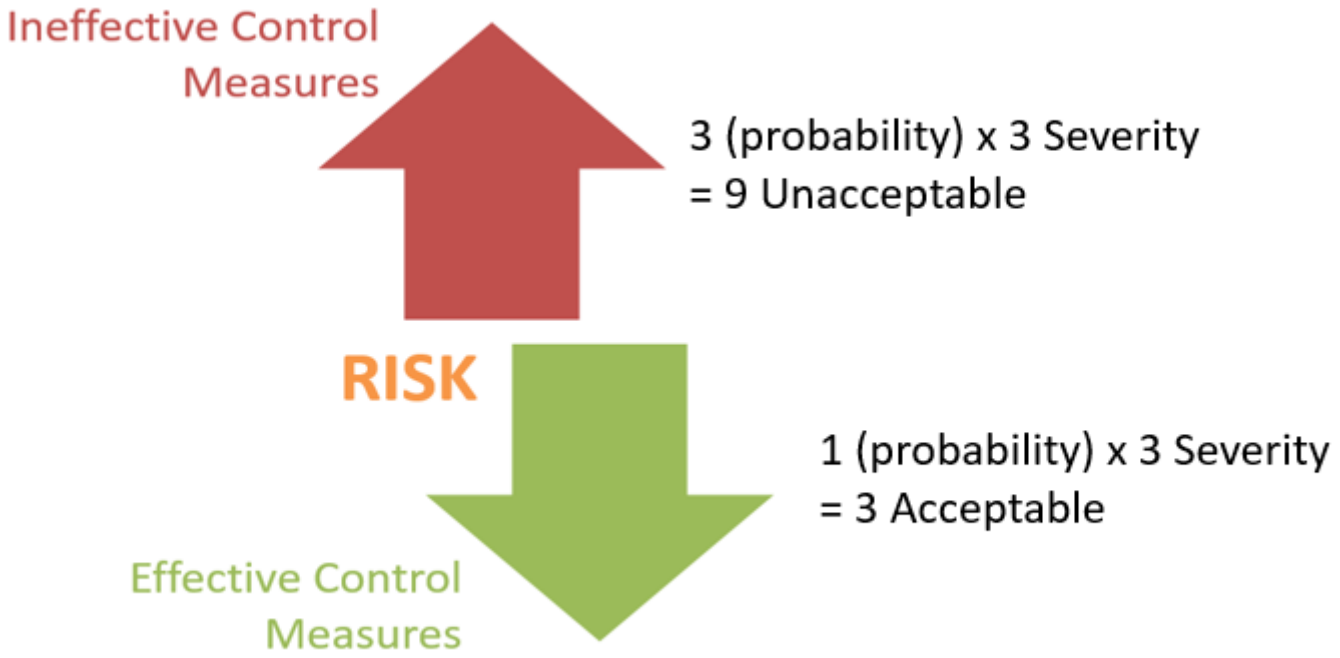
General Pre-requisites (oPRP's)
- Cleaning & Sanitizing
- Plant and Equipment
- Employee Facilities
- Calibration
- Maintenance
- Personal Hygiene
- Contamination Controls

FSMA Specific Preventive Controls

The following a specifically required under FSMA Rules
- Supply Chain Control
- Training
- Product Recall System
- Process Controls - heat processing, acidifying, irradiating, and refrigerating foods
- Food Allergen Control
- Labelling
- Sanitation Controls

The Role of Risk Mitigation from Preventive Controls

Application of Preventive Controls is designed to reduce the likelihood of a hazard creating an adverse health impact. Preventive Controls only impact on the Probability and NOT the Severity



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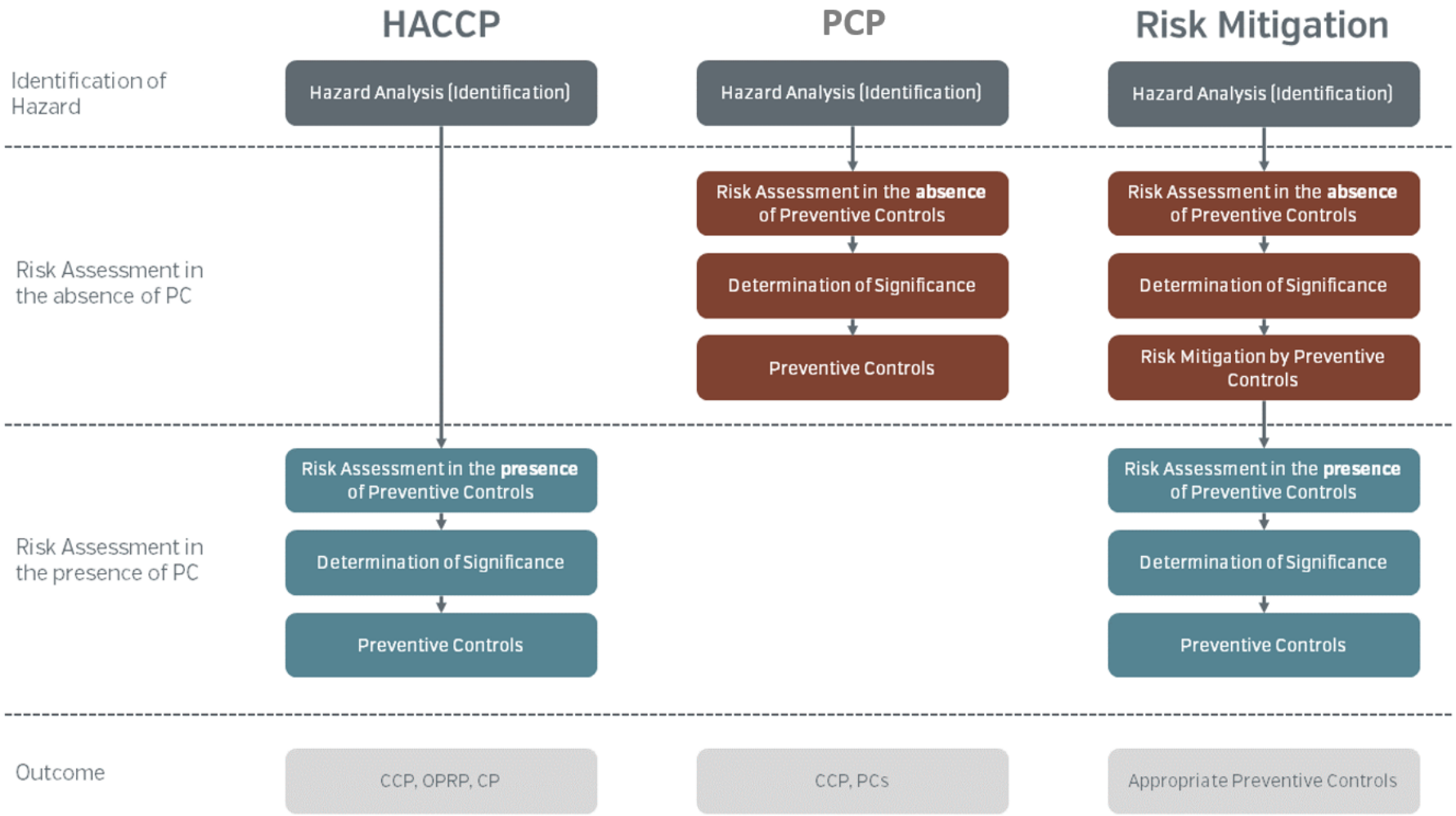
Difference between HACCP and PCP Plans

The graph depicts the key difference between HACCP and PCP plans and the role of risk mitigation.



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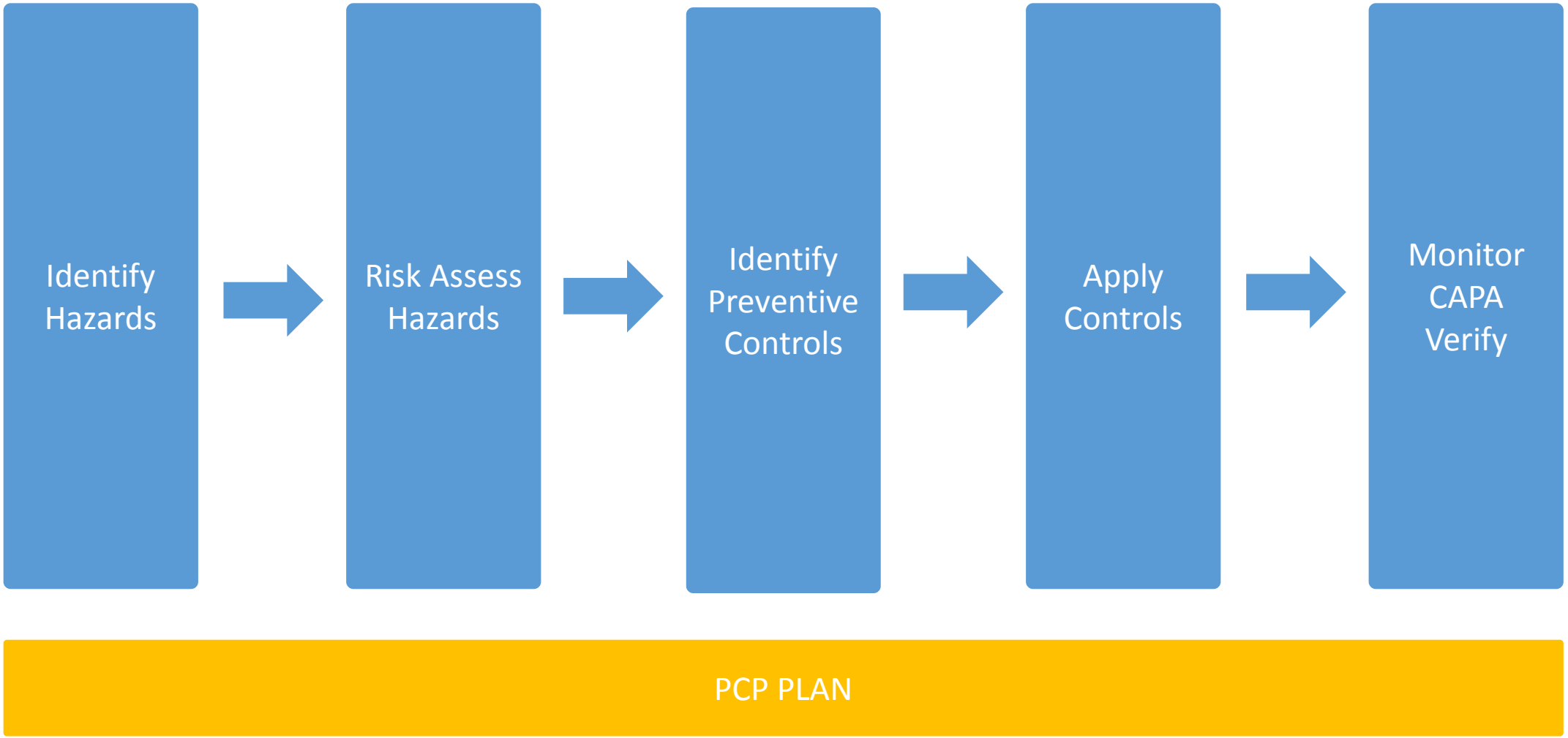
So What Do You Need To Do?



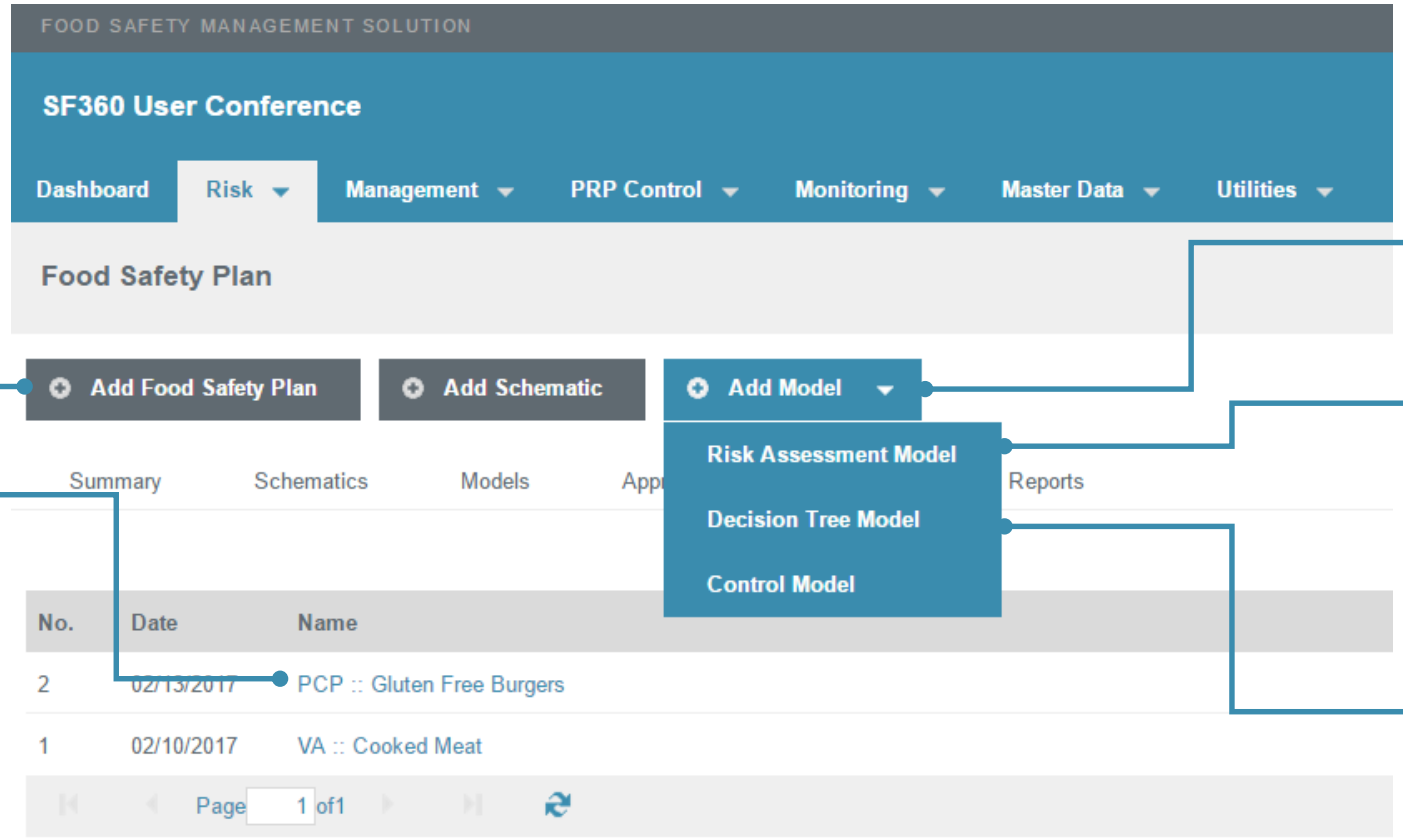
Preventive Control Plans (PCP's) with Safefood 360°

Food Safety Plan Module

PCP Plans developed and managed in the **Risk** centre under the **Food Safety Plans** module.

Add Food Safety Plan
Used to create a new PCP plan.

PCP Plans
Used to access / view / edit / copy / delete existing PCP plans



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.

Preventive Control Plans (PCP's) with Safefood 360°

Three Building Blocks of a Preventive Control Plan (PCP)

The three building blocks of a PCP plan include RA Model, Decision Tree Model and PCP Plan.

Risk > Food Safety Plan > Food Safety Plan

- Food Safety Plan is used to build your PCP plan based on a defined workflow
- Addresses FSMA requirements
- Final output is a PCP Plan listing all control details

Risk > Food Safety Plan > Decision Tree Model

- Decision Tree Model is a logical question / answer decision tree
- Used to determine the appropriate controls to be used at a specific process step
- User can replicate their existing decision trees in SF360

Risk > Food Safety Plan > Risk Assessment Model

- Risk Assessment Model is usually a matrix
- Probability x Severity = Risk
- User can define the ratings for both probability and severity for use in PCP building

Preventive Control Plans (PCP's) with Safefood 360°

Risk Assessment Models

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

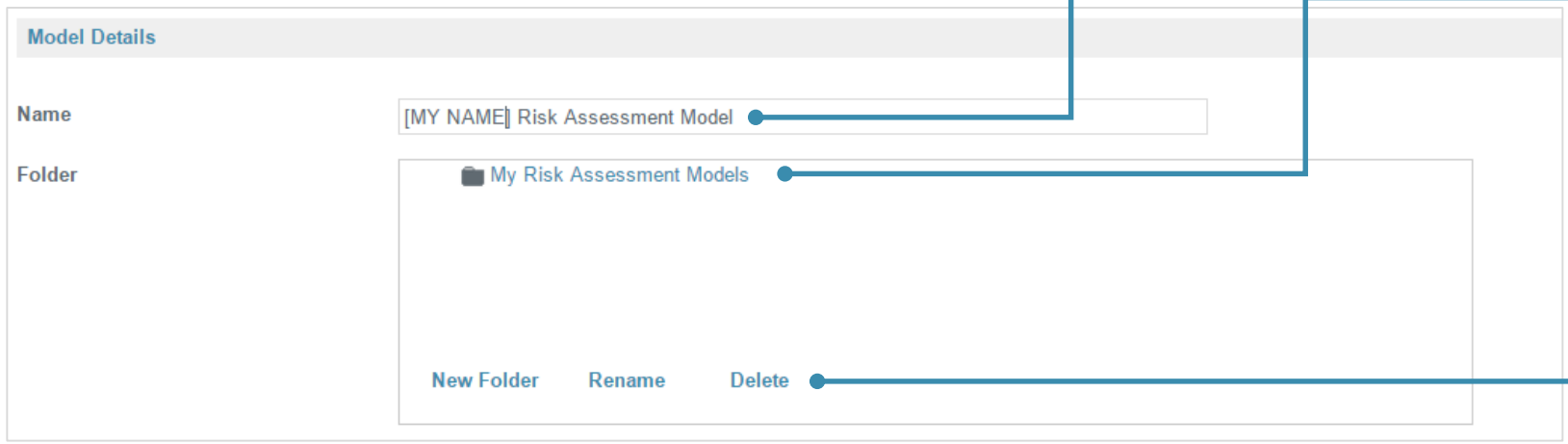
Risk Assessment Models

- Risk Assessment models are used to assist PCQI's determine which hazards are significant and require a preventive control
- SF360 allows you build your own Matrix Risk Assessment models or use predefined SF360 FSMA ready models
- Most models are matrix based with two factors. Probability x Severity = Risk
- Risk are usually defined as High / Medium / Low. High and Medium risks are usually consider significant and require a control measure

		Severity				
		Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Probability	Rare (1)	1	2	3	4	5
	Unlikely (2)	2	3	6	8	10
	Possible (3)	3	6	9	12	15
	Likely (4)	4	8	12	16	20
	Almost Certain (5)	5	10	15	20	25

Creating a Risk Assessment Model (Part 1)

Model Details Section - Name and Folder. Details are entered.



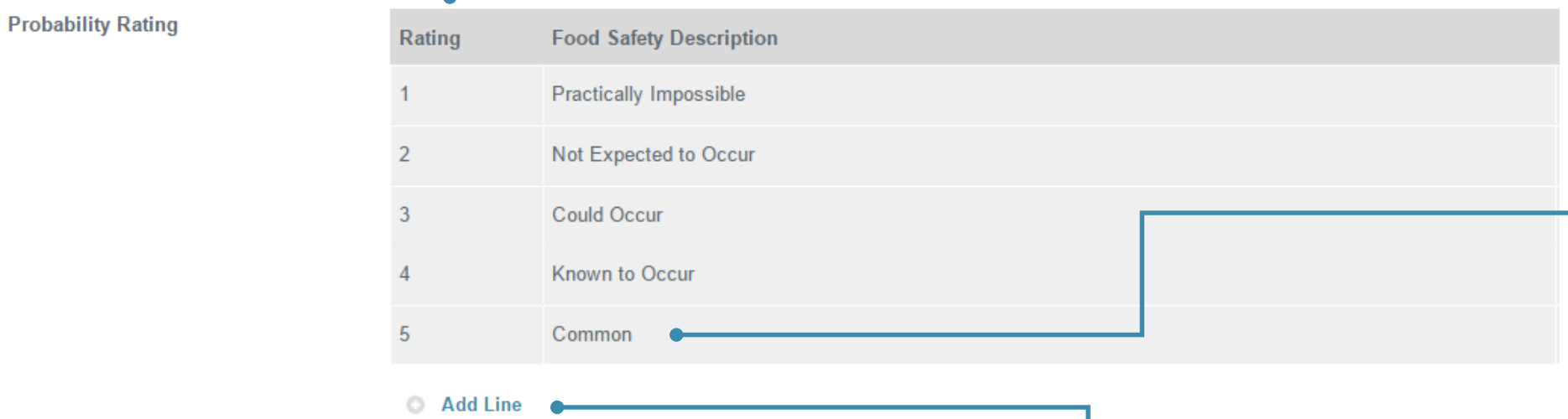
Name
The name should be sufficiently descriptive, particularly with many models.

Folder
A good idea to bucket similar models into folders so that they can be easily found.

Folder Control
This is useful to create new, rename and delete folders

Creating a Risk Assessment Model (Part 2)

Model Details Section - Probability Rating. The probability rating is built by clicking Add Line. If a 5 x 5 matrix is to be used then you will click until 5 rating lines are open.



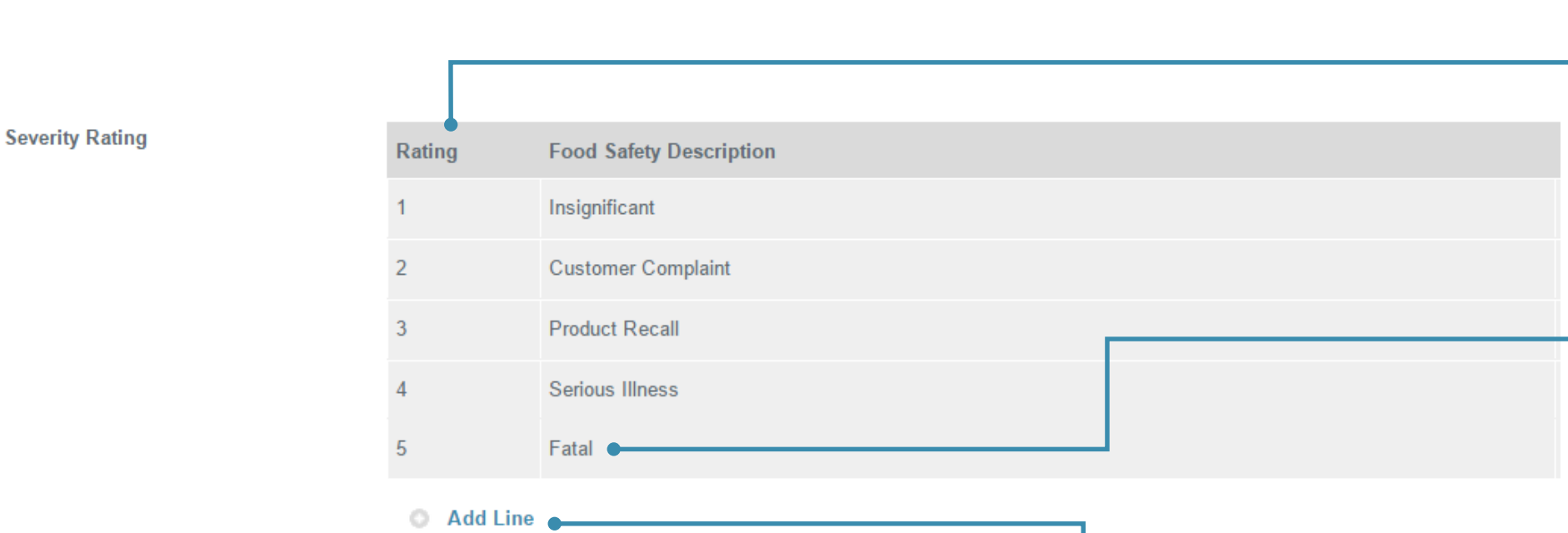
Rating
The rating is the value assigned to the food safety description. NOTE: The ratings are in ascending order where 1 = lowest risk while 5 is the highest risk in this example.

Food Safety Description
This describes the rating value so that the PCQI can select the correct one.

Add Line
Use to add the required number of lines for risk ratings.

Creating a Risk Assessment Model (Part 3)

Model Details Section - Severity Rating. The severity rating is built by clicking Add Line. If a 5 x 5 matrix is to be used then you will click until 5 rating lines are open.



Rating
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Food Safety Description
This describes the rating value so that the PCQI can select the correct one.

Add Line
Use to add the required number of lines for risk ratings.

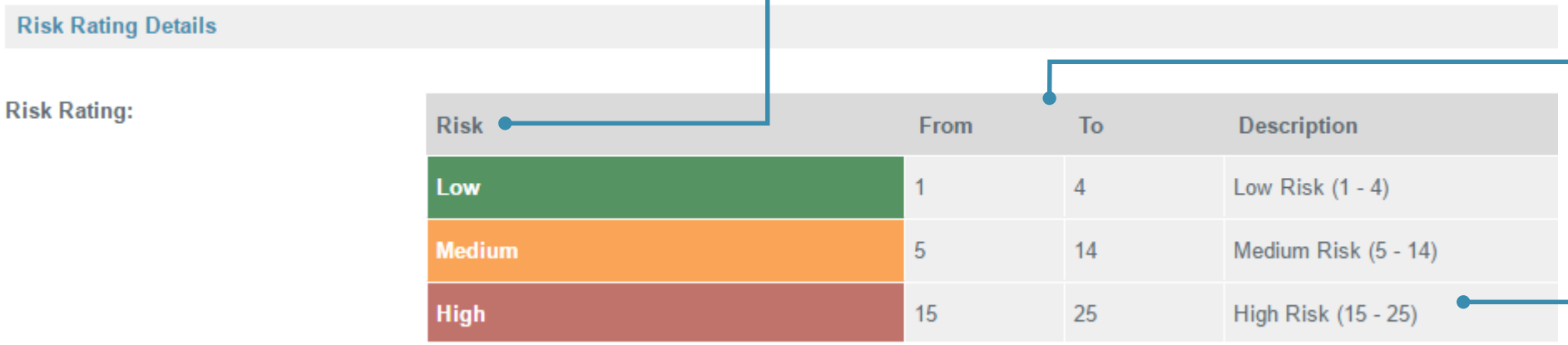
Creating a Risk Assessment Model

Risk Rating Details. In this section you define the ranges for risk e.g. High / Medium / Low.

Risk
Risk is defined as either High, Medium or Low. Low is considered to be not significant while Medium and High are considered significant.

From To (Range)
This defines the range of value (from / To) which apply to the risk

Description
Provides explanation of the value ranges to assist the PCQI.



Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – Create Risk Assessment Model

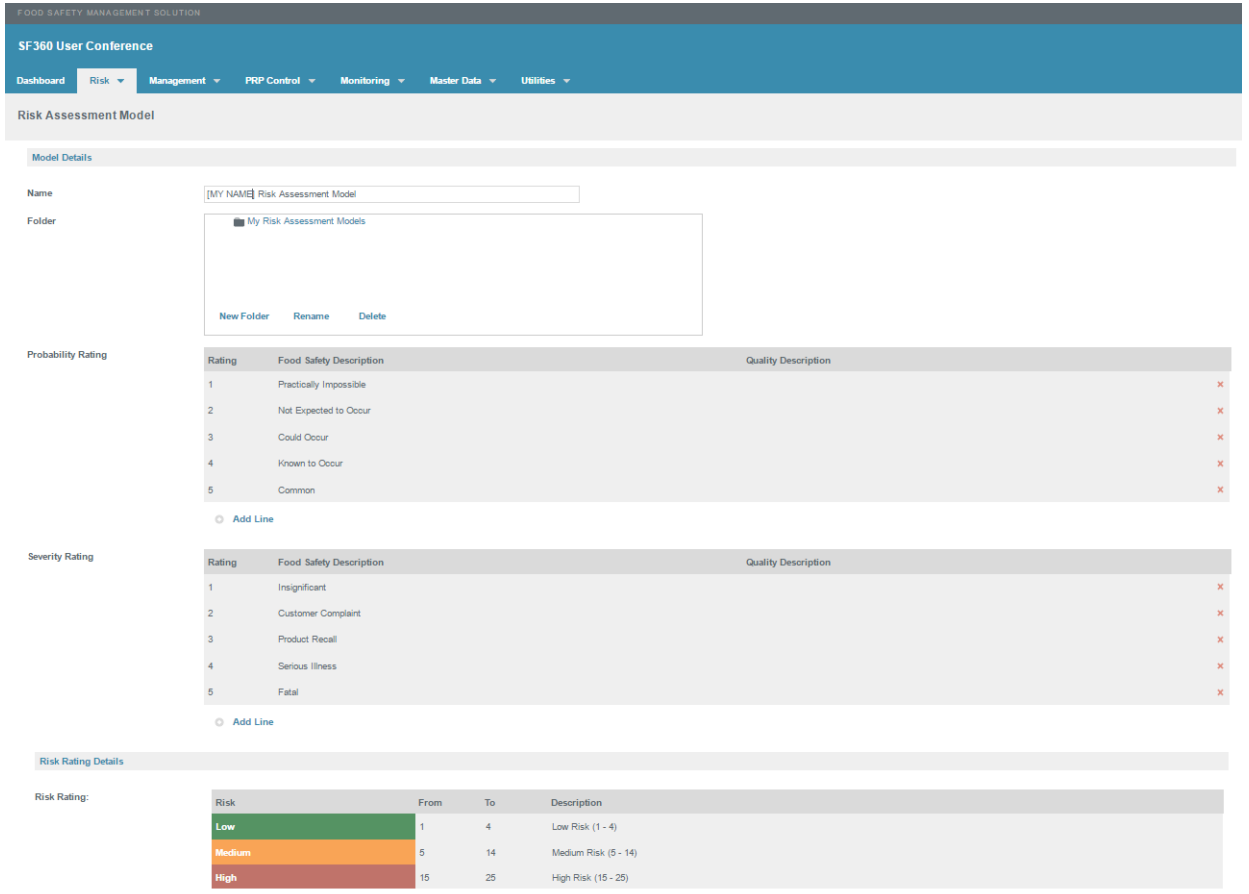
Task

Create a Risk Assessment Model (5 x 5 matrix) in the risk centre

10-15 minutes

Instructions

- Click **Risk** > **Food Safety Plan** > **Add Model** > **Risk Assessment Model**
- Complete Model Name – use [MY NAME – RISK ASSESSMENT]
- Complete Probability Rating
- Complete Severity Rating
- Complete Risk Rating Details



Preventive Control Plans (PCP's) with Safefood 360°

Three Building Blocks of a Preventive Control Plan (PCP)

The three building blocks of a PCP plan include RA Model, Decision Tree Model and PCP Plan.

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Risk > Food Safety Plan > Decision Tree Model

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- User can replicate their existing decision trees in SF360

Risk > Food Safety Plan > Risk Assessment Model

- Risk Assessment Model is usually a matrix
- Probability x Severity = Risk
- User can define the ratings for both probability and severity for use in PCP building

Decision Tree Models

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

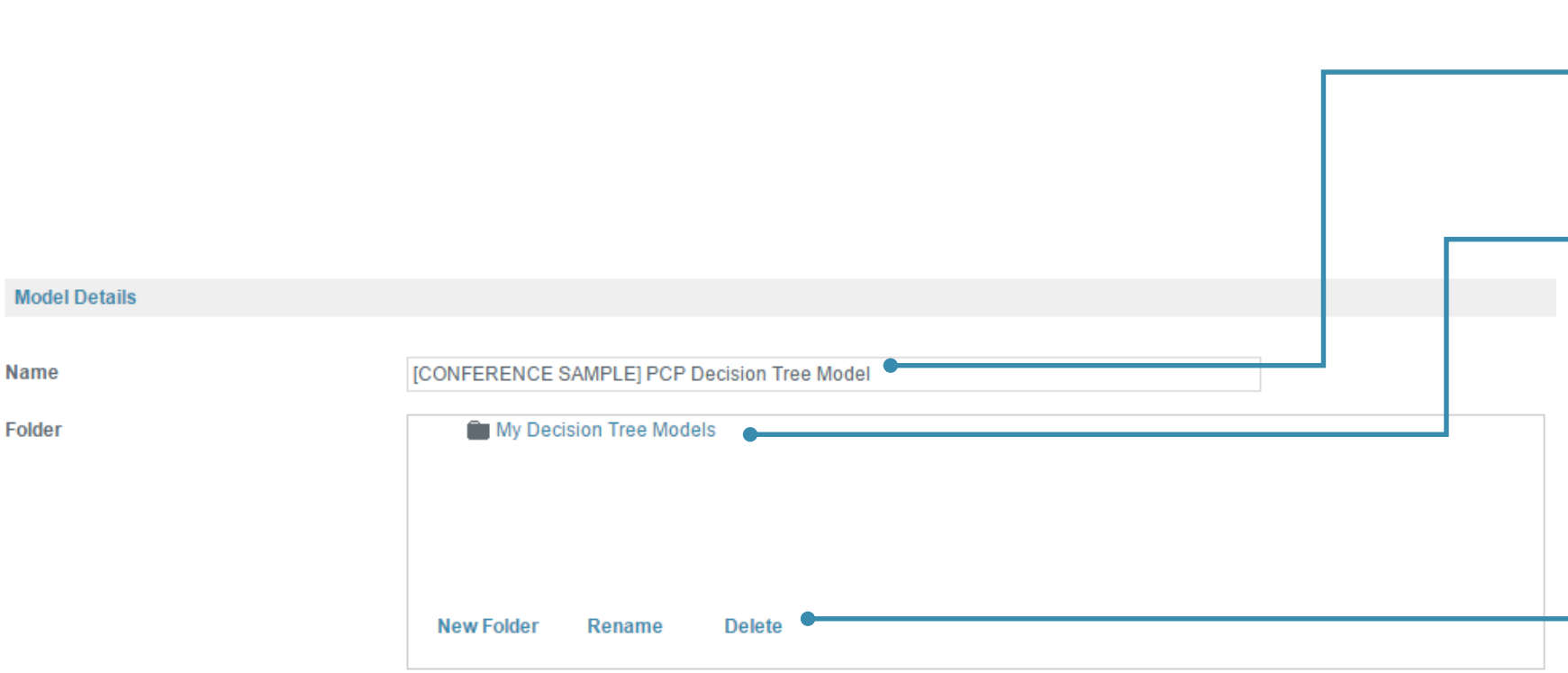
Decision Tree Models

- Decision Tree Models are used to assist PCQI's determine which controls measures are required to address the identified hazard
- SF360 allows you build your own Decision Tree models or use predefined SF360 FSMA ready models
- Decision Trees are a sequence of questions which when answered all you determine what control(s) if any required for the step
- Under FSMA controls may include CCP's, PRP's, and other procedures

No.	Question	Yes Decision	Monitor?	No Decision	Monitor?
1	Can the food type (determined and documented) be consumed without application of an appropriate control?	Preventive Control Not Required	No	Go to 2	
2	Do we rely on an internal appropriate control to ensure that the indentified hazard will be significantly minimized or prevented?	Go to 4		Go to 3	

Creating a Decision Tree Model (Part 1)

Model Details Section - Name and Folder. Details are entered.



Name
The name should be sufficiently descriptive, particularly with many models.

Folder
A good idea to bucket similar models into folders so that they can be easily found.

Folder Control
This is useful to create new, rename and delete folders

Creating a Decision Tree Model (Part 2)

Model Details Section – Decision Tree. In this section you create specific questions and define the Yes and No answer outputs. This may include directing the PCQI to the next question, indicating that control is required and no control is required and to STOP the process.

No.
This is the questions number

Question
Each question is a closed question with either a yes or no answer or decision. Questions seek to determine some aspect or characteristic about the hazard e.g. can the food

Yes / No Decision
A yes or no Decision will drive the PCQI to either another question of a final decision to have a control or no control

Monitor
Selecting Yes will open the control planning section

No.	Question	Yes Decision	Monitor?	No Decision	Monitor?
1	Can the food type (determined and documented) be consumed without application of an appropriate control?	Preventive Control Not Required	No	Go to 2	
2	Do we rely on an internal appropriate control to ensure that the indentified hazard will be significantly minimized or prevented?	Go to 4		Go to 3	
3	Do we rely on the customer or an entity subsequent to the customer, who is subject to the requirements for PCHF rule to ensure that the identified hazard will be significantly minimized or prevented: or where not subject to PCHF rule provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety standards?	Preventive Control Not Required - Document disclosure of hazard required - Obtain annually customer assurances	No	Stop purchase and distribution of product until requirements are addressed	No
4	Is this Step specifically designed to prevent or eliminate the hazard or reduce it to an acceptable level?	CCP - Preventive Control - CCP	Yes	Go to 5	
5	Could contamination occur or increase to an unacceptable level?	Go to 6		Preventive Control Not Required	No
6	Will a subsequent Step eliminate or reduce the hazard to an acceptable level?	Preventive Control Not Required	No	Go to 7	
7	Is the hazard addressed under a Preventive Control - General?	Go to 8		Go to 9	
8	Will this Step of the hazard workflow be used to define and monitor the Preventive Control - General?	PRP - Preventive Control - General	Yes	Stop	No
9	Is the Preventive Control specific to this Step?	oPRP - Preventive Control - Specific - This Step	Yes	Modify	No

Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – Create Decision Model

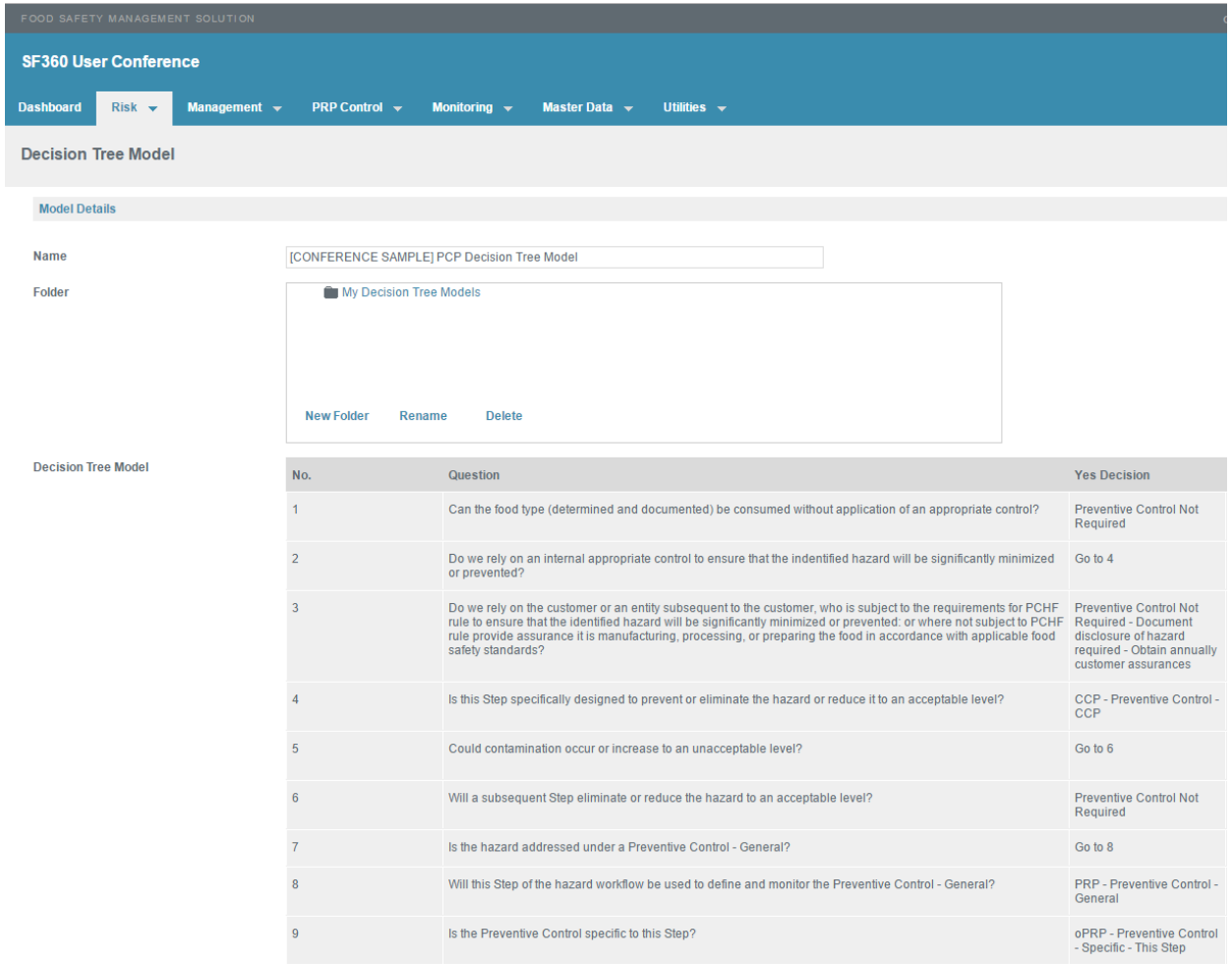
Task

Create a Decision Model in the risk centre

10-15 minutes

Instructions

- Click **Risk** > **Food Safety Plan** > **Add Model** > **Decision Tree Model**
- Complete Model Name – use [MY NAME – DECISION TREE]
- Complete Question 1 "Can the food be consumed without application of an appropriate control?"
- YES DECISION enter – "Preventive Control Not Required" and select NO for Monitor
- NO DECISION select – GO TO QUESTION 2
- Complete Question 2 "Will the customer or consumer apply an appropriate control?"
- YES DECISION enter – "Preventive Control Not Required"
- NO DECISION select – "Preventive Control Required"
- MONITOR for NO DECISION – select YES



No.	Question	Yes Decision
1	Can the food type (determined and documented) be consumed without application of an appropriate control?	Preventive Control Not Required
2	Do we rely on an internal appropriate control to ensure that the indentified hazard will be significantly minimized or prevented?	Go to 4
3	Do we rely on the customer or an entity subsequent to the customer, who is subject to the requirements for PCHF rule to ensure that the identified hazard will be significantly minimized or prevented: or where not subject to PCHF rule provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety standards?	Preventive Control Not Required - Document disclosure of hazard required - Obtain annually customer assurances
4	Is this Step specifically designed to prevent or eliminate the hazard or reduce it to an acceptable level?	CCP - Preventive Control - CCP
5	Could contamination occur or increase to an unacceptable level?	Go to 6
6	Will a subsequent Step eliminate or reduce the hazard to an acceptable level?	Preventive Control Not Required
7	Is the hazard addressed under a Preventive Control - General?	Go to 8
8	Will this Step of the hazard workflow be used to define and monitor the Preventive Control - General?	PRP - Preventive Control - General
9	Is the Preventive Control specific to this Step?	oPRP - Preventive Control - Specific - This Step

Preventive Control Plans (PCP's) with Safefood 360°

Three Building Blocks of a Preventive Control Plan (PCP)

The three building blocks of a PCP plan include RA Model, Decision Tree Model and PCP Plan.

Build PCP Plan

Risk > Food Safety Plan > Food Safety Plan

- Food Safety Plan is used to build your PCP plan based on a defined workflow
- Addresses FSMA requirements
- Final output is a PCP Plan listing all control details

Create Decision Tree

Risk > Food Safety Plan > Decision Tree Model

- Decision Tree Model is a logical question / answer decision tree
- Used to determine the appropriate controls to be used at a specific process step
- User can replicate their existing decision trees in SF360

Create RA Model

Risk > Food Safety Plan > Risk Assessment Model

- Risk Assessment Model is usually a matrix
- Probability x Severity = Risk
- User can define the ratings for both probability and severity for use in PCP building

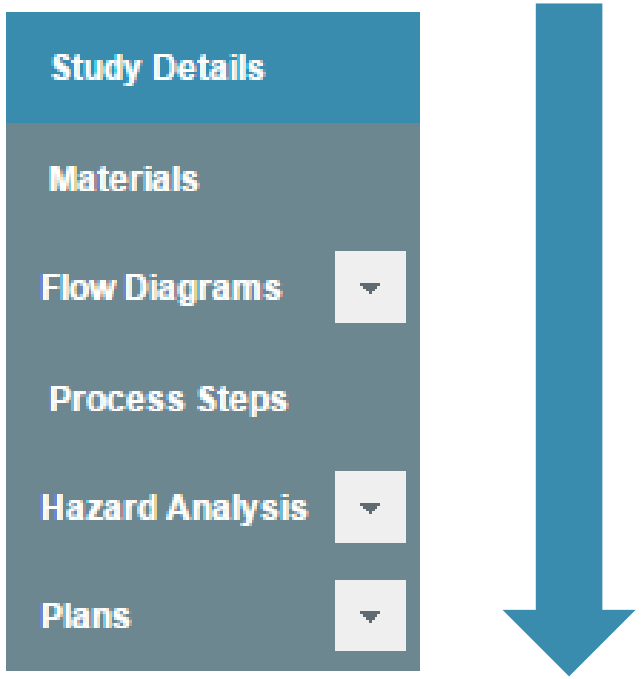
Preventive Control Plans (PCP's) with Safefood 360°

Preventive Control Plans (PCP's)

Risk > Food Safety Plans > Add Food Safety Plan

Food Safety Plans

- Preventive Control Plans are created and located in the Risk centre under the Food Safety Plan module.
- PCQI's can build any number of PCP plans.
- They contain a standard workflow to assist the PCQI in preparing plans in a structured and systematic way.
- PCP plans are usually focused on a specific process or product
- They address both General and Specific controls
- Workflow covers all the requirements for FSMA



Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – Copy Example PCP Plan

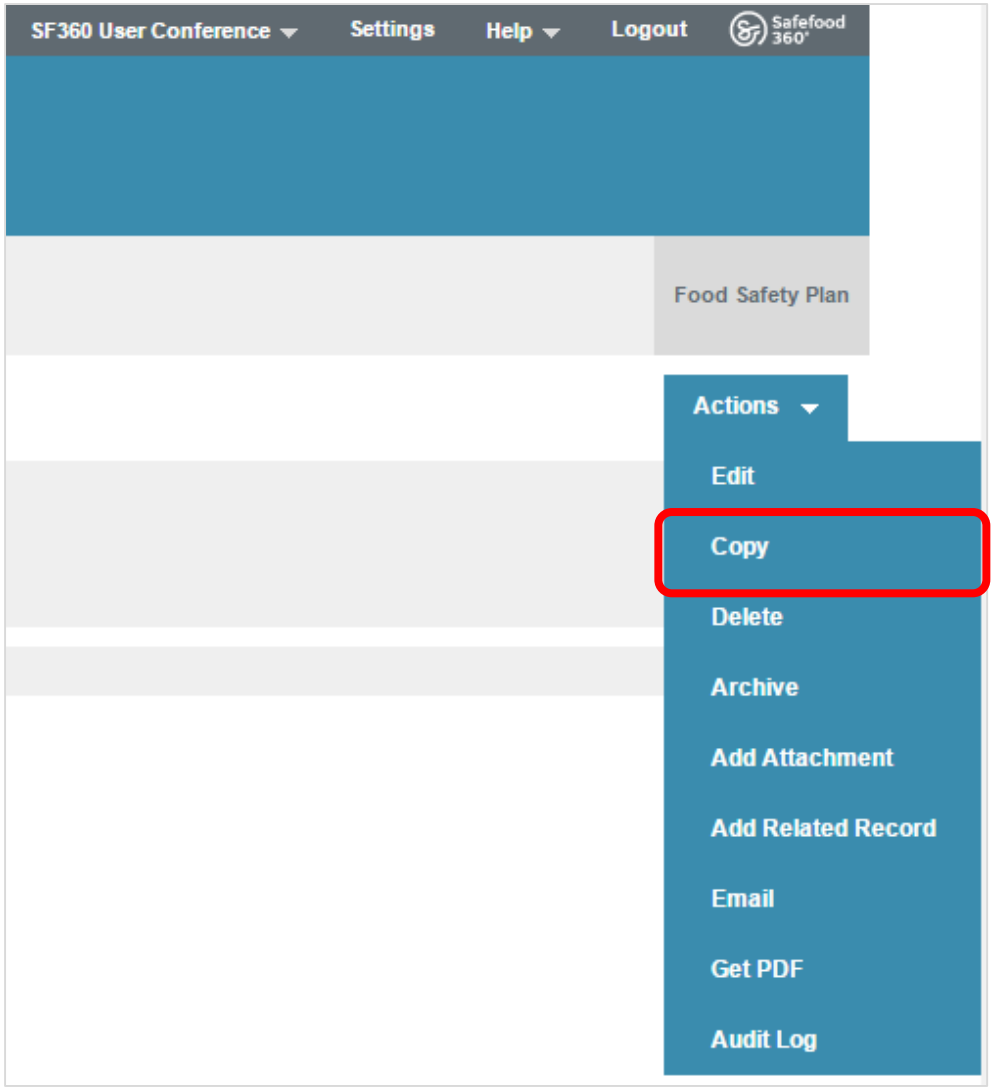
Task

Copy Example PCP Plan in Safefood 360

5 minutes

Instructions

- Click **Risk** > **Food Safety Plan** > **Actions (Tab)**
- Click [PCP :: Gluten Free Burgers] in the table
- In the PCP plan 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**



Preventive Control Plans (PCP'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

Study Details

- Define the scope of your PCP plan
- Where it starts (e.g. materials) and finishes (e.g. delivery to the final customer)
- Define your team members including PCQI's
- Define product and process details
- Select models to be used in the PCP plan

Materials

- Link the materials, ingredients, packaging used in the manufacture of the product
- Displays the Risk arising from your material assessments in the Supplier Control Module

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 hazards at each step of the process
- Determine the risk of each hazard
- Determine is controls are required
- Plan you control activities

PCP Plans

- Automatic building of your final PCP plans
- Approval of PCP plans by your PCQI's

Preventive Control Plans (PCP'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

Study Details

- Define the scope of your PCP plan
- Where it starts (e.g. materials) and finishes (e.g. delivery to the final customer)
- Define your team members including PCQI's
- Define product and process details
- Select models to be used in the PCP plan

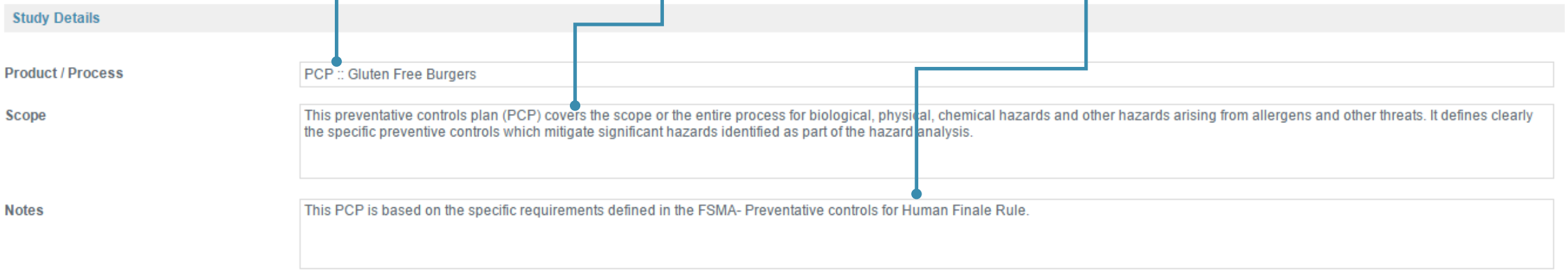
STEP 1 :: Build PCP Plan – Study Details (Part 1)

Study Details Section. General details of the PCP plan including name.

Product / Process
Define the name of the product or process under study for PCP plan development

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

Notes
Enter any additional or relevant notes supporting the PCP plan study.



Preventive Control Plans (PCP's) with Safefood 360°

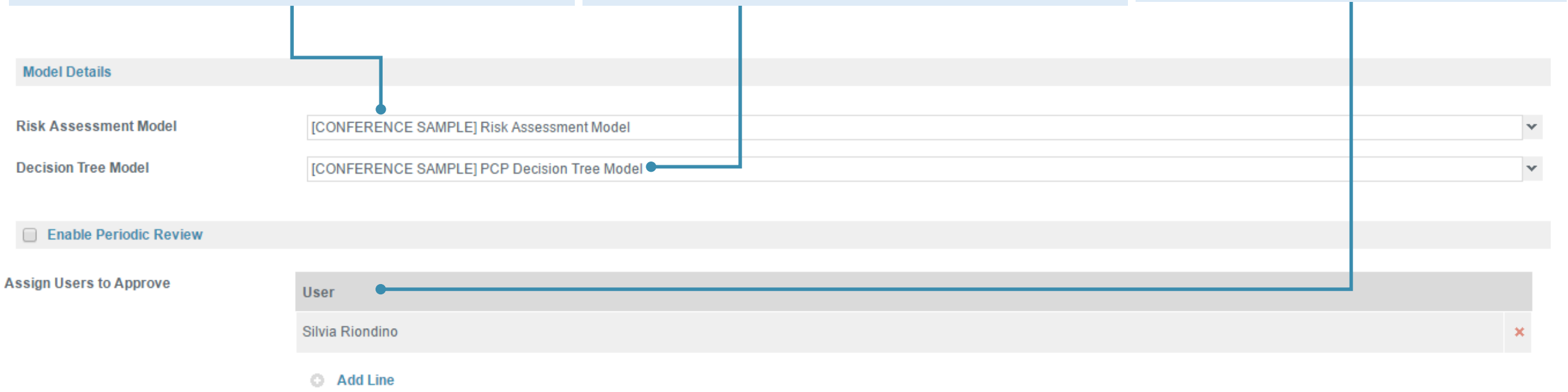
STEP 1 :: Build PCP Plan – Model Details (Part 2)

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

Risk Assessment Model
Select the Risk Assessment Model you wish to use in the PCP plan

Decision Tree Model
Select the Decision Tree Model you wish to use in the PCP plan

Assign Users to Approve
Select those members of your team who will approve the PCP plan



Preventive Control Plans (PCP's) with Safefood 360°

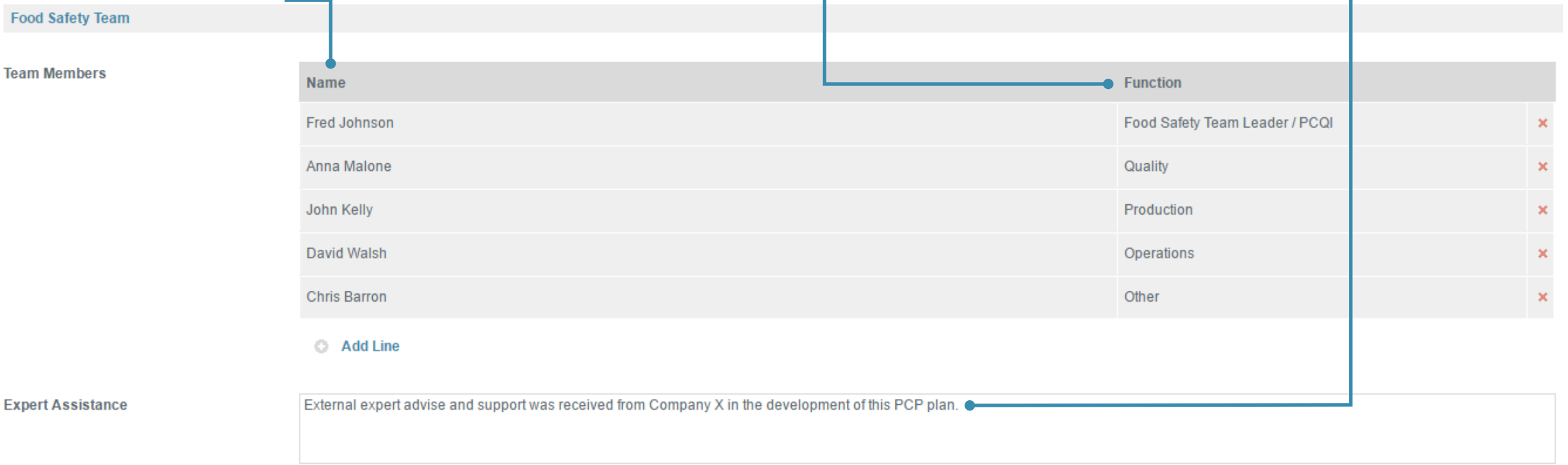
STEP 1 :: Build PCP Plan – Food Safety Team (Part 3)

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 PCP plan

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

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



STEP 1 :: Build PCP Plan – Product Data (Part 4)

Product Data. FSMA requires the PCQI to define fully the product and process as part of building the PCP plan

Item
This are the product data items which FSMA require the PCQI to define

Description
Enter the a full description of the product data item

Item	Description	
Composition/Formulation of the food	Raw meat (99%), salt, black pepper, water	×
Raw materials and other ingredients	Raw meat is sourced locally. Other ingredients are sourced from a variety of countries including domestically and abroad.	×
Physical, Biological & Chemical Properties	Fully cooked and frozen meat burgers	×
Manufacturing/processing procedures	Meat blended with ingredients cooked and frozen	×
Packaging and Packaging activities	As per customer or internal specification. All packaging is sourced from approved suppliers.	×
Storage & Distribution Conditions	The product is stored and dispatched at <-4°F. The principle of first in first out is followed.	×
Shelf life	12 months	×
Labeling and instructions for use	Store and cook as per instructions.	×
Intended or reasonably foreseeable use	It will be sold at retail service/self service or food service.	×

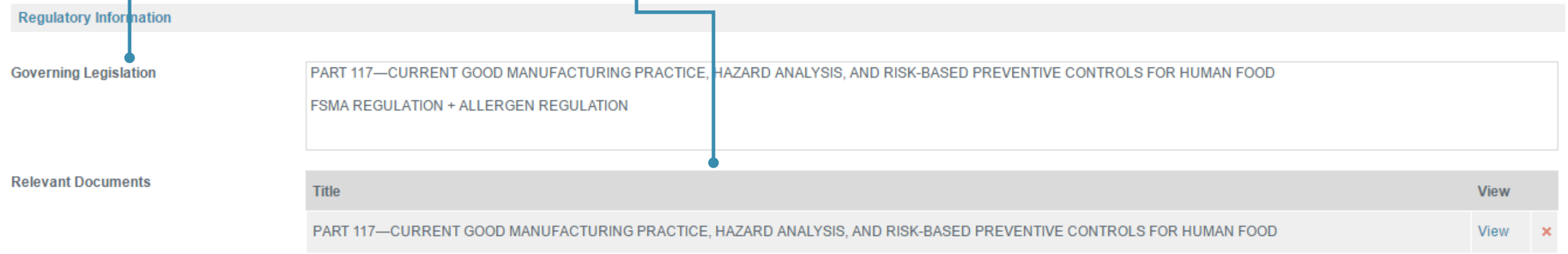
Preventive Control Plans (PCP's) with Safefood 360°

STEP 1 :: Build PCP Plan – Regulatory Information (Part 5)

Regulatory Legislation. In this section you provide clear reference to the legislation governing the PCP plan

Governing Legislation
Provide details of the legislation that is governing this PCP plan

Relevant Documents
Attach copies of the legislation for full reference



Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – Complete Study Details

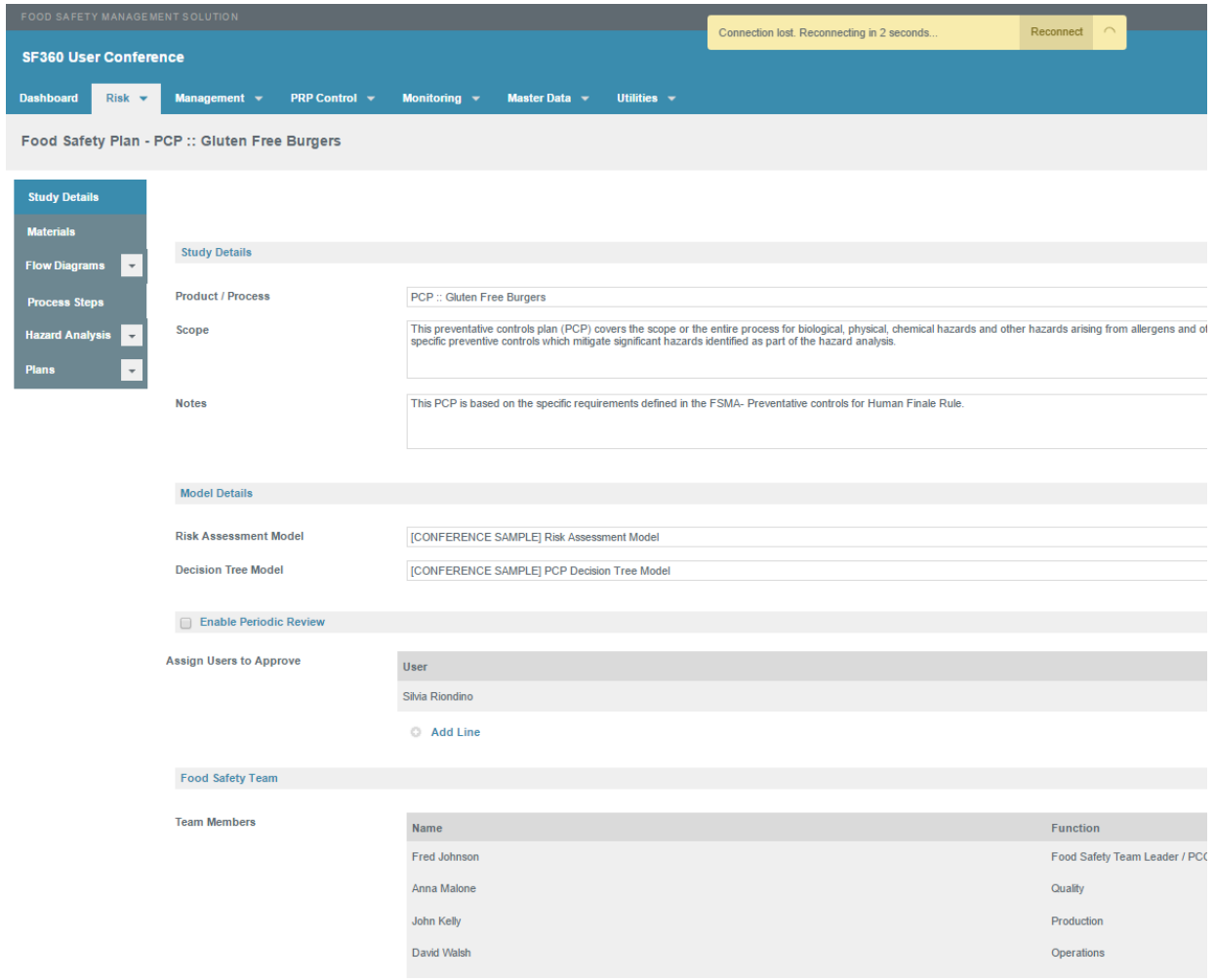
Task

Complete the Study Details Section of your PCP plan

10-15 minutes

Instructions

- Click **Risk** > **Food Safety Plan** > **Actions**
- Click the name of your PCP plan in the table
- Click **Actions** > **Edit**
- Go to Model Details Section and select the **Risk Assessment Model** you have already built
- Go to **Model Details** section and select the **Decision Tree Model** you have already built
- Go to **Food Safety Team** section and add an additional team member
- Go to **Product Data** section and add an additional item
- Scroll to the end of the scree and click **Save**



Preventive Control Plans (PCP'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

Study Details

- Define the scope of your PCP plan
- Where it starts (e.g. materials) and finishes (e.g. delivery to the final customer)
- Define your team members including PCQI's
- Define product and process details
- Select models to be used in the PCP plan

STEP 2

Materials

- Link the materials, ingredients, packaging used in the manufacture of the product
- Displays the Risk arising from your material assessments in the Supplier Control Module

Preventive Control Plans (PCP's) with Safefood 360°

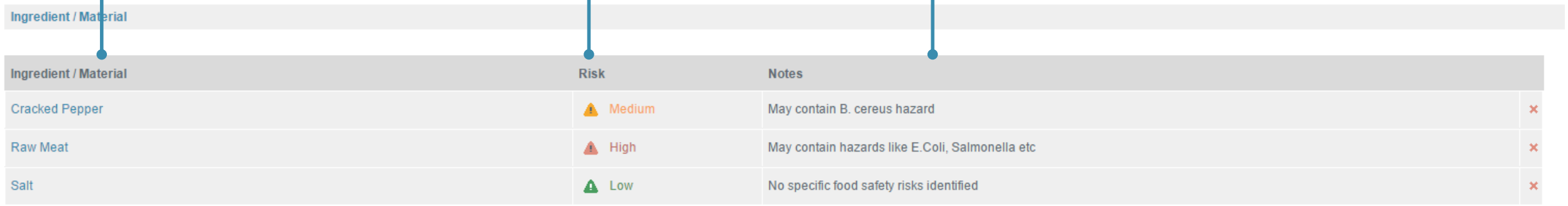
STEP 2 :: Build PCP Plan – Materials

Materials Section. In this section of the PCP workflow you can select the materials, ingredients, packing etc. which are used to make the product

Ingredients / Materials
Select the Materials which are used in the process / product

Risk
Define the risk for the material. This is usually carried over from the material risk assessment conducted in the Supplier Control module

Notes
Enter any additional or relevant notes supporting the material risk



Add Line
Click to add additional materials to the list

Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – Add a Material to the List

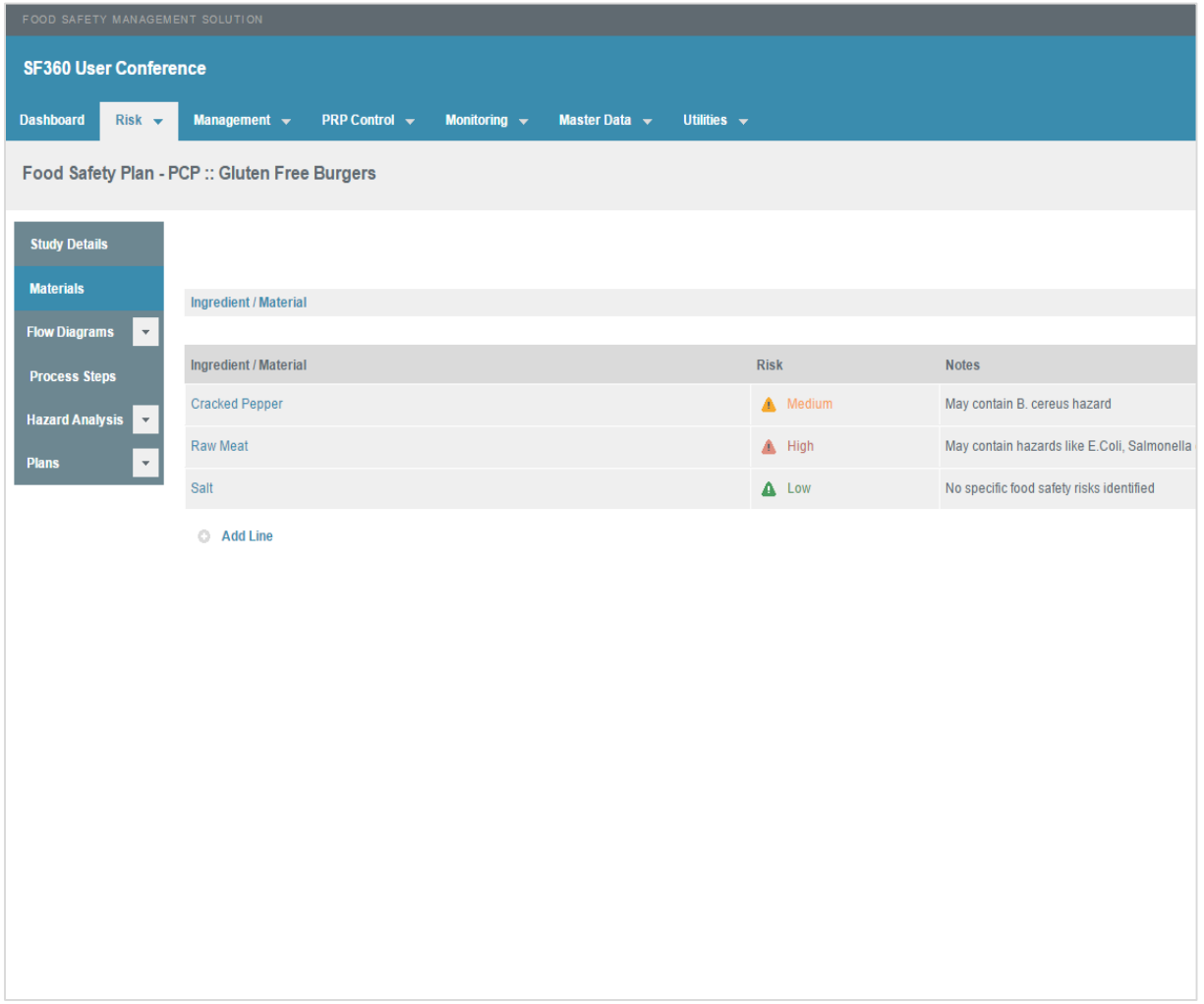
Task

Add a material to the list of materials

5 minutes

Instructions

- Click **Risk** > **Food Safety Plan** > **Actions**
- Click the name of your PCP plan in the table
- Click **Actions** > **Edit**
- Click **Materials**
- Click **Add Line** and click **Ingredients / Material** field to open search box
- Click Folders **Materials** > **Ingredients** > **Salt** > **US Salt LLC**
- Click **Save**



Preventive Control Plans (PCP'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

Study Details

- Define the scope of your PCP plan
- Where it starts (e.g. materials) and finishes (e.g. delivery to the final customer)
- Define your team members including PCQI's
- Define product and process details
- Select models to be used in the PCP plan

STEP 2

Materials

- Link the materials, ingredients, packaging used in the manufacture of the product
- Displays the Risk arising from your material assessments in the Supplier Control Module

STEP 3

Flow Diagrams

- Draft you process flow diagrams with the in application flow charting tool

STEP 3 :: Build PCP Plan – Flow Diagram

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

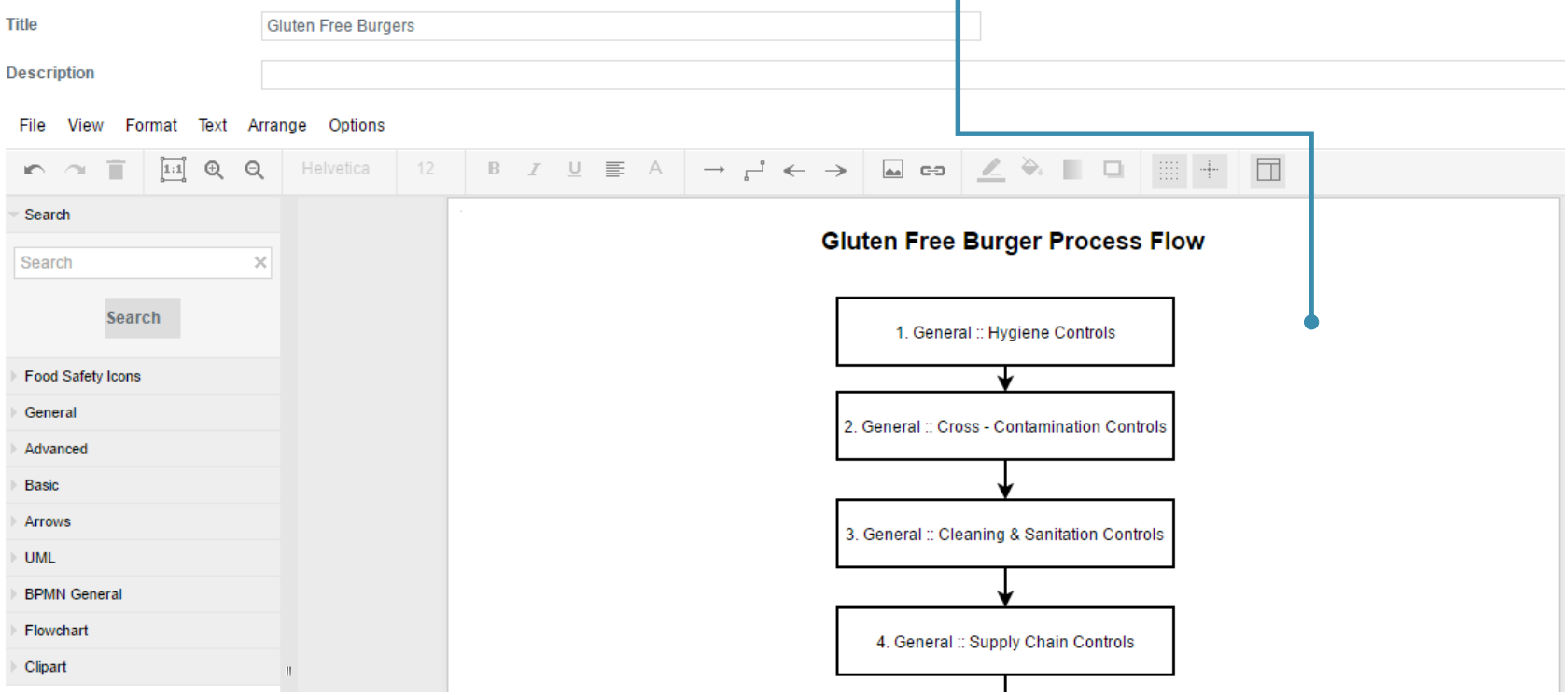
Title
Enter the title of the process flow diagram

Description
Enter a description for the process flow

Menus
Charting Menus

Tools
Charting Tools

Canvass
Draft your process flow diagram in this area



Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – View Process Flow Diagram

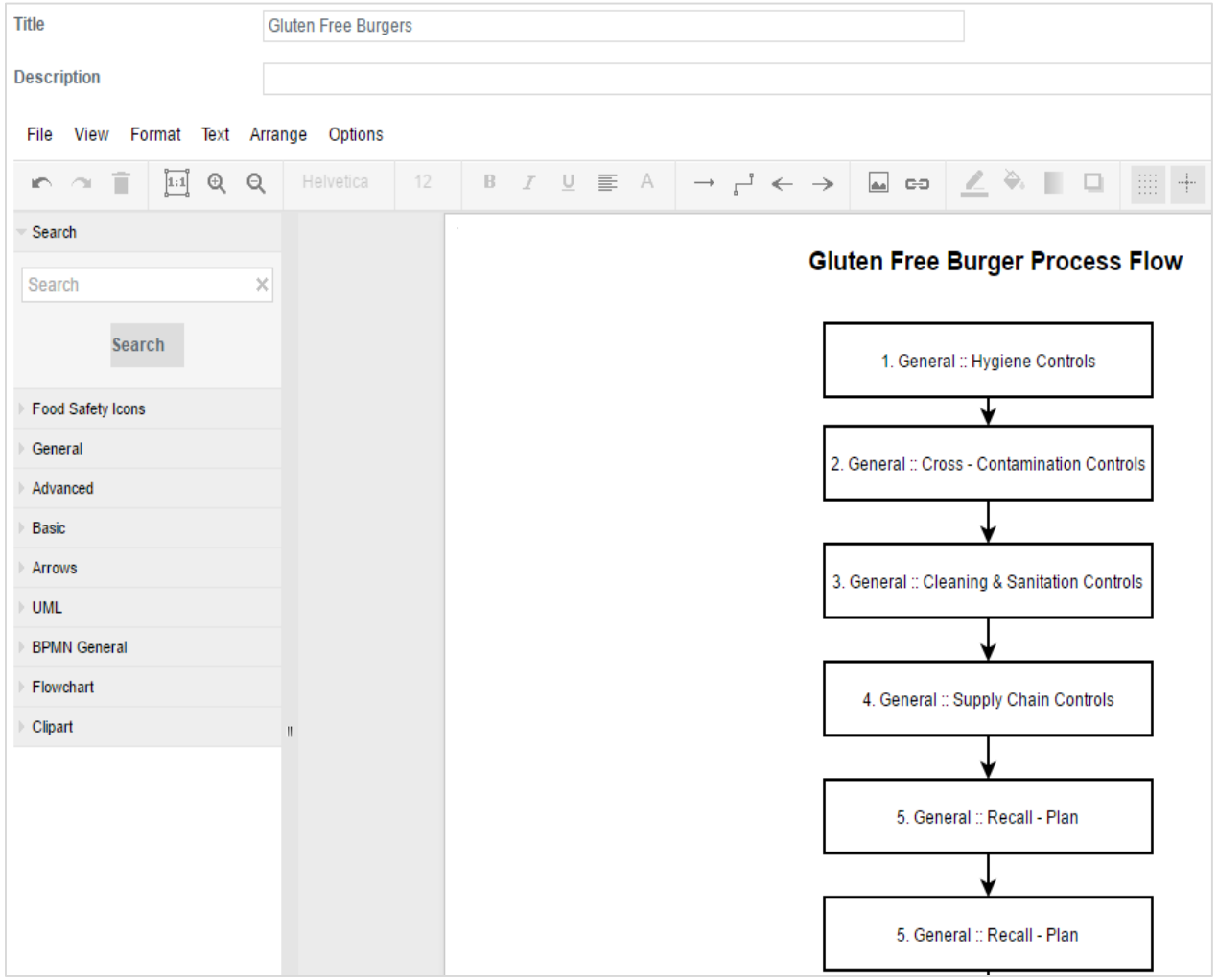
Task

View flow diagram

5 minutes

Instructions

- Click **Risk** > **Food Safety Plan** > **Actions**
- Click the name of your PCP plan in the table
- Click **Actions** > **Edit**
- Click **Flow Diagrams** and select the flow diagram
- View flow diagram



Preventive Control Plans (PCP'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 | STEP 2 | STEP 3 | STEP 4

Study Details

- Define the scope of your PCP plan
- Where it starts (e.g. materials) and finishes (e.g. delivery to the final customer)
- Define your team members including PCQI's
- Define product and process details
- Select models to be used in the PCP plan

Materials

- Link the materials, ingredients, packaging used in the manufacture of the product
- Displays the Risk arising from your material assessments in the Supplier Control Module

Flow Diagrams

- Draft you process flow diagrams with the in application flow charting tool

Process Steps

- Describe each step in the process

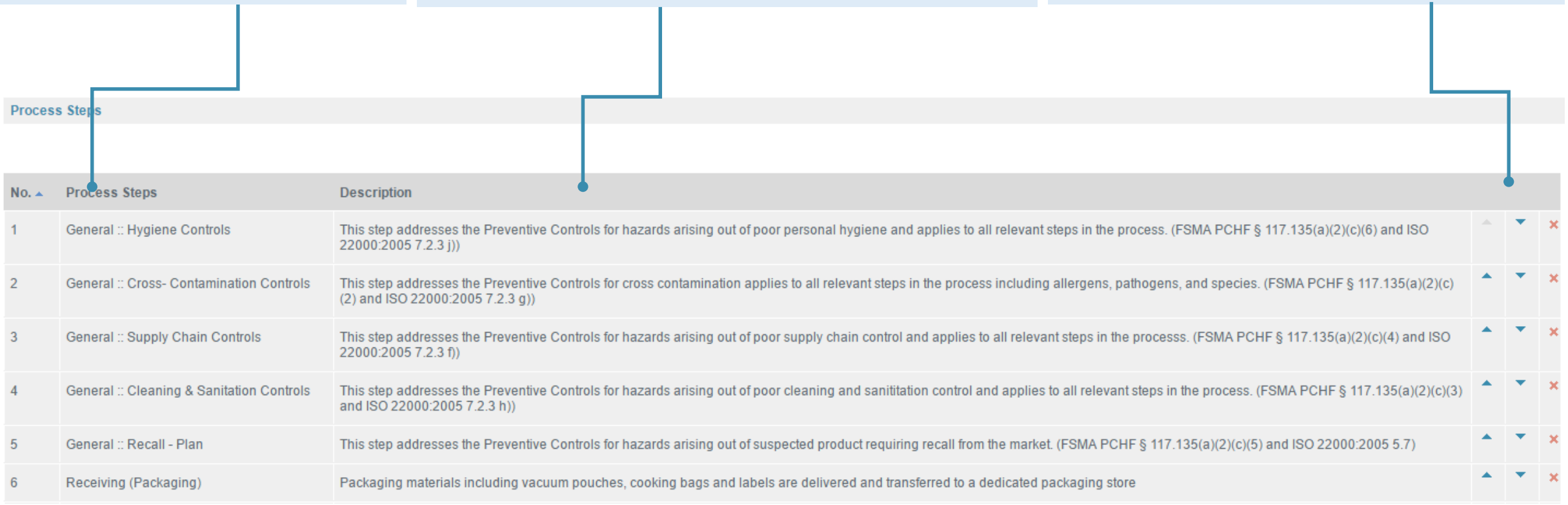
STEP 4 :: Build PCP Plan – Process Steps

Process Steps Section. In this section of the PCP 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



Process Steps

No.	Process Steps	Description
1	General :: Hygiene Controls	This step addresses the Preventive Controls for hazards arising out of poor personal hygiene and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 j))
2	General :: Cross- Contamination Controls	This step addresses the Preventive Controls for cross contamination applies to all relevant steps in the process including allergens, pathogens, and species. (FSMA PCHF § 117.135(a)(2)(c)(2) and ISO 22000:2005 7.2.3 g))
3	General :: Supply Chain Controls	This step addresses the Preventive Controls for hazards arising out of poor supply chain control and applies to all relevant steps in the processs. (FSMA PCHF § 117.135(a)(2)(c)(4) and ISO 22000:2005 7.2.3 f))
4	General :: Cleaning & Sanitation Controls	This step addresses the Preventive Controls for hazards arising out of poor cleaning and sanititation control and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(3) and ISO 22000:2005 7.2.3 h))
5	General :: Recall - Plan	This step addresses the Preventive Controls for hazards arising out of suspected product requiring recall from the market. (FSMA PCHF § 117.135(a)(2)(c)(5) and ISO 22000:2005 5.7)
6	Receiving (Packaging)	Packaging materials including vacuum pouches, cooking bags and labels are delivered and transferred to a dedicated packaging store

Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – Add a Process Step

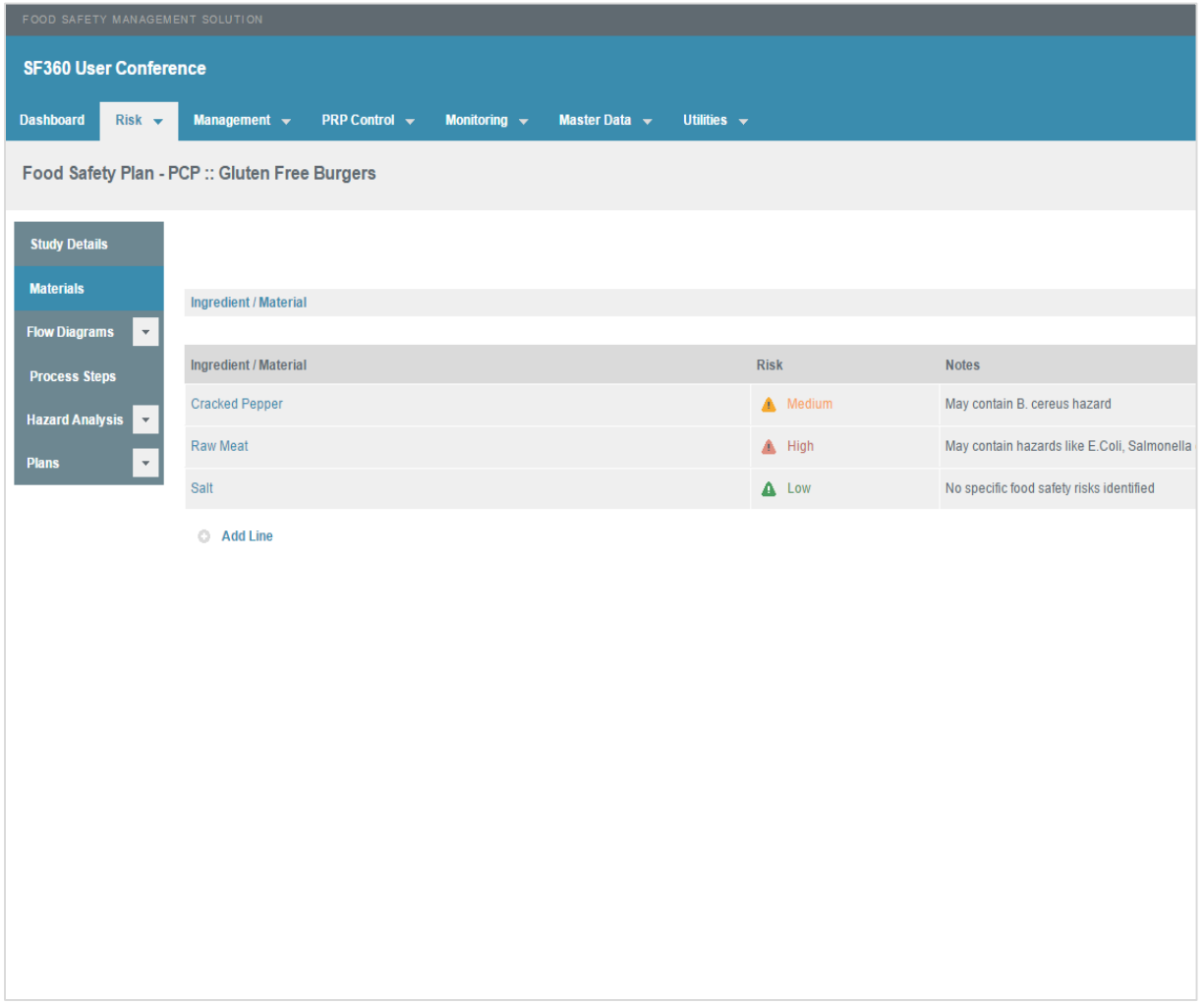
Task

Add a process step

5-10 minutes

Instructions

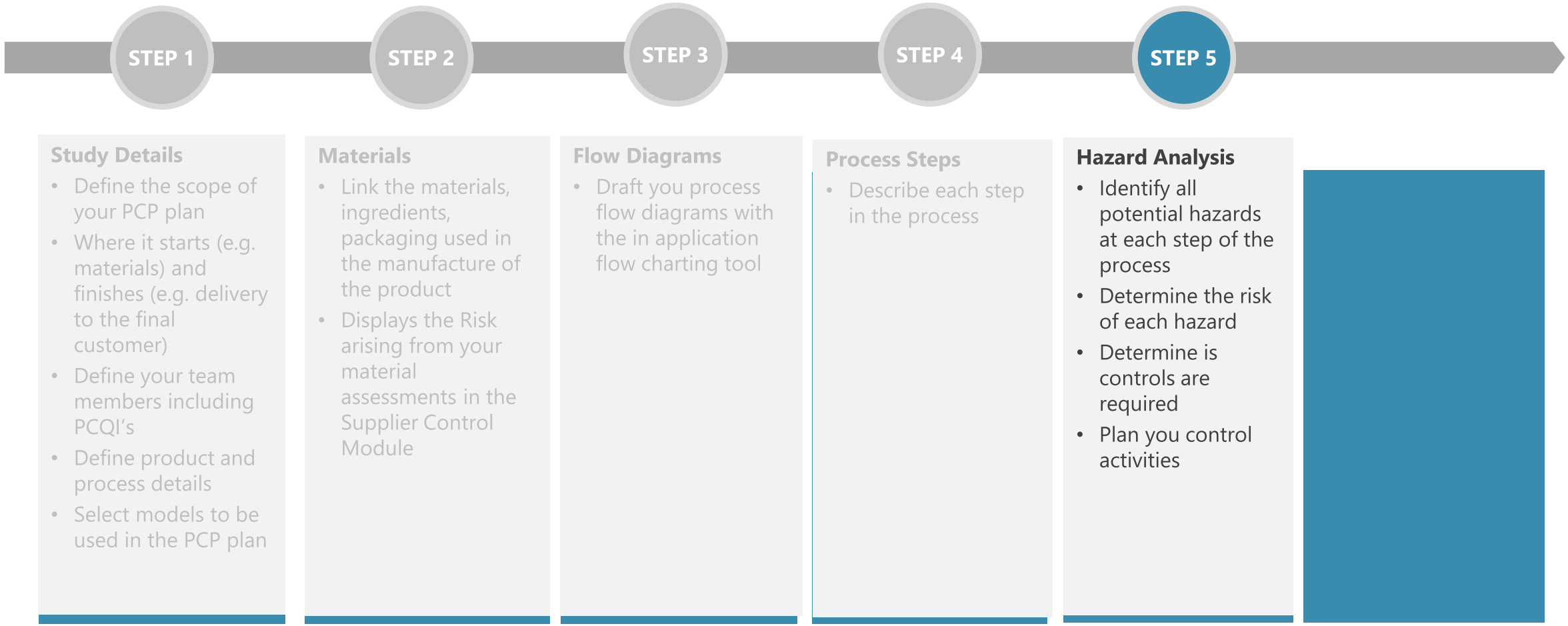
- Click **Risk** > **Food Safety Plan** > **Actions**
- Click the name of your PCP plan in the table
- Click **Actions** > **Edit**
- Click **Process Steps**
- Click **Add Line** to add a new process step
- Enter the **Name** of the process step
- Enter the **Description** of the process step
- Click **Save**



Preventive Control Plans (PCP'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



Preventive Control Plans (PCP's) with Safefood 360°

STEP 5 :: Build PCP Plan – Hazard Analysis – Hazard Details Section

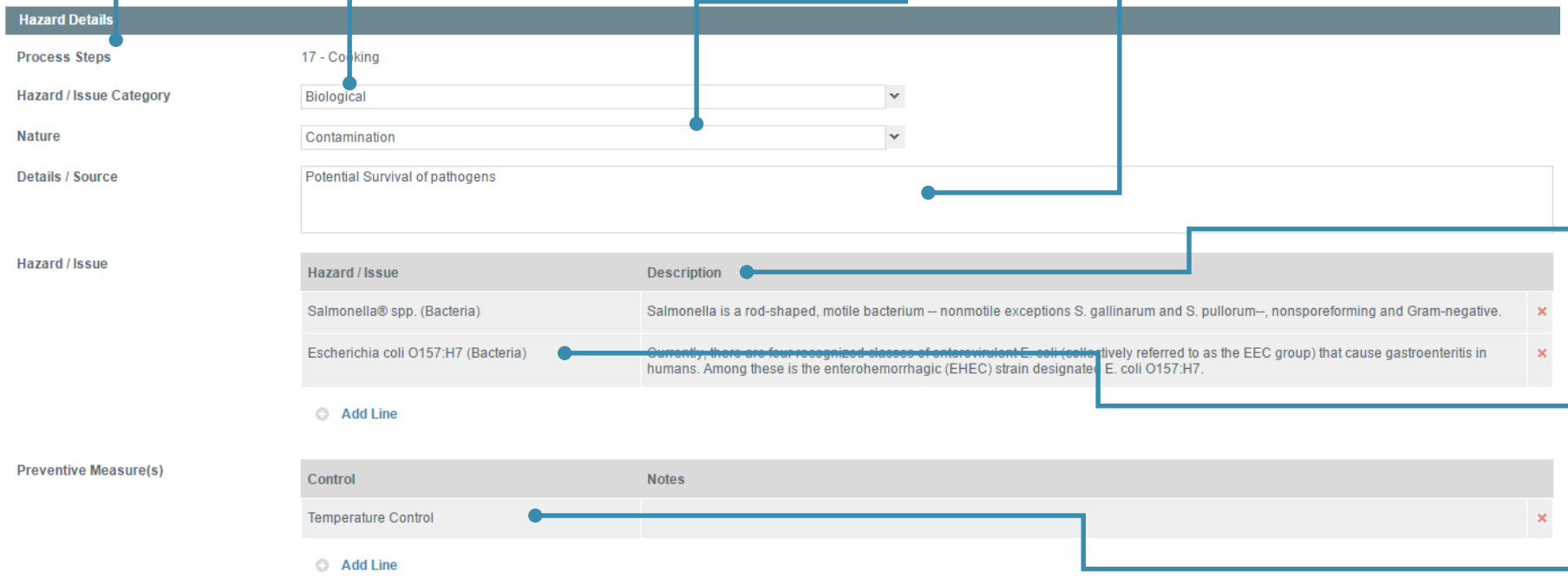
Hazard Details Section. In this section of the PCP workflow you can select the materials, ingredients, packing etc. which are used to make the product

Process Step
Displays name of the process step

Hazard / Issue Category
Select the category of hazard e.g. biological, physical, chemical

Nature
Select the nature of the hazard e.g. survival, 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

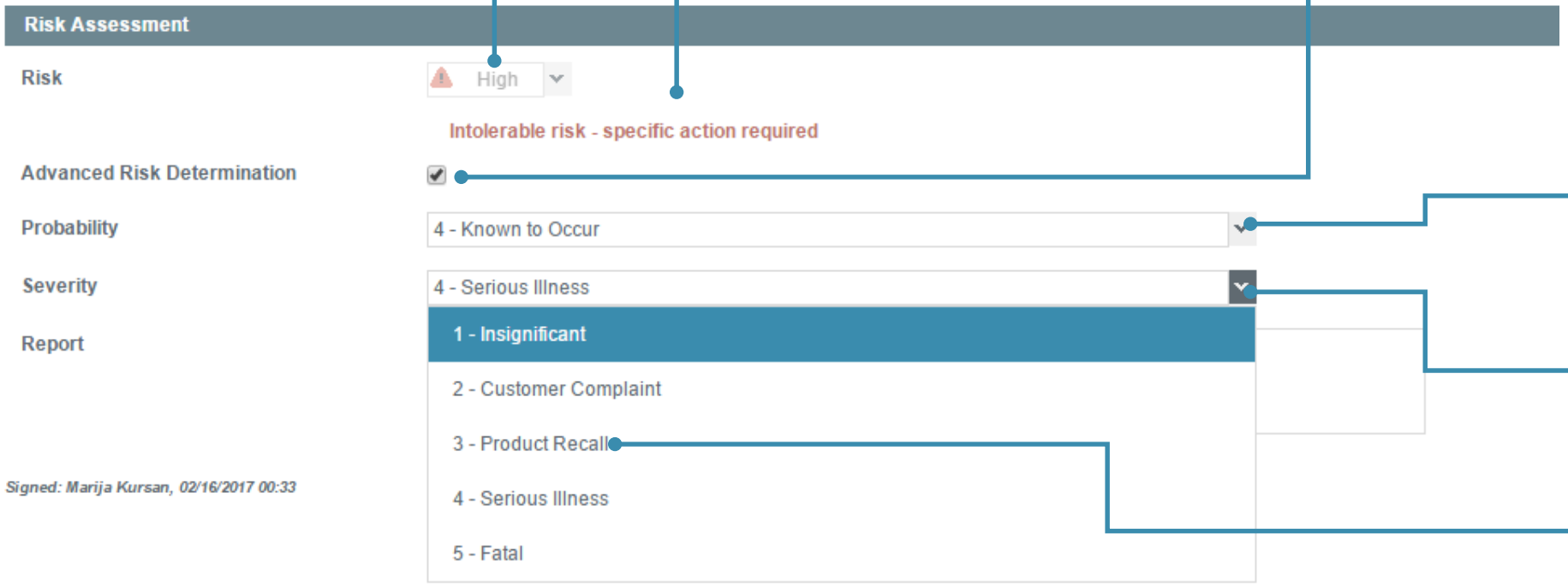
STEP 5 :: Build PCP Plan – Hazard Analysis – Risk Assessment Section

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

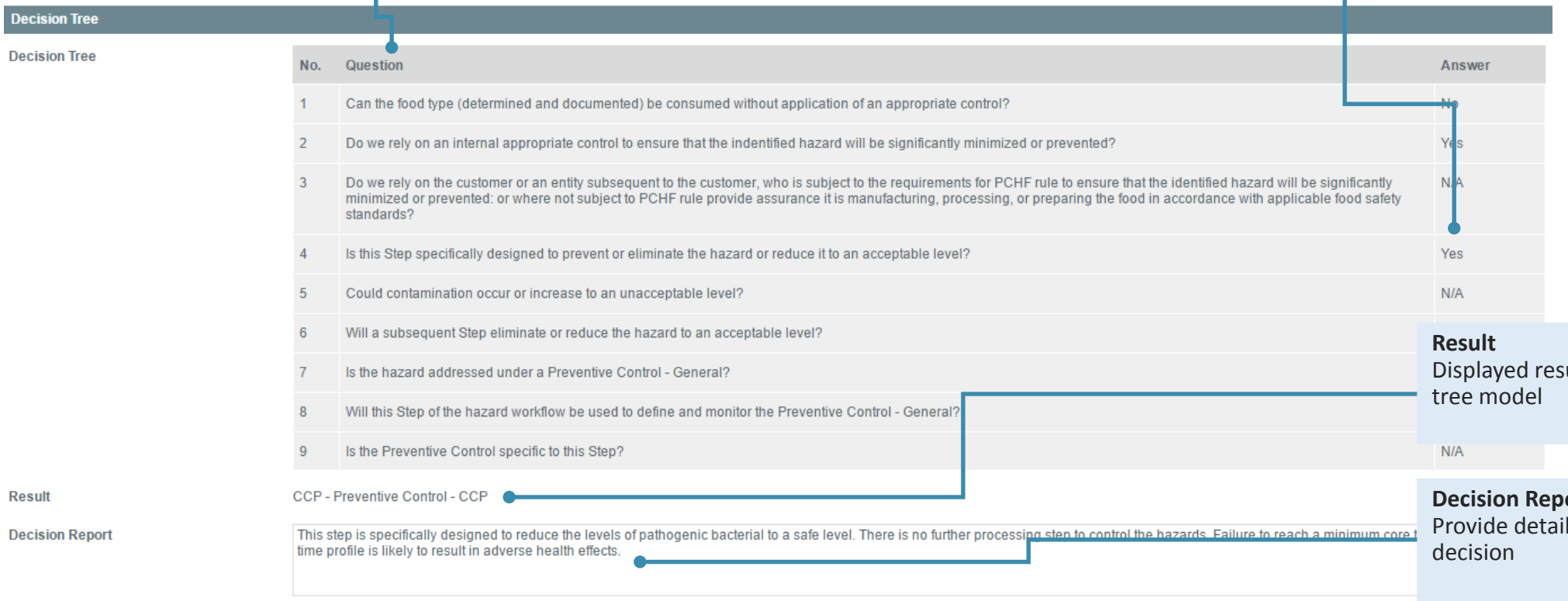
Rating
Select the appropriate rating for the hazard

STEP 5 :: Build PCP Plan – Hazard Analysis – Decision Tree Section

Decision Tree Section. In this section the PCQI can determine what if any control measures are required

Question
Used to conduct a simple risk assessment

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



Decision Tree

Decision Tree

No.	Question	Answer
1	Can the food type (determined and documented) be consumed without application of an appropriate control?	No
2	Do we rely on an internal appropriate control to ensure that the indentified hazard will be significantly minimized or prevented?	Yes
3	Do we rely on the customer or an entity subsequent to the customer, who is subject to the requirements for PCHF rule to ensure that the identified hazard will be significantly minimized or prevented: or where not subject to PCHF rule provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety standards?	N/A
4	Is this Step specifically designed to prevent or eliminate the hazard or reduce it to an acceptable level?	Yes
5	Could contamination occur or increase to an unacceptable level?	N/A
6	Will a subsequent Step eliminate or reduce the hazard to an acceptable level?	
7	Is the hazard addressed under a Preventive Control - General?	
8	Will this Step of the hazard workflow be used to define and monitor the Preventive Control - General?	
9	Is the Preventive Control specific to this Step?	N/A

Result: CCP - Preventive Control - CCP

Decision Report: This step is specifically designed to reduce the levels of pathogenic bacterial to a safe level. There is no further processing step to control the hazards. Failure to reach a minimum core t
time profile is likely to result in adverse health effects.

Result
Displayed result based on the decision tree model

Decision Report
Provide details support the final risk decision

Preventive Control Plans (PCP's) with Safefood 360°

STEP 5 :: Build PCP Plan – Hazard Analysis – Monitoring Details Section

Monitoring Details Section. In this section the PCQI can detail the preventive controls and monitoring details

Control
Enter the name of the preventive control

Control Limit
Enter the control specification / limit

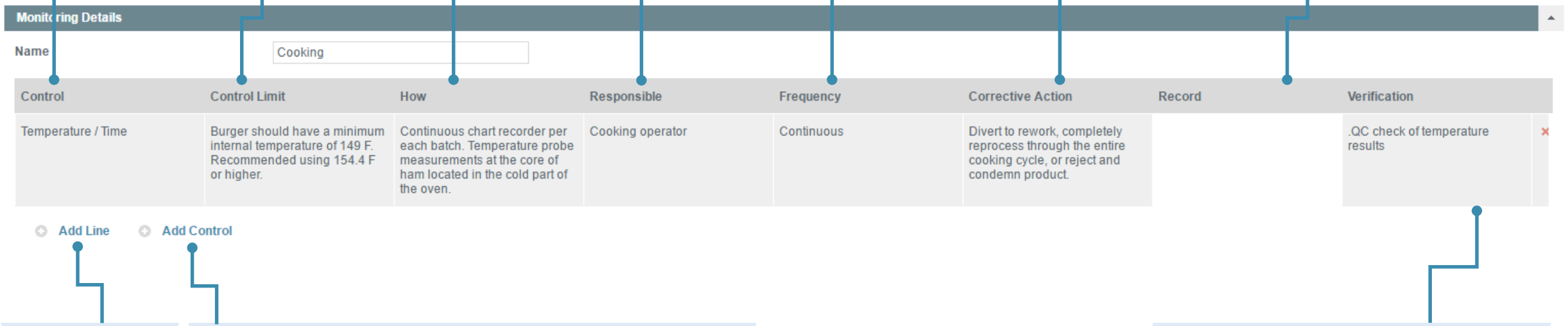
How
Enter the method for monitoring

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 control

Add Control
Click to add a standard control from the list of controls pre-built in the software.

Verification
Enter details of the verification activities regard this control measure

Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – Add New Hazard and Complete

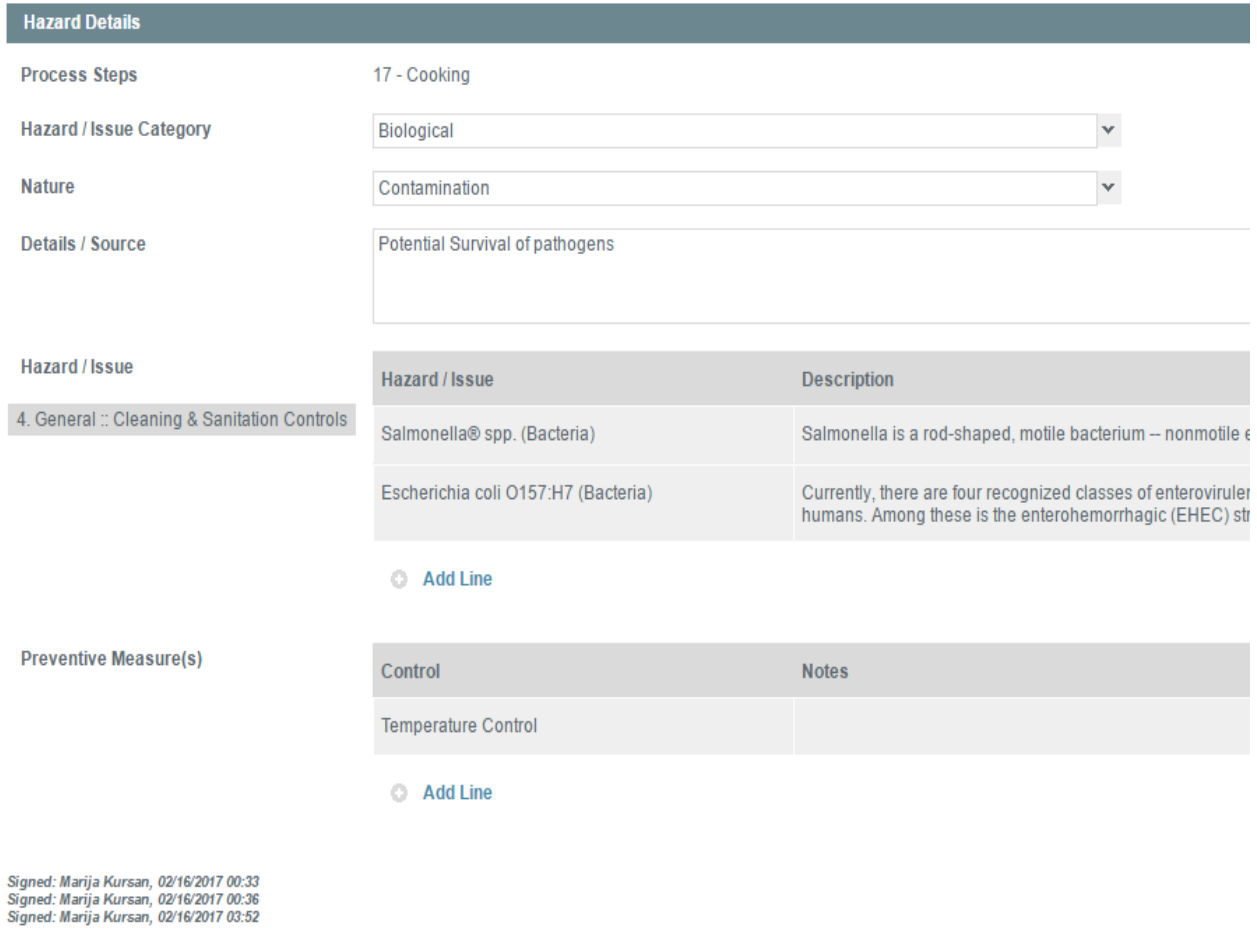
Task

Add new hazard to the PCP plan and complete details

15 - 20 minutes

Instructions

- Click **Risk** > **Food Safety Plan** > **Actions**
- Click the name of your PCP plan in the table
- Click **Actions** > **Edit**
- Click **Hazard Analysis > Cooking > Add Hazard**
- Complete **Hazard Details**
- Complete **Risk Assessment**
- Complete **Decision Tree**
- Complete **Monitoring Details**
- Click **Save**



Preventive Control Plans (PCP'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

Study Details

- Define the scope of your PCP plan
- Where it starts (e.g. materials) and finishes (e.g. delivery to the final customer)
- Define your team members including PCQI's
- Define product and process details
- Select models to be used in the PCP plan

Materials

- Link the materials, ingredients, packaging used in the manufacture of the product
- Displays the Risk arising from your material assessments in the Supplier Control Module

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 hazards at each step of the process
- Determine the risk of each hazard
- Determine is controls are required
- Plan you control activities

PCP Plans

- Automatic building of your final PCP plans
- Approval of PCP plans by your PCQI's

Preventive Control Plans (PCP's) with Safefood 360°

STEP 6 :: Build PCP Plan – Plans

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

Food Safety Plan - CCP - Preventive Control - CCP

No.	Hazard	Control	Control Limit	How	Frequency	Responsible	Corrective Action	Record	Verification
#1Chill Storage - (11 / Chill Storage (32 - 41 °F))	Biological: Growth / Proliferation (Salmonella® spp.)	Temperature	41 °F	Probe and chart record	Hourly	Production Manager	Reject/rework product of above critical limit		Daily review of records before shipping product by Supervisor. 6 Monthly calibration of temperature recording devices. Weekly internal temperature checks to verify time/temperature parameters are reaching desired internal temperature.
#2Cooking - (17 / Cooking)	Biological: Contamination (Salmonella® spp., Escherichia coli O157:H7)	Temperature / Time	Burger should have a minimum internal temperature of 149 F. Recommended using 154.4 F or higher.	Continuous chart recorder per each batch. Temperature probe measurements at the core of ham located in the cold part of the oven.	Continuous	Cooking operator	Divert to rework, completely reprocess through the entire cooking cycle, or reject and condemn product.		.
#3Freezer - (19 / Freeze to -4 °F)	Biological: Growth / Proliferation (Salmonella® spp., Escherichia coli O157:H7)	Temperature	Temp: - 4°F	Probe and chart recorder	Hourly	Quality Controller	Rework / reject product if above critical limit		Daily review of records before shipping product by an individual who did not complete the records and who is responsible establishment official. Periodic calibration of temperature recording devices (recommend at least weekly calibration.) Periodic internal temperature checks to verify time/temperature parameters are reaching desired internal temperature (recommend at least weekly checks.)
#4Metal Detection - (20 / Metal Detection)	Physical: Contamination (Metal)	Metal	Ferrous 2.5 mm, Non Ferrous 3.0 mm, SS 3.00 mm	Test check	Hourly	Quality Controller	Put on hold Reject product from last clear check, re-metal detect product and discard product if required.		.

Preventive Control Plans (PCP's) with Safefood 360°

Practical Exercise – View PCP Plan

Task

View PCP Plan

5 minutes

Instructions (PCP Plan)

- Click **Risk** > **Food Safety Plan** > **Actions**
- Click the name of your PCP plan in the table
- Click **Actions** > **Edit**
- Click **Plans**
- To get PDF copy
- Click **Risk** > **Food Safety Plan** > **Actions**
- Click the name of your PCP plan in the table
- Click **Actions** > Get PDF