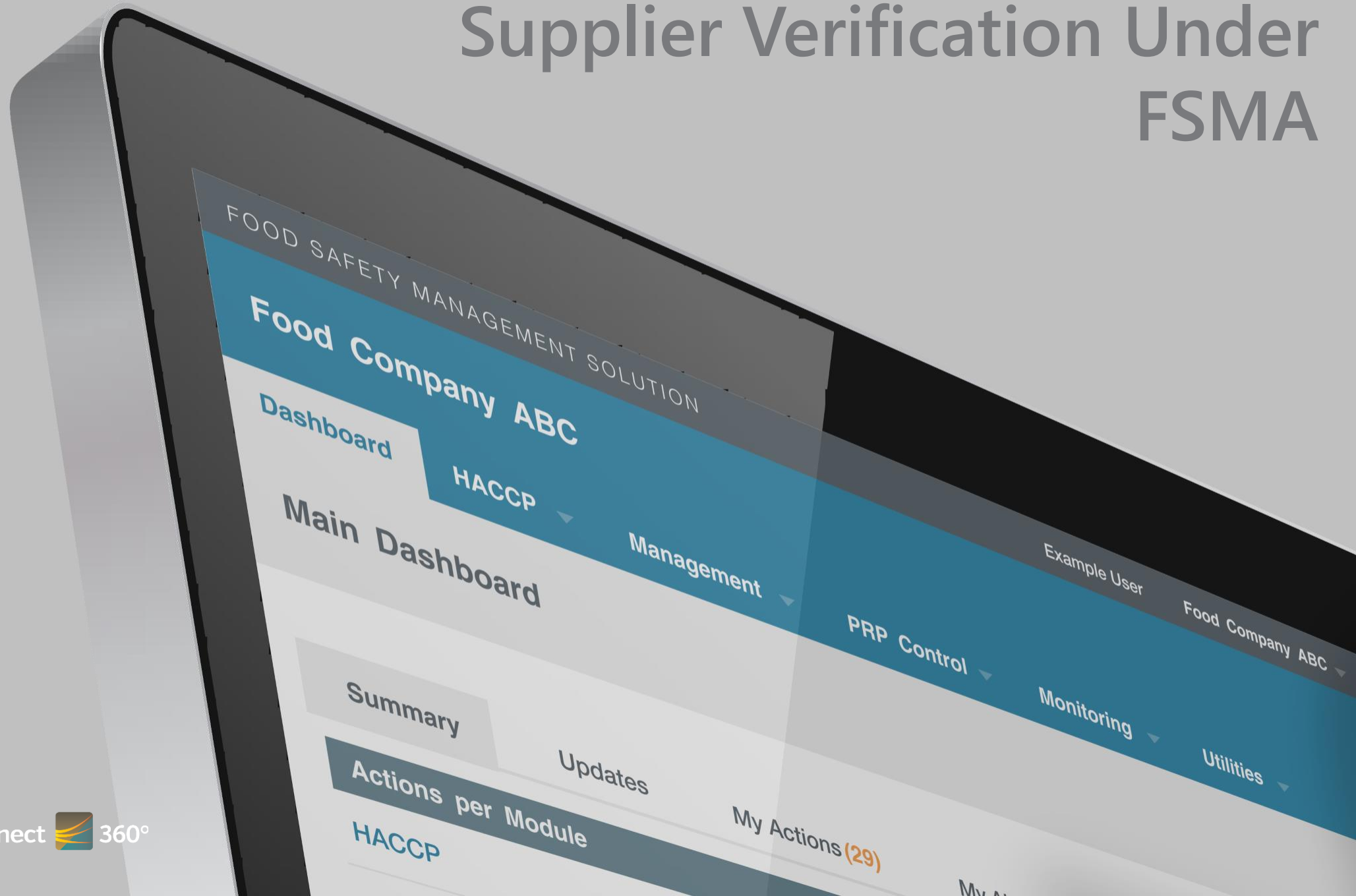


Supplier Verification Under FSMA



Session Overview

Purpose:

- To review the requirements for supplier verification under FSMA.
- To review how SF360 addresses these requirements in the solution.
- To thoroughly understand the capabilities of the Supplier Control Module.
- To build a supplier assessment program and review an assessment record.

Session Leader:

- George Howlett, CEO, Safefood 360

Timing:

- 125 Minutes

Agenda:

- FSMA Requirements for Supplier Verification
- Overview of Safefood 360 Supplier Control Module
- Three Building Blocks of a Supplier Verification Program
 - Master Data
 - Assessment Programs
 - Assessment Records
- Practical Exercise



Some Interesting Facts about Supplier Verification

2

**FSMA Rules Call for
SVP**

**Each Supplier
Facility Assessed**

**Each Product
Assessed**

PCQI

**Must Conduct
Assessments**

**Domestic
Applicable**

**Foreign
Applicable**

Useful Supporting Information

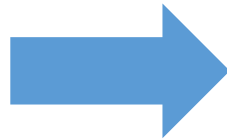
Safefood 360 reference sources of information for conducting supplier verification under FSMA requirements.

Type	Name	Location
Presentation	FSMA Supplier Verification with Safefood 360°	URL available after conference
Website	FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm
Factsheet	FDA - Final Rule on Foreign Supplier Verification Programs	https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472890.pdf
Blog	Safefood 360 - What is the best Supplier Quality Management System for foreign suppliers under FSMA?	http://safefood360.com/2017/01/what-is-the-best-supplier-quality-management-system-for-foreign-suppliers-under-fsma/

Objectives of Today's Session



FSMA Supplier
Verification
Requirements



Safefood 360 Supplier
Control Solution

Practical Exercises

FSMA Final Rule on Foreign Supplier Verification Programs

Objective

- The FDA Food Safety Modernization Act (FSMA) final rules are aimed at ensuring food (imported and domestic) are not adulterated or present a risk to human health.

Requirements

- FSVP Final Rule requires owner of food to have in place supplier verification programs.

Application

- FSVP Rule applies to an importer who is the owner or a consignee of a food offered for import into the United States.
- If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner or consignee at the time of entry.
- Exceptions provided in the final rule.

Approach

- FDA has taken an approach consistent with the management of risk.
- Conducting clear hazard identification followed by risk assessment and the application of controls (verification).



FEDERAL REGISTER

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Part II

Department of Health and Human Services

Food and Drug Administration
21 CFR Parts 1, 11, and 111
Foreign Supplier Verification Programs for Importers of Food for Humans
and Animals; Final Rule



What Does FSVP Call For?

FSMA FSVP Final Rule sets out clear requirements which must be complied with to verify that their foreign suppliers are producing food in a manner that assures public health protection and that the supplier's food is not adulterated.

➔	HAZARD IDENTIFICATION – Determining known or reasonably foreseeable hazards within each food
➔	RISK ASSESSMENT – Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
➔	CONTROLS – Using Risk Assessment to approve suppliers and determine appropriate supplier verification activities
➔	VERIFICATION – Conduct supplier verification activities
➔	CORRECTIVE ACTIONS – Conduct corrective action
➔	SYSTEMATIC – Best practice dictates that a systematic and scientific approach should be adopted

What Additional Requirements Are There in FSVP?

FSMA FSVP Final Rule sets out additional requirements which must be complied with when developing your systems.



PROCEDURES – System must be based on written procedures



SCOPE – Must develop a FSVP for each food and for the foreign supplier of that food

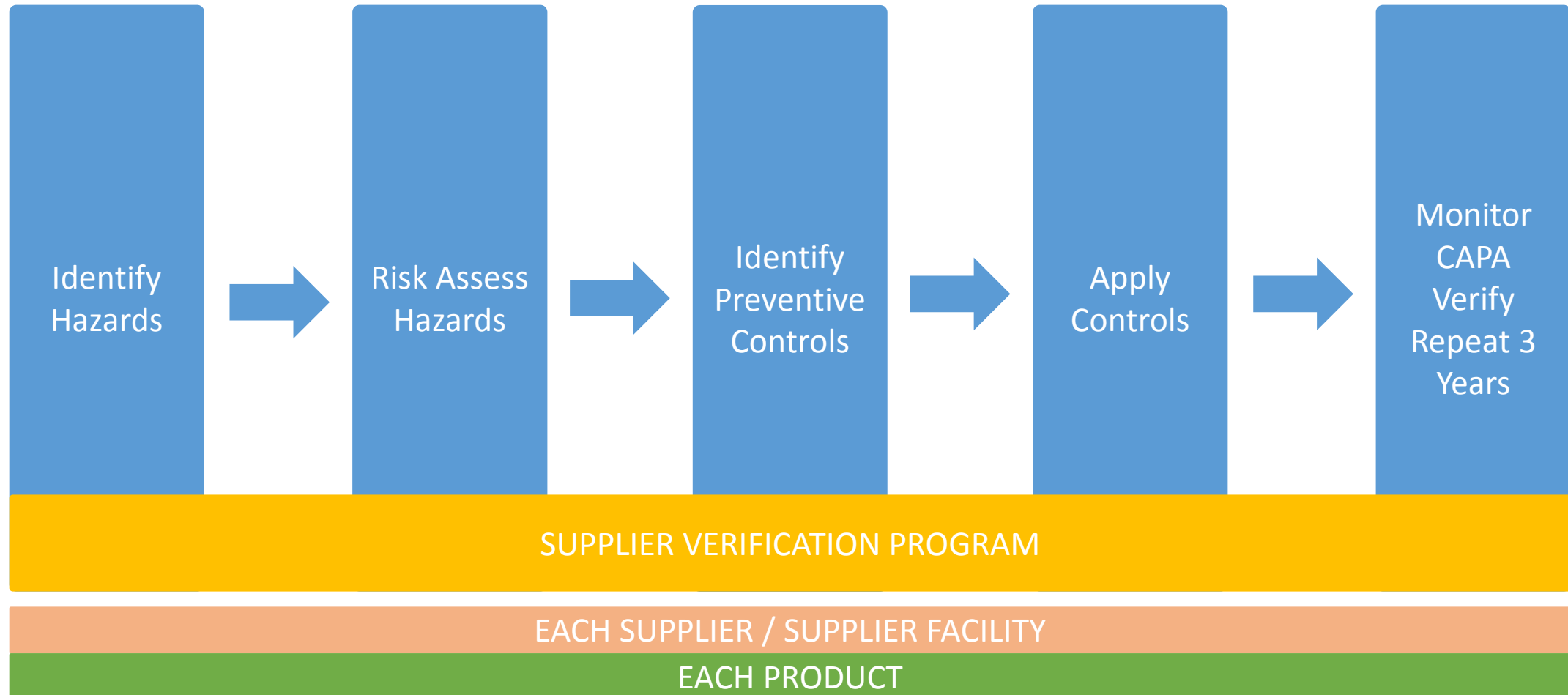


RE-EVALUATION – Must be conducted every 3-years



QUALIFICATION – Assessments to be conducted by a PCQI

So What Do You Need To Do?



Verification Activities- Examples

Document and Data Collection

- Statements of Assurance
- Certificates of Conformance / Analysis
- PCP Plans
- Data on Hazards
- Audit Reports
- Specifications
- Suppliers Legal Compliance and History
- Supplier Procedures

Inspection & Testing

- On products and materials purchased
- Internal & External

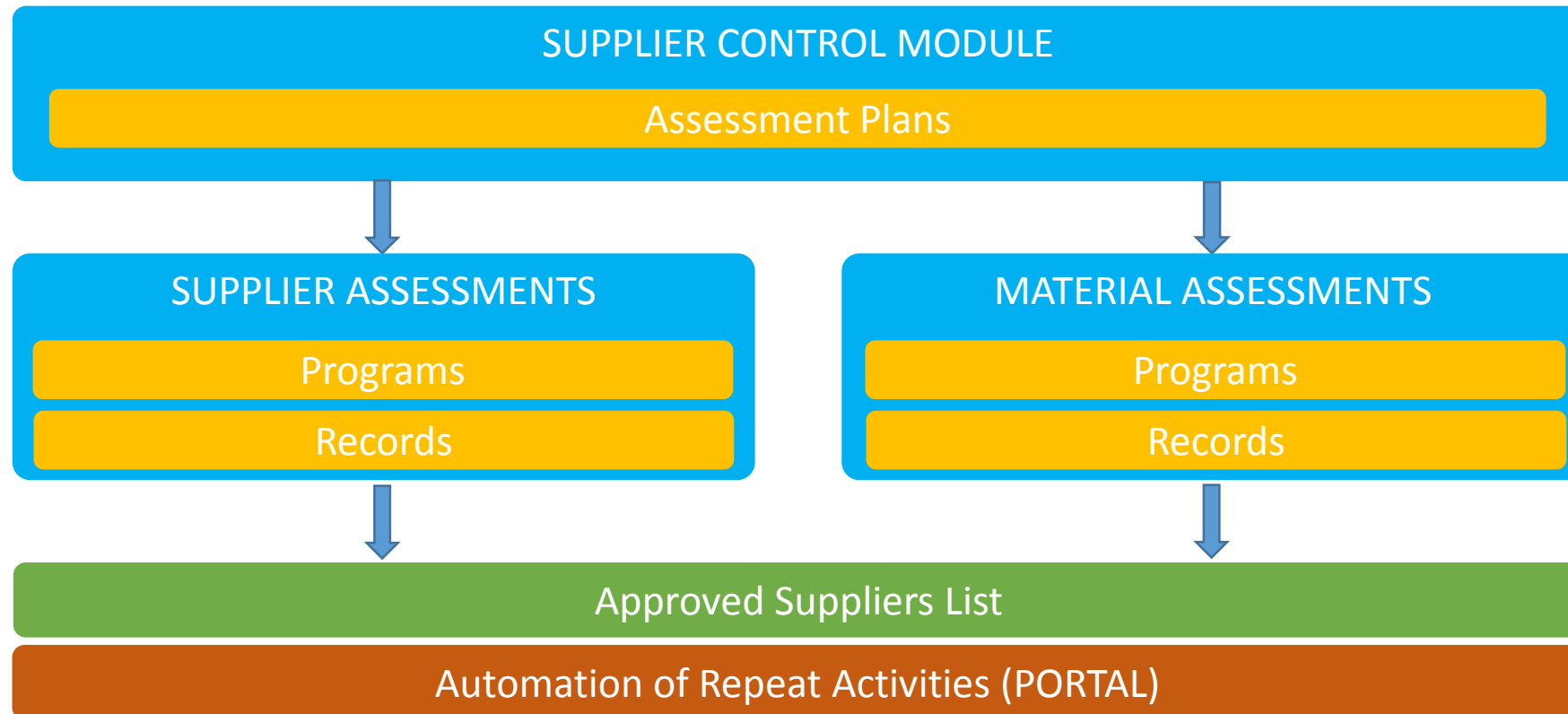
Auditing

- On Site Audits



How Does SF360 Manage These Requirements?

Safefood 360 contains a ready made workflow which is aligned to the specific requirements of FSMA FSVP. It is configurable to your specific needs.



SF360 Portal and How It Works

SF360 Supplier Portal allows you to collaborate, communicate and exchange data/documents without the need for phone calls, emails or visits.



Suppliers

Suppliers in Safefood 360 can represent a variety of supply chain entities which may need to be assessed and controlled. Suppliers are located in the Master Data > Contacts Module.

FOOD SAFETY MANAGEMENT SOLUTION

SF360 User Conference

Dashboard Risk Management PRP Control Monitoring Master Data Utilities

Supplier

Supplier Details

Name

Identifier

Folder

- Contract - Engineer
- Contract - Laboratory
- Contract - Transport
- Contract - Pest
- Ingredient - Manufacturer
- Machinery

New Folder Rename Delete

Categories

Category

Add Line

Reference

Agent / Importer

Phone

Fax

Direct Dial

Supplier Types

- Suppliers (General)
- Agents
- Supplier Facility / Sites
- Distributors
- Brokers
- Importers
- Supplier Facility Production Line
- Ingredient Suppliers
- Packaging Supplier
- Service Suppliers

Supplier Module Environment

Master Data > Contacts > Supplier. Click on a supplier name from the Supplier List to access the Supplier Module Environment. This is where all the specific dashboards and data relating to the Supplier can be found. You will also find the various action buttons you will need to perform tasks such as creating programs and completing records.

Add Assessment Program
Used to add a new assessment programs

Add Audit Program
Used to add a new audit programs

Add Assessment
Used to create a new assessment record

Add Supplier Corrective Action
Used to create a new supplier corrective action

Actions
Used to perform various actions on the supplier

Supplier: Cheese Company

Add Assessment Program

Add Audit Program

Add Assessment

Add Audit

Add Supplier Corrective Action

Actions

SummaryCompletePlanActionsMaterialsDocumentsScorecardReports

Status

Approved

Risk Level

Low

Open Actions


0

Contact Details

24 HOUR CONTACT :-
Mr. Jack Johnson
Position: Mgr
Phone: +0199234323402
Email: jack.johnson@supplier.com

PHYSICAL ADDRESS :-
7 West Lancaster Road
Richmond
Virginia 23222
United States

Location



GoogleMap DataTerms of Use

Status
Displays current supplier status e.g. Approved, Unapproved etc.

Risk Level
Displays the current risk status based on the Assessment

Open Actions
Displays the total number of actions to be completed relating to the supplier

Score Card
Used to view supplier performance and trends including compliance score

Supplier Scorecard

Master Data > Contacts > Supplier > Scorecard. Click on the supplier scorecard tab to view data relating to the Supplier's performance.

Report Range
Data range from which scorecard is based

Report Rating
% Compliance rating for the supplier

Contact Details
Contact name and details for the supplier

Status
Current approval status of the supplier

Corrective Action Monthly
Monthly trend graph for complaints

Supplier Records
Access and view the most recent records relating to supplier

Report Range
12 Months
17-Feb-16 to 16-Feb-17

Report Rating
99.0%

Status
Approved

Risk Rating
Low

Portal User
Yes

Contact Details
Cheese Company
Main Contact: Jack Johnson
7 West Lancaster Road
Richmond
Virginia
United States

Supplier Rating Details

Category	Count	Fail	Rating %
Receiving	0	0	
Corrective Actions	2		96.0%
Complaints	0		100.0%
Audit	0	0	
Assessment	1	0	100.0%
Certification	0	0	
Actions	4	0	100.0%

Supplier Nonconformances

Record Type	Count	High Risk	Medium Risk	Low Risk	Open
Nonconformance Records	0	0	0	0	0
Corrective Action Records	2	0	1	1	0
Complaint Records	0	0	0	0	0

Supplier Nonconformances By Risk Percentage

Supplier Records

Module	Record	Date	Status	Result
Corrective Actions	Supplier Corrective Action (3)	2/16/2017	Completed	N/A

Risk Rating
Current risk rating e.g. high, medium or low risk

Portal User
Indicates if the supplier is set up as a portal user

Supplier Rating Details
Displays a breakdown of the elements making up the supplier rating including Certifications, Audits and Assessments

Supplier Non-conformances
Displays a breakdown of the number of non-conformances by type

Materials

Materials in Safefood 360 can represent a variety of materials, products or services which may need to be individually assessed and controlled. Materials are located in the **Master Data > Product & Materials** Module.

FOOD SAFETY MANAGEMENT SOLUTION

SF360 User Conference

DashboardRiskManagementPRP ControlMonitoringMaster DataUtilities

Ingredient / Material

Ingredient / Material Details

Name

Raw Milk

Identifier

6

Folder

Materials

Cleaning Chemicals

Ingredients

Banana Pudding

Commodities

Demo Ingredients

New FolderRenameDelete

Categories

Category

+ Add Line

Reference

Country Of Origin

Country

Ukraine

+ Add Line

Material Types

- Ingredients
- Final Products
- Packaging
- Services

DocLists

DocList are used to define which documents and data are required to be collected from Suppliers about their operations and materials. They are used directly in the assessment workflow. DocLists are located in the **Master Data > Categories** Module.

FOOD SAFETY MANAGEMENT SOLUTION

SF360 User Conference

DashboardRiskManagementPRP ControlMonitoringMaster DataUtilities

Assessment Record

COMPLETED

No.	Date	Name	Supplier
17	02/15/2017	CHEESE COMPANY :: Raw Milk (17)	Cheese Company

Related Records

Supplier Corrective Action (3) - Completed

Details

Data Collection

Doclist

No.	Requirement	Review Date
MD001	Materials Assessment Questionnaire: Download questionnaire. Complete, sign, date and attach. This document addresses the specific hazards for the raw material	02/15/2019
MD003	Product Specification Sheet: Attach a product specification sheet for the material.	02/15/2018
MD005	Process Flow Diagram: Attach your the Process Flow Diagram/ HACCP summary which includes CCPs	02/15/2018
MD010	Country of Origin Statement: Attach a statement on the Country of Origin.	02/15/2018
MD011	Regulatory Compliance Statement: Attach any documents which prove any countries where your material is registered and can be legally traded.	02/15/2018

Documents and Data Types

- Assessment Questionnaires
- Audit Certificates
- Statements
- Reports
- Plans
- COA's / COC's

Risk Assessment Models

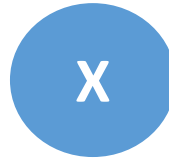
Safefood 360 uses risk assessment models embedded in the assessment workflow. These can be defined for the company's specific use. RA models are located in the **Risk > Food Safety Plan > Models** Module.

Probability Rating

Rating	Food Safety Description
1	Practically Impossible
2	Not Expected to Occur
3	Could Occur
4	Known to Occur
5	Common

Severity Rating

Rating	Food Safety Description
1	Insignificant
2	Customer Complaint
3	Product Recall
4	Serious Illness
5	Fatal



Risk Rating:

Risk	From	To	Description
Low	1	4	Low Risk (1 - 4)
Medium	5	14	Medium Risk (5 - 14)
High	15	25	High Risk (15 - 25)

Decision Tree Models

Safefood 360 uses Decision Trees embedded directly in the workflow to determine which verification program is applicable to the materials and supplier assessment. Decision Tree Models are located in the **Risk > Food Safety Plan > Models** Module.

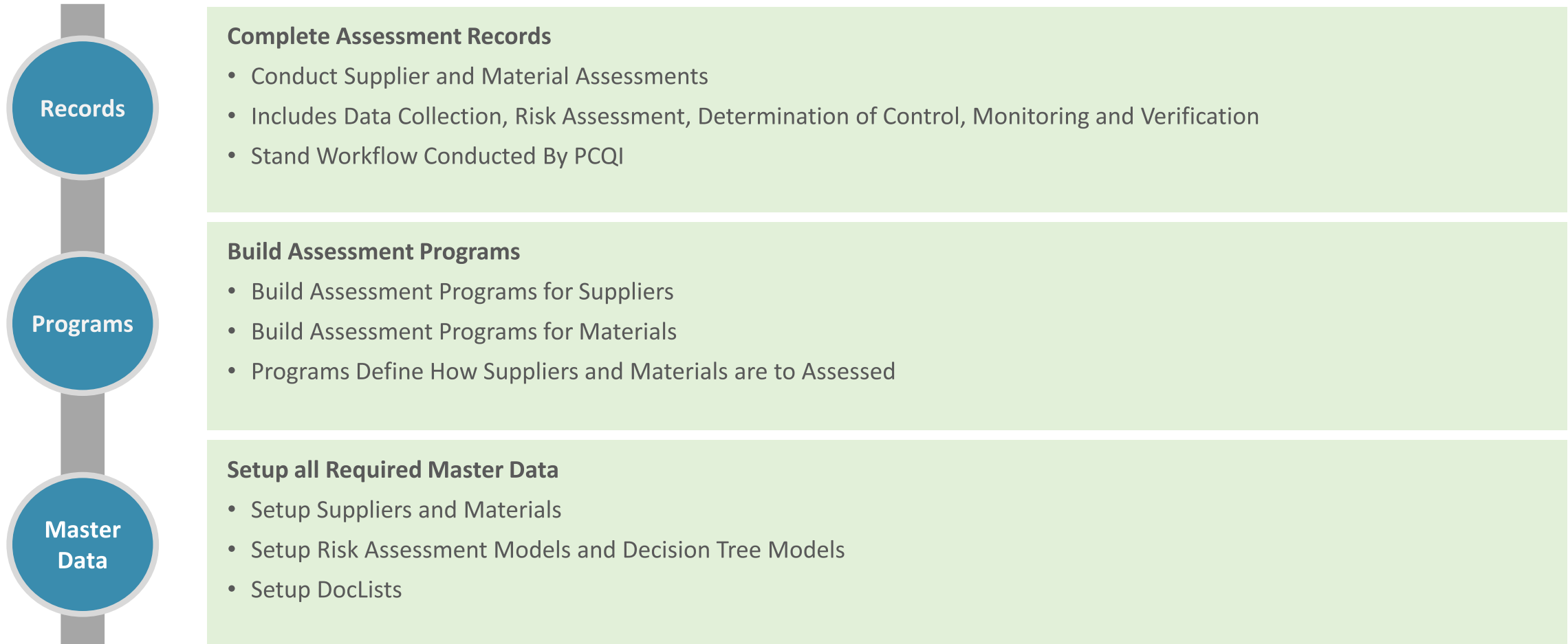
Determination of Control

Decision Tree

No.	Question	Answer
1	Is the material sourced from a foreign supplier?	Yes
2	Is the material for research or evaluation?	N/A
3	Is the material a Juice or fish / fishery or Dairy Grade A product subject to HACCP?	N/A
4	Is the material a low acid canned food (LACF)?	N/A
5	Is the material safe for its intended use without an appropriate control?	N/A
6	Do we rely on an internal appropriate control to ensure that the identified hazard will be significantly minimized or prevented?	N/A
7	Do we rely on the supplier to apply a supply-chain-applied control for significant identified hazards which are likely to occur?	N/A
8	Do we rely on an entity other than the supplier to apply a supply-chain-applied control?	N/A
9	Is the imported material one of the following (Food for personal consumption; alcoholic beverages; food that this transhipped; food for re-export; food for research or evaluation)?	No

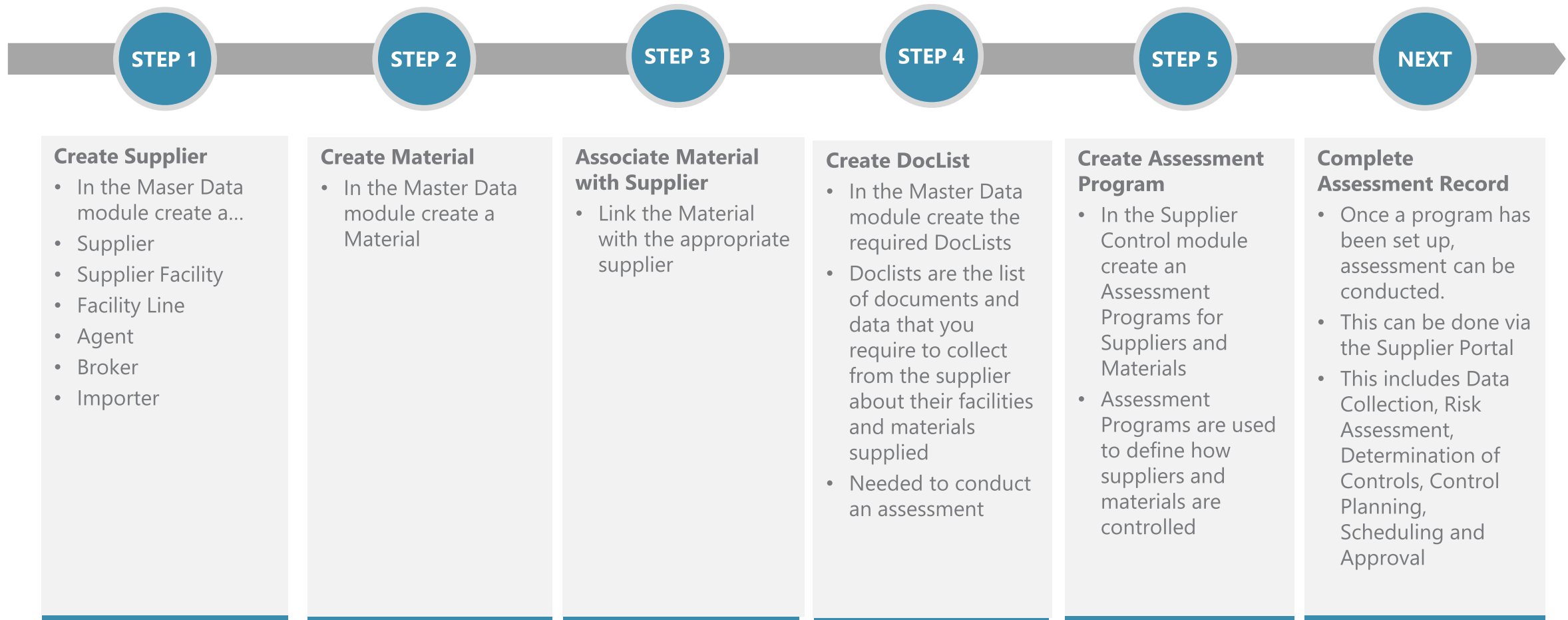
3 Building Blocks of Supplier Verification in Safefood 360

The 3 building blocks of Supplier Verification include Master Data, Assessment Programs and Assessment Records.



Supplier & Material Assessment (Preliminary Steps)

The following details the preliminary steps required to conduct a Supplier or Material assessment in Safefood 360 to meet the requirements of supplier verification under FSMA



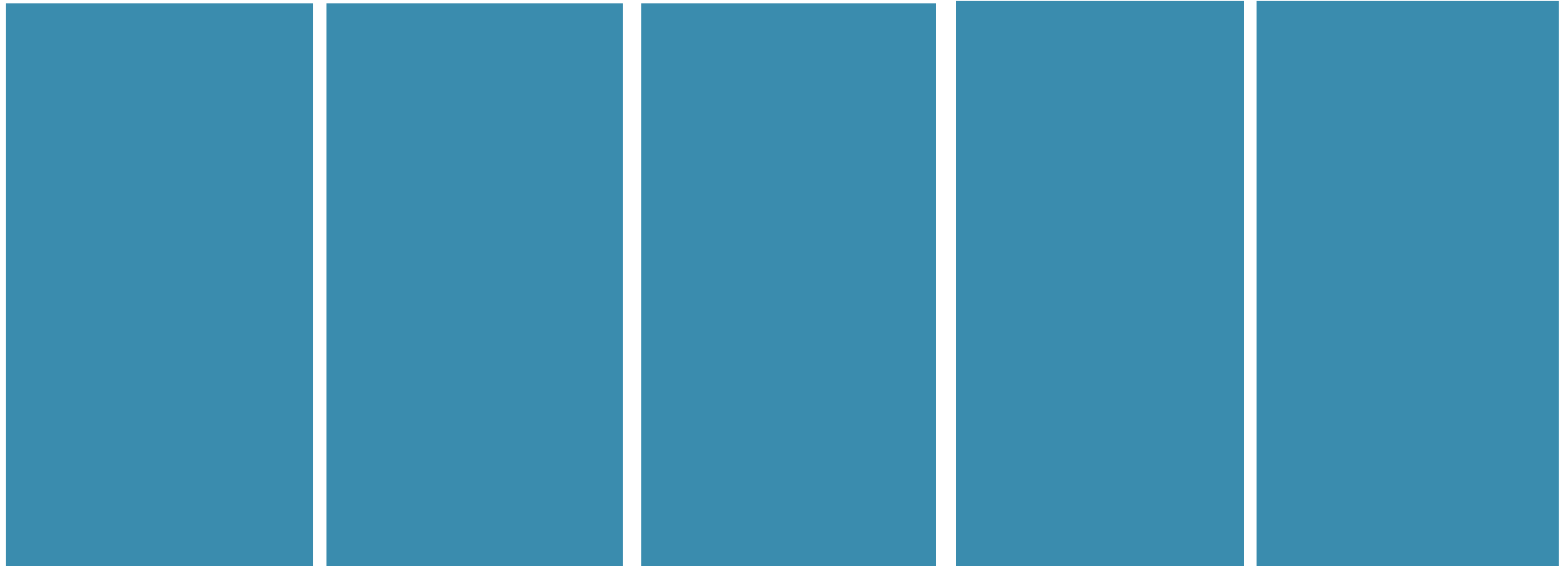
Supplier & Material Assessment (Preliminary Steps)

The following details the preliminary steps required to conduct a Supplier or Material assessment in Safefood 360 to meet the requirements of supplier verification under FSMA

STEP 1

Create Supplier

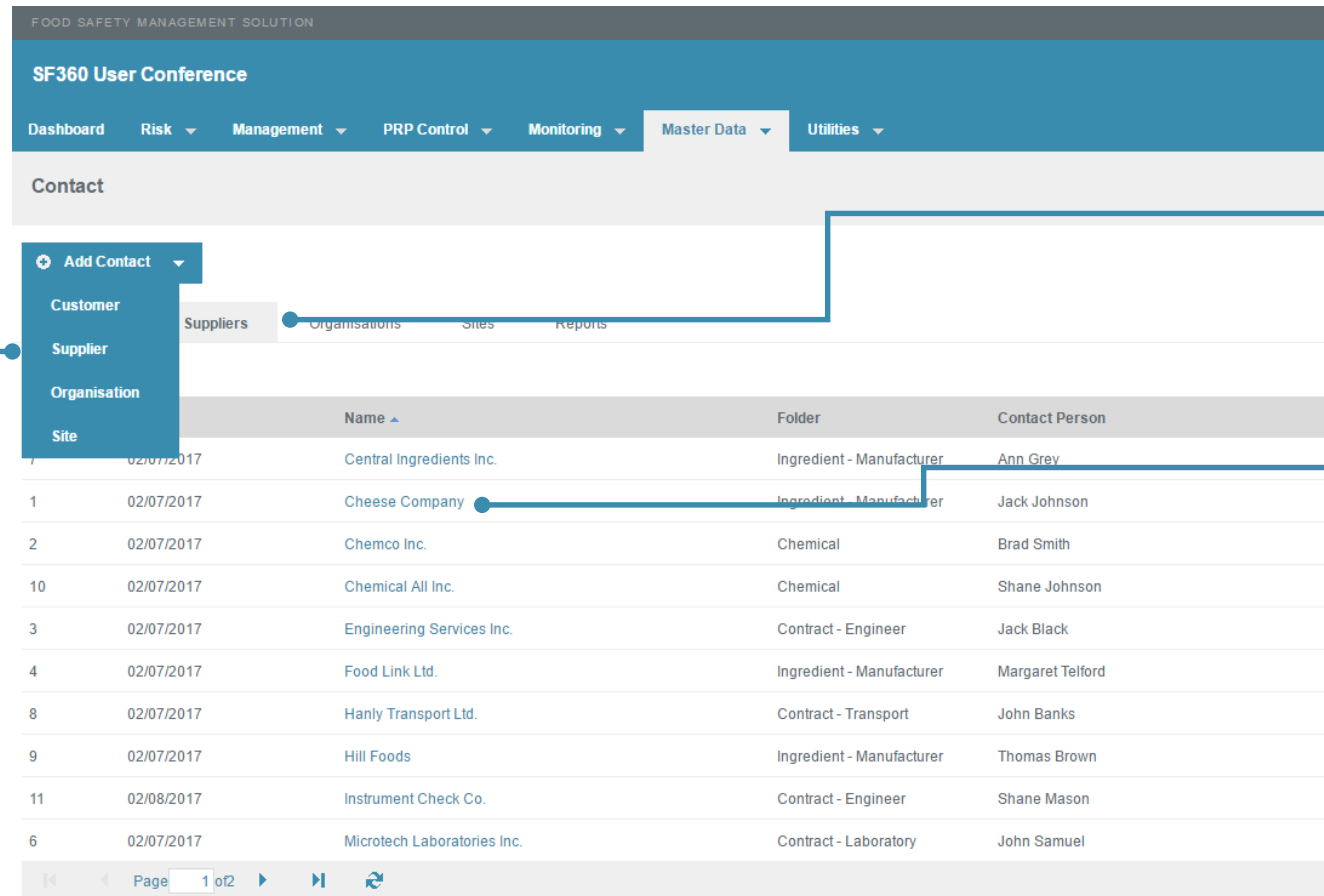
- In the Master Data module create a Supplier
- Supplier
- Supplier Facility
- Facility Line
- Agent
- Broker
- Importer



Contacts Module

Master Data > Contacts. Contacts include Suppliers which are a core building block of your supplier verification system in Safefood 360. The Contacts module is used to set-up all a full list of all your Suppliers, Supplier Facilities, Brokers, Agents and where required individual production lines within your supplier facilities.

Add Contact > Supplier
Used to add a new supplier to the Master Data list



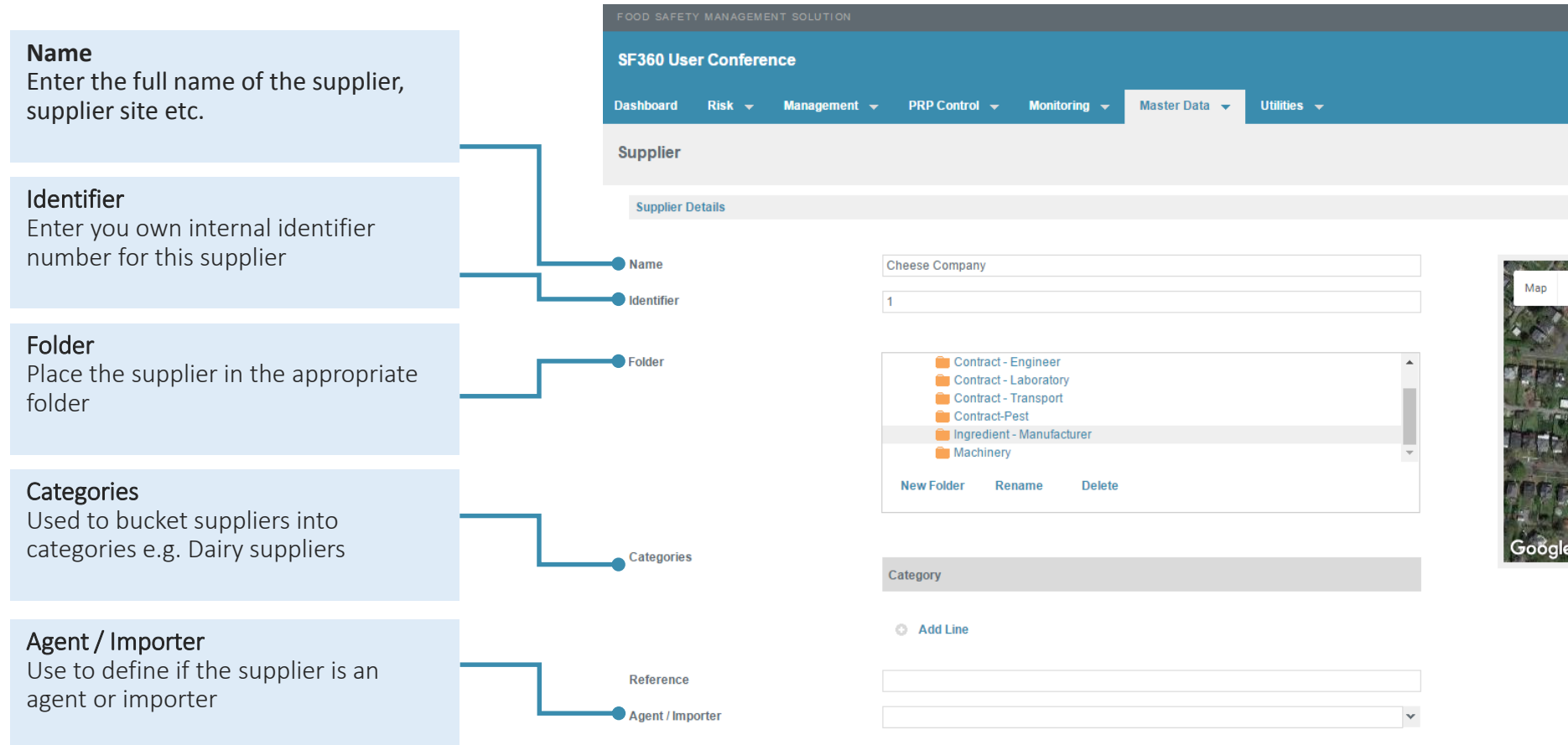
		Name ▲	Folder	Contact Person
	02/07/2017	Central Ingredients Inc.	Ingredient - Manufacturer	Ann Grey
1	02/07/2017	Cheese Company	Ingredient - Manufacturer	Jack Johnson
2	02/07/2017	Chemco Inc.	Chemical	Brad Smith
10	02/07/2017	Chemical All Inc.	Chemical	Shane Johnson
3	02/07/2017	Engineering Services Inc.	Contract - Engineer	Jack Black
4	02/07/2017	Food Link Ltd.	Ingredient - Manufacturer	Margaret Telford
8	02/07/2017	Hanly Transport Ltd.	Contract - Transport	John Banks
9	02/07/2017	Hill Foods	Ingredient - Manufacturer	Thomas Brown
11	02/08/2017	Instrument Check Co.	Contract - Engineer	Shane Mason
6	02/07/2017	Microtech Laboratories Inc.	Contract - Laboratory	John Samuel

Supplier Tab
Used to display the list of suppliers currently set up in the Master Data List

Supplier Entity
Used to access the **Supplier Module Environment** where you can view / edit / delete data relating to an existing supplier

STEP 1 :: Create a Supplier

Master Data > Contacts > Add Contact > Supplier. In the Contacts module you can set up your suppliers which will be assessed later for compliance against FSMA.



The screenshot shows the 'SF360 User Conference' interface with the 'Master Data' tab selected. The 'Supplier' section is active, showing a 'Supplier Details' form. A diagram on the left maps the form fields to their purposes:

- Name:** Enter the full name of the supplier, supplier site etc. (points to the 'Name' field).
- Identifier:** Enter your own internal identifier number for this supplier (points to the 'Identifier' field).
- Folder:** Place the supplier in the appropriate folder (points to the 'Folder' dropdown menu).
- Categories:** Used to bucket suppliers into categories e.g. Dairy suppliers (points to the 'Categories' dropdown menu).
- Agent / Importer:** Use to define if the supplier is an agent or importer (points to the 'Agent / Importer' dropdown menu).

The form fields are as follows:

- Name:** Cheese Company
- Identifier:** 1
- Folder:** Contract - Engineer, Contract - Laboratory, Contract - Transport, Contract - Pest, Ingredient - Manufacturer, Machinery
- Categories:** (Empty)
- Agent / Importer:** (Empty)

Buttons: New Folder, Rename, Delete, Add Line.

Practical Exercise

Task - Create a Supplier

Set-up a Supplier in the Master Data > Contact module



5 minutes



Instructions

- Click **Master Data > Contacts**
- Click **Add Contact > Supplier**
- Complete Supplier Details in the supplier form
- Use your Name as the Supplier Name
- Save supplier form



FOOD SAFETY MANAGEMENT SOLUTION

SF360 User Conference

Dashboard Risk Management PRP Control Monitoring Master Data Utilities


Supplier

Supplier Details

Name

Identifier

Folder

►  Suppliers

New Folder Rename Delete

Categories

Category

⊕ Add Line

Reference

Agent / Importer

Supplier & Material Assessment (Preliminary Steps)

The following details the preliminary steps required to conduct a Supplier or Material assessment in Safefood 360 to meet the requirements of supplier verification under FSMA

STEP 1

Create Supplier

- In the Master Data module create a Supplier
- Supplier
- Supplier Facility
- Facility Line
- Agent
- Broker
- Importer

STEP 2

Create Material

- In the Master Data module create a Material



Master Data > Products Materials> Add Material. In the Products Materials module you can set up your materials which will be assessed later for compliance against FSMA.

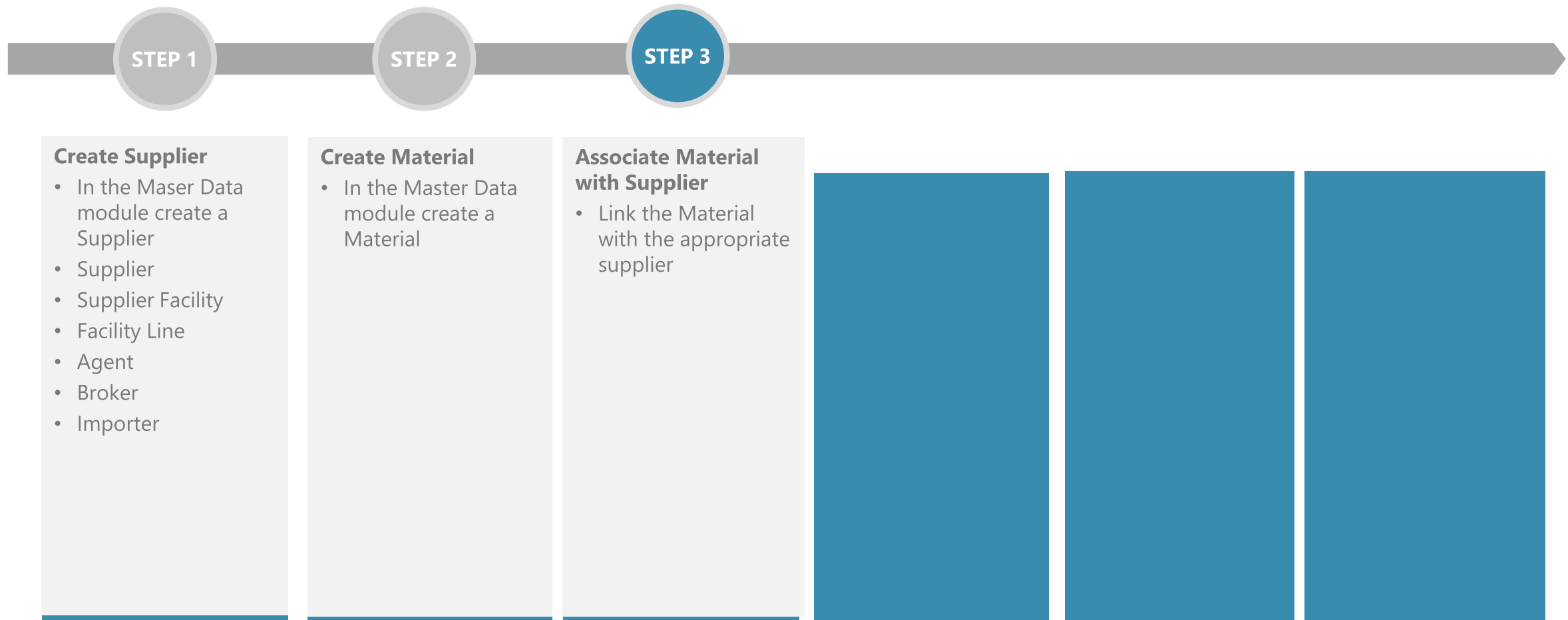
The screenshot shows the 'SF360 User Conference' interface for the 'Ingredient / Material' section. The form includes the following fields and annotations:

- Name:** A text input field containing 'Raw Milk'. An annotation box on the left explains: 'Name: Enter the name of the material, ingredient, packaging etc.'
- Identifier:** A text input field containing '6'. An annotation box on the left explains: 'Identifier: Enter your own unique identifier number'.
- Folder:** A dropdown menu showing a tree structure: 'Materials' > 'Ingredients' > 'Demo Ingredients' (selected). An annotation box on the left explains: 'Folder: Place the material in the appropriate folder'.
- Categories:** A text input field. An annotation box on the left explains: 'Categories: Used to bucket suppliers into categories e.g. Dairy ingredients'.
- Reference:** A text input field. An annotation box on the left explains: 'Reference: Used for additional referencing of the material where required'.
- Country Of Origin:** A dropdown menu showing 'Ukraine'. An annotation box on the right explains: 'Country Of Origin: Select the country from which the material is originating'.

Navigation tabs at the top include: Dashboard, Risk, Management, PRP Control, Monitoring, Master Data (selected), and Utilities.

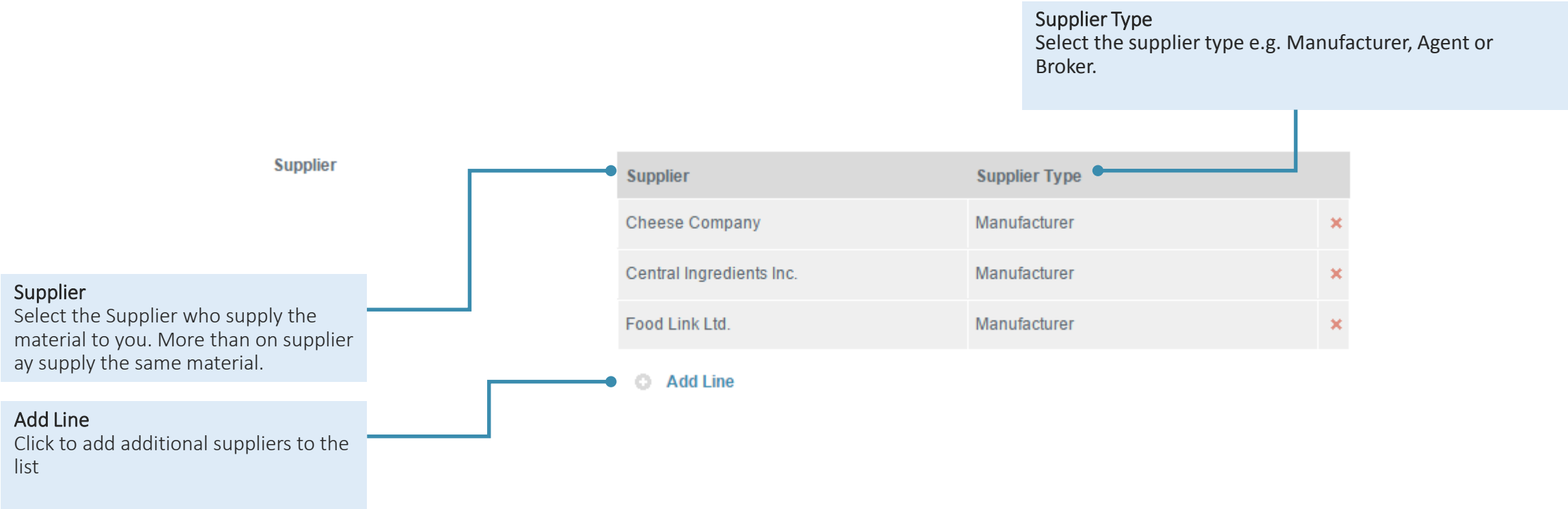
Supplier & Material Assessment (Preliminary Steps)

The following details the preliminary steps required to conduct a Supplier or Material assessment in Safefood 360 to meet the requirements of supplier verification under FSMA



STEP 3 :: Associate a Material with a Supplier

Materials Record. While completing the Materials record, you can complete the supplier field which allows you to link the material to a specific supplier or suppliers. This relationship is important as it allows SF360 to build your approval list based on Supplier and Materials



Practical Exercise

Task – Create a Material and Associate with Supplier

Set-up a Material in the Master Data > Product Materials module and associate with a Supplier



5 minutes



Supplier

Instructions

- Click **Master Data > Products Materials**
- Click **Add Material**
- Complete Material Details in the materials form
- Use your name as the Material
- In the Supplier Field select the appropriate supplier
- Save Material form

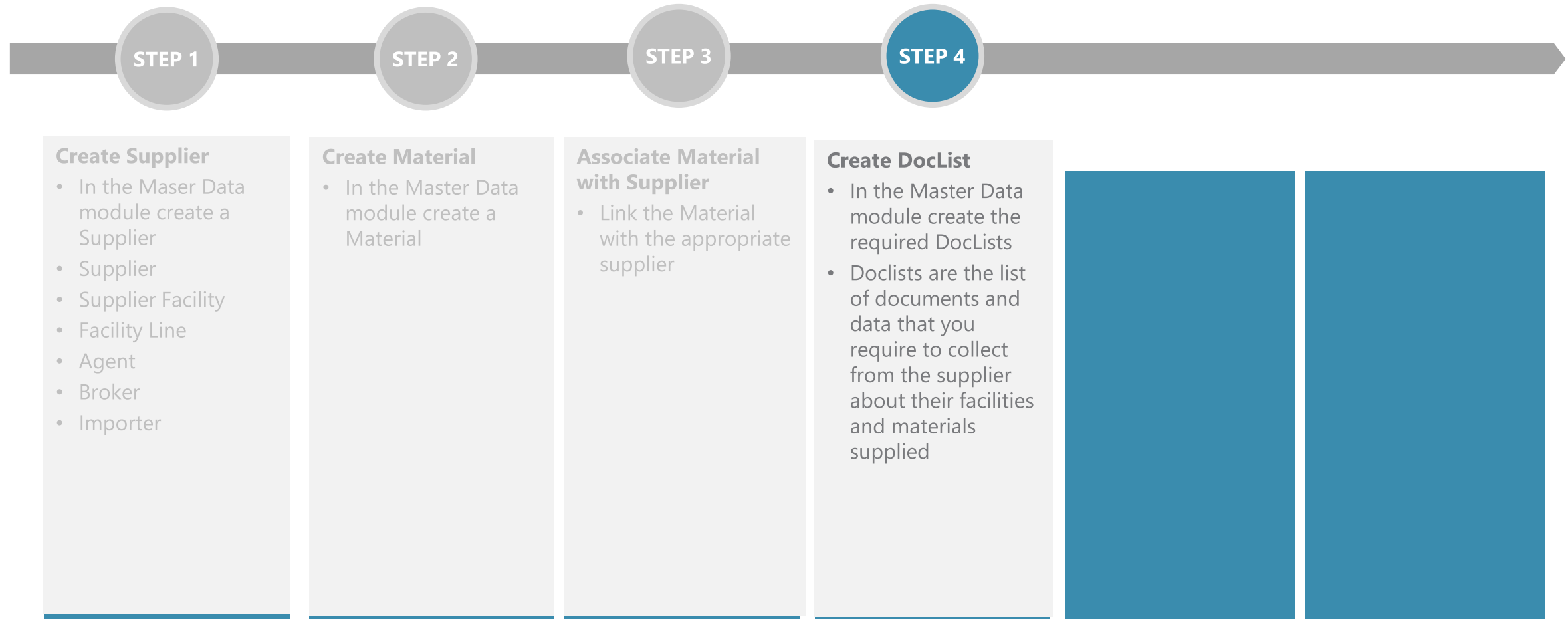


Supplier	Supplier Type	
Cheese Company	Manufacturer	×
Central Ingredients Inc.	Manufacturer	×
Food Link Ltd.	Manufacturer	×

 [Add Line](#)

Supplier & Material Assessment (Preliminary Steps)

The following details the preliminary steps required to conduct a Supplier or Material assessment in Safefood 360 to meet the requirements of supplier verification under FSMA



STEP 4 :: Create DocList

Master Data > Categories > Add Category > Checklist. DocLists are the lists of documents and data you wish to collect from your supplier regarding their operations and materials.

Name

Enter a name for your DocList
e.g. Foreign Supplier DocList

Checklist Details

Name

Folder

Folder

Select an appropriate folder to locate the DocList.

Type

Click DocList to create a DocList

Type

Checklist

Checklist

Enter the name of the document you wish to collect from supplier. Instructions may also be provided to assist the supplier

Add Line / Checklist

Click to add additional Lines and Documents to be collected

[CONFERENCE SAMPLE] Supplier Doclist

- My Checklists
 - Material Doclist
 - Pre-Production Checklists
 - Supplier Doclist

New Folder Rename Delete

☐ Checklist ☒ Doclist

No.	Description	Document	Heading
D001	Supplier Pre-Assessment Questionnaire: Attach your Pre-Assessment Questionnaire	Supplier Questionnaire	
D002	GFSI Certificate: Attach your current valid Food Safety GFSI Certificate - BRC/IFS/FSSC 22000/SQF		
D003	GFSI Audit and Corrective Actions: Attach your GFSI or equivalent audit and related corrective actions		
D004	Product Specification: Attach your product specification sheet		
D005	HACCP/PCP Plan: Attach your HACCP/PCP program for review		
D006	Process Flow Diagram: Attach your Process Flow Diagram including clear indication of CCP and other relevant control points		
D007	Certificate of Analysis/Conformity: Attach your Certificate of Analysis or Conformity		
D008	Kosher Certificate: Attach (if applicable) your Kosher Certificate		
D009	Halal Certificate: Attach your valid Halal Certificate for the product		
D010	Organic Certificate: Attach (if applicable) your Organic Certificate		
D011	GMO Statement: Attach your GMO Free statement		

Search:

- Documents
 - Legislation Documents
 - Sample Documents
 - Supplier
 - Templates

Add New Select Cancel

Document

Attach a standard form or document which you would like the supplier to download and use e.g. Templates

☒ Add Line ☐ Add Checklist

Practical Exercise

Task – Create a Simple DocList

Set-up a DocList in the Master Data > Categories module



10 minutes



Instructions

- Click **Master Data > Categories**
- Click **Add Category > Checklist**
- Complete Checklist form
- Add two simple checks
- Use your name as the Checklist Name
- Save Doclist form



FOOD SAFETY MANAGEMENT SOLUTION

SF360 User Conference

Dashboard Risk Management PRP Control Monitoring Master Data Utilities

Checklist

Checklist Details

Name

Folder

New Folder Rename Delete

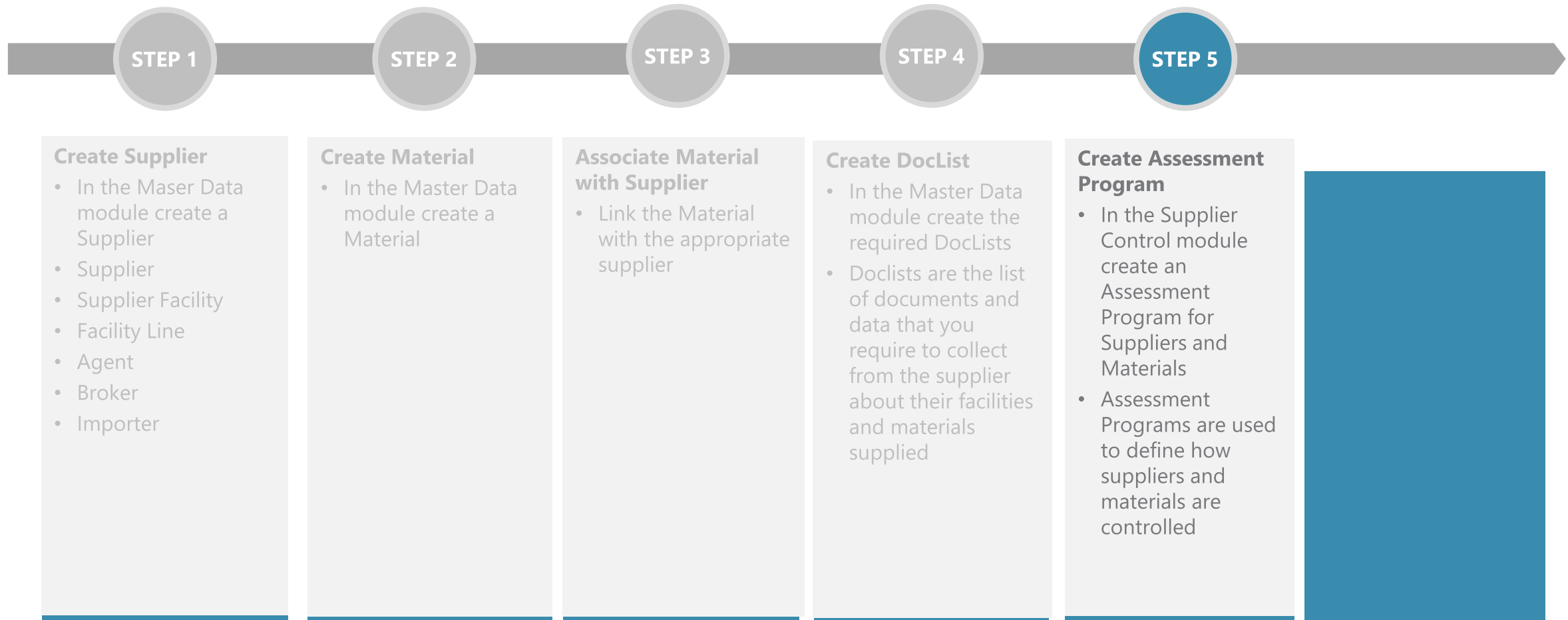
Type ☐ Checklist ☒ Doclist

No.	Description

+ Add Line + Add Checklist

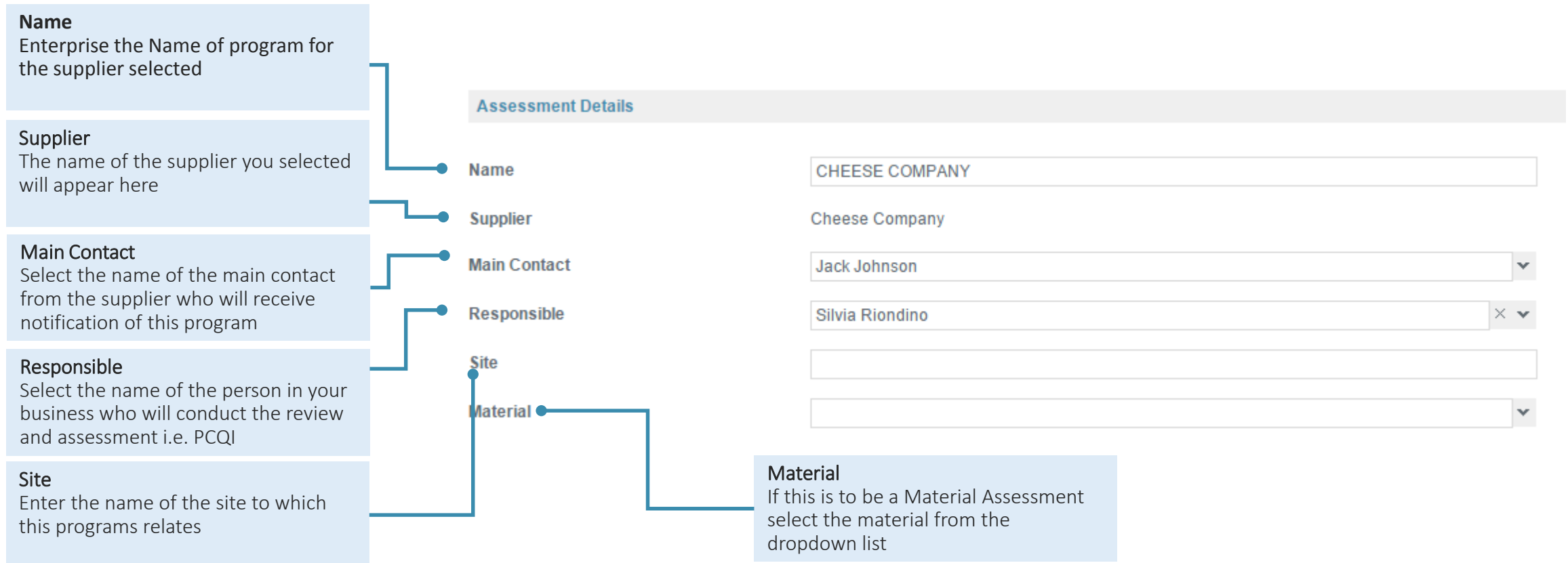
Supplier & Material Assessment (Preliminary Steps)

The following details the preliminary steps required to conduct a Supplier or Material assessment in Safefood 360 to meet the requirements of supplier verification under FSMA



STEP 5 :: Create Supplier Assessment Program (Part 1)

PRP Control > Supplier Control > Add Assessment Program > . Using the Master Data already setup we will create an assessment program for a Supplier



Name
Enter the Name of program for the supplier selected

Supplier
The name of the supplier you selected will appear here

Main Contact
Select the name of the main contact from the supplier who will receive notification of this program

Responsible
Select the name of the person in your business who will conduct the review and assessment i.e. PCQI

Site
Enter the name of the site to which this programs relates

Material
If this is to be a Material Assessment select the material from the dropdown list

Assessment Details

Name
CHEESE COMPANY

Supplier
Cheese Company

Main Contact
Jack Johnson

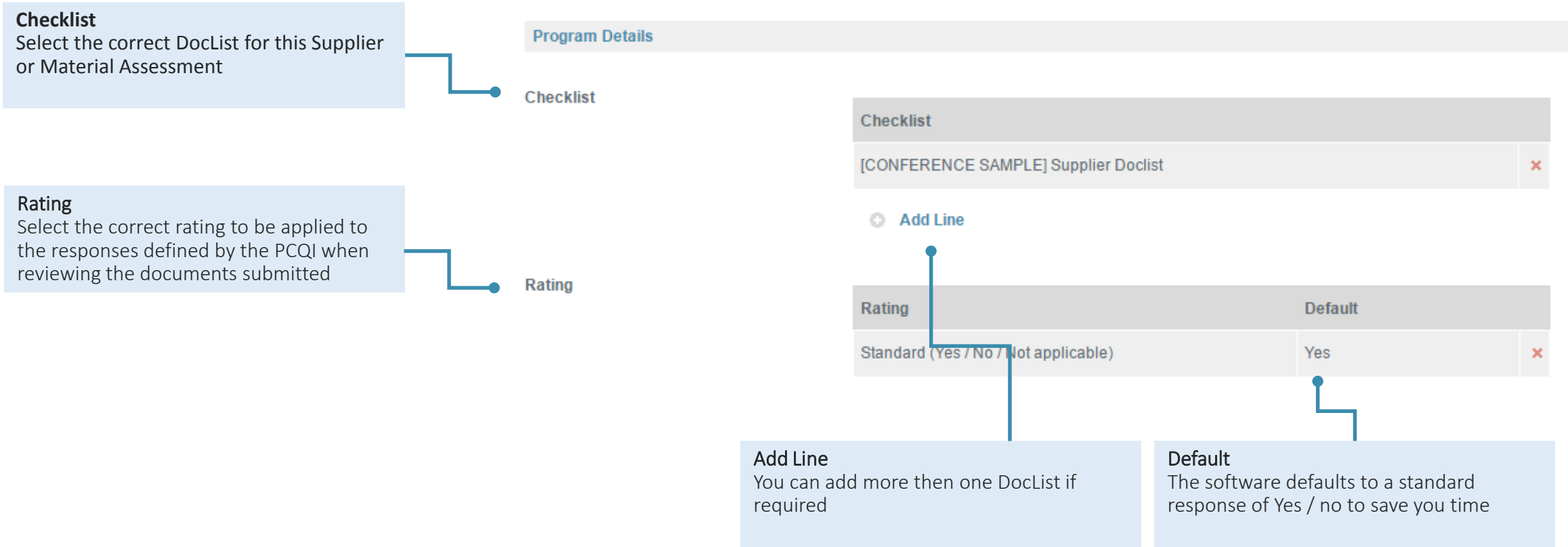
Responsible
Silvia Riondino

Site

Material

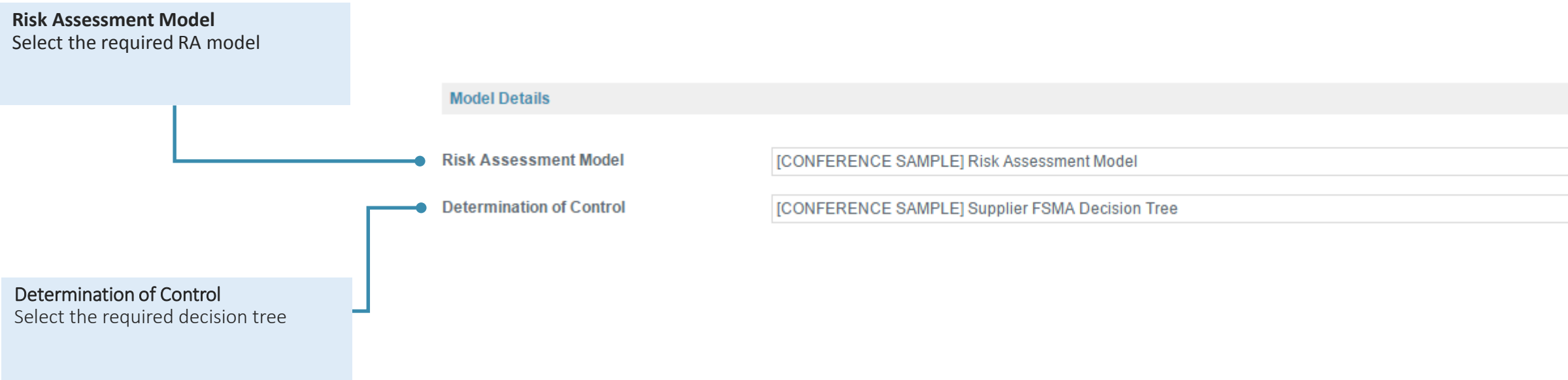
STEP 5 :: Create Supplier Assessment Program (Part 2)

Program Details Section. Complete the Program Details section. This section allows you to define the correct DocList and Rating system for assessment.



STEP 5 :: Create Supplier Assessment Program (Part 3)

Model Details Section. Next you can select which Risk Assessment and Decision Tree models you wish to use in this Assessment Program. SF360 has already built the required models for you for FSMA to save you time but you can build your own.



Practical Exercise

Task – Create a Supplier Assessment Program

Set-up a Supplier Assessment Program in the Supplier Control Module

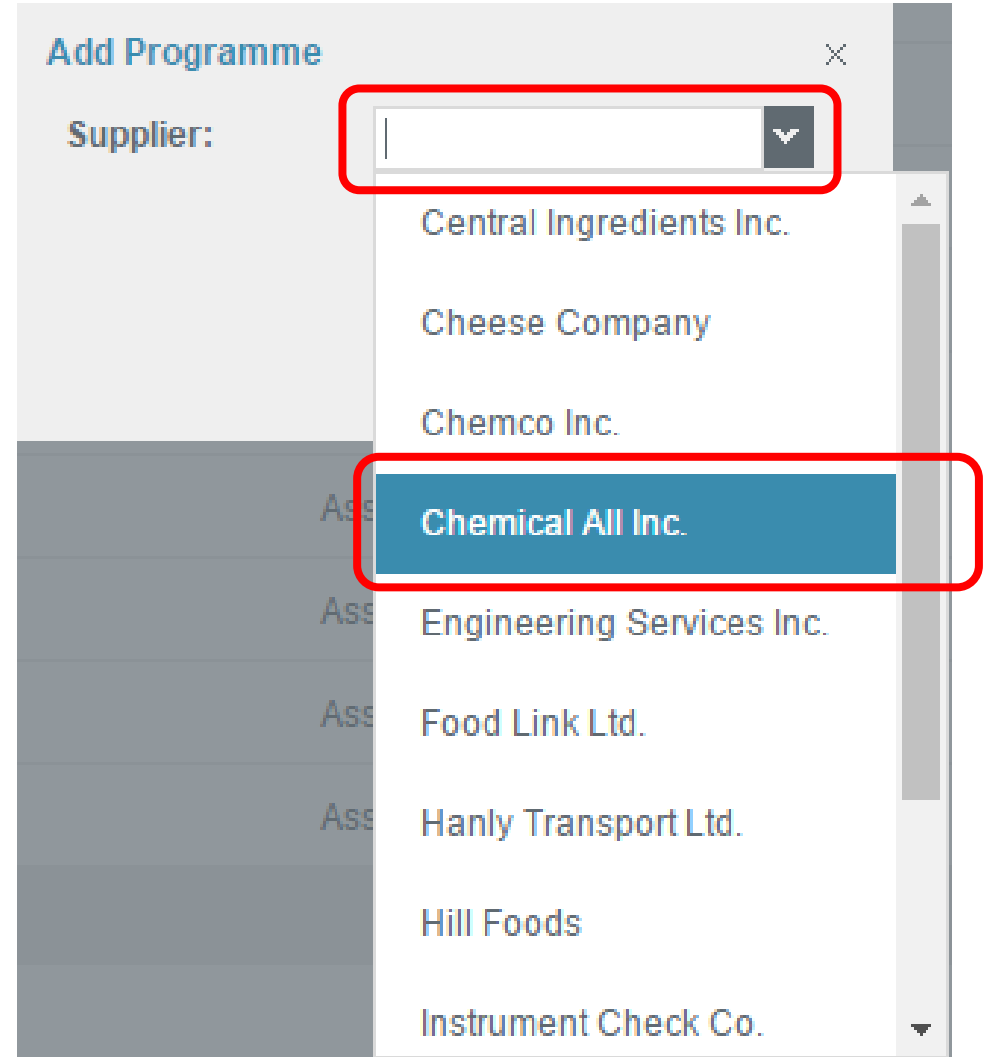


15 minutes



Instructions

- Click **PRP Control > Supplier Control**
- Click **Add Assessment Program**
- In the **Add Program** box select the required Supplier
- Complete the Program Details
- Use your Name as the Program Name
- Save Program



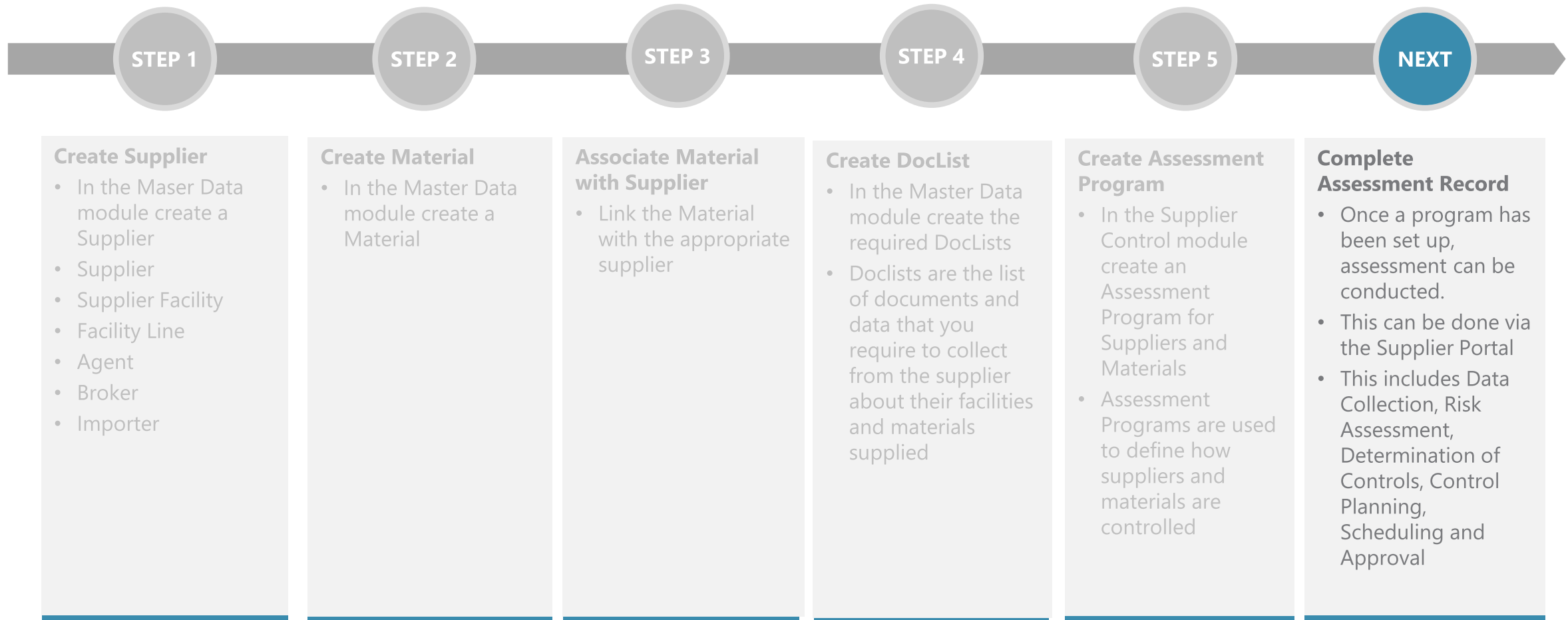
Add Programme [X]

Supplier: [Dropdown Arrow]

- Central Ingredients Inc.
- Cheese Company
- Chemco Inc.
- Chemical All Inc.**
- Engineering Services Inc.
- Food Link Ltd.
- Hanly Transport Ltd.
- Hill Foods
- Instrument Check Co.

Supplier & Material Assessment (Preliminary Steps)

The following details the preliminary steps required to conduct a Supplier or Material assessment in Safefood 360 to meet the requirements of supplier verification under FSMA



Practical Exercise

Task – View and Discuss Assessment Record

View a prepared Assessment Record and discuss



20 minutes



Instructions

- Click **PRP Control** > **Supplier Control**
- Click **Complete** Tab
- In the list click **CHEESE COMPANY**



FOOD SAFETY MANAGEMENT SOLUTION

SF360 User Conference

Dashboard Risk Management **PRP Control** Monitoring Master Data Utilities

Supplier Control

+ Add Assessment Program + Add Audit Program + Add Assessment + Add Audit

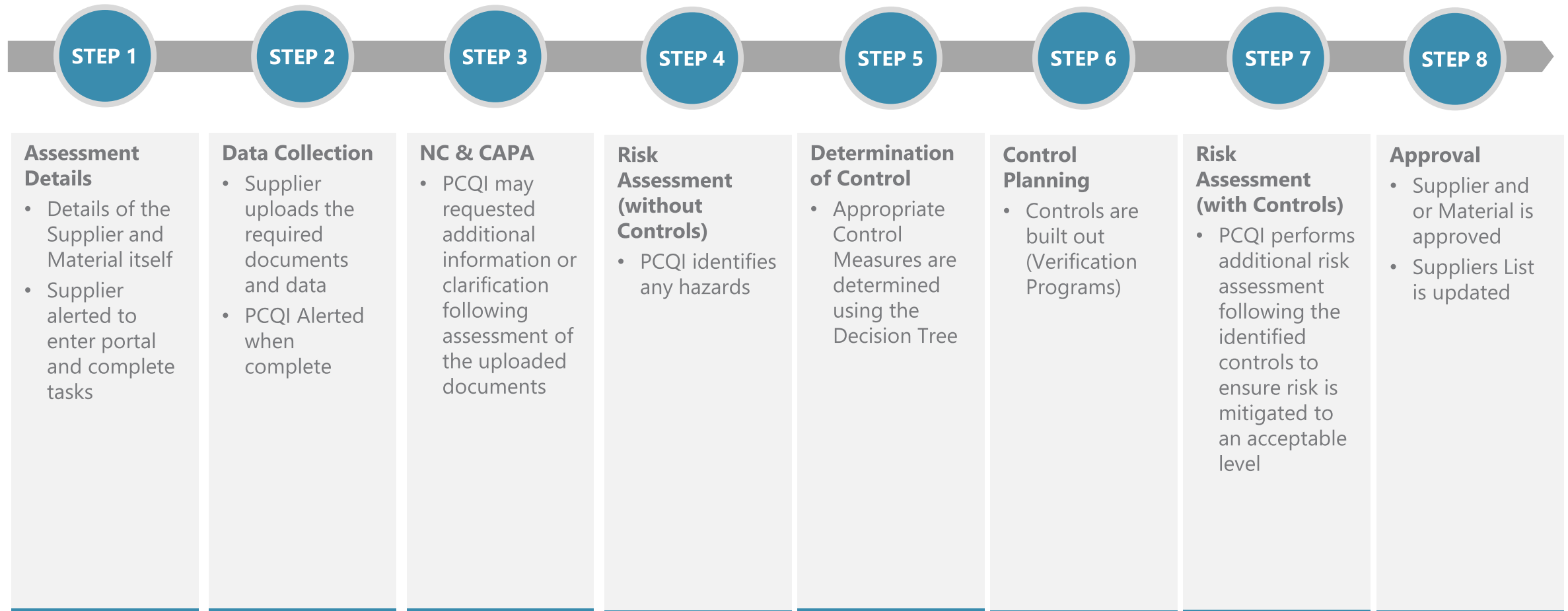
Summary Approved Supplier List **Complete** Plan Actions Suppliers Ma

No.	Date ▼	Name	Type
3	02/16/2017	Supplier Corrective Action (3)	Supplier Corrective Acti
17	02/15/2017	CHEESE COMPANY :: Raw Milk (17)	Assessment Record
2	02/14/2017	Supplier Corrective Action (2)	Supplier Corrective Acti
16	02/14/2017	CHEESE COMPANY (16)	Assessment Record

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Supplier & Material Assessment (Assessment Record Steps)

The following are the steps to complete the Assessment once the provisional steps have been completed. We will be completing all these task in the session. Instead we will view them in a prepared assessment and discuss each step.



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STEP 1

**Assessment
Details**

- Details of the Supplier and Material itself
- Supplier alerted to enter portal and complete tasks

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STEP 1 :: Assessment Details

Assessment Details Section. This section captures all the high level detail regarding the Assessment including the Supplier, Contact Persons, Site and the Material if it is a material assessment.

Date

Select the date the assessment was conducted

Supplier

The name of the Supplier will appear here

Site

The name of the Supplier Site will appear here

Material

The name of the Material to which the assessment applies will appear here

Details

Date

02/14/2017

Supplier

Cheese Company

Site

Material

Main Contact

Jack Johnson

Completed By

Jack Johnson

Position

QA Manager

Completed By

Select the name of the PCQI who conducted the assessment

Supplier & Material Assessment (Assessment Record Steps)

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STEP 2 :: Data Collection

Data Collection Section. In this section, the Supplier has uploaded all the required documents and data ready for the PCQI to conduct their Assessment. The PCQI will add relevant comments and decided if the data is sufficient. Corrective Actions can be generated if required.

No.	Requirement	Review Date	Comments / Observations	File	Corrective Action
D001	Supplier Pre-Assessment Questionnaire: Attach your Pre-Assessment Questionnaire	02/14/2019	Pre-assessment questionnaire review and fully complete with all required data.	Supplier Questionnaire_Cheese Company.xlsx (Awaiting Approval (Marija Kursan))	<input type="checkbox"/>
D002	GFSI Certificate: Attach your current valid Food Safety GFSI Certificate - BRC/IFS/FSSC 22000/SQF	02/14/2018	Certificate is valid for the coming 12 months	GFSI Certificate Sample.docx (Awaiting Approval (Marija Kursan))	<input type="checkbox"/>
D003	GFSI Audit and Corrective Actions: Attach your GFSI or equivalent audit and related corrective actions	02/14/2018	Report was reviewed including the individual actions. No critical non-conformances recorded	GFSI Audit Sample.docx (Awaiting Approval (Marija Kursan))	<input type="checkbox"/>
D004	Product Specification: Attach your product specification sheet	02/14/2019	Specification reviewed and contains all require product data	Product specification_Milk.jpg (Awaiting Approval (Marija Kursan))	<input type="checkbox"/>
D005	HACCP/PCP Plan: Attach your HACCP/PCP program for review	02/14/2019	PCP plan reviewed and includes appropriate control measures	PCP SAMPLE.docx (Awaiting Approval (Marija Kursan))	<input checked="" type="checkbox"/>

No
The reference number of the document

Requirement
The specific documents and instructions to the Supplier will appear here

Review Date
This is the date which the next uploading of this document will take place. It is set by the supplier and modified by PCQI

Comments / Observations
This field contains the PCQI's notes and comments relating to the requirement

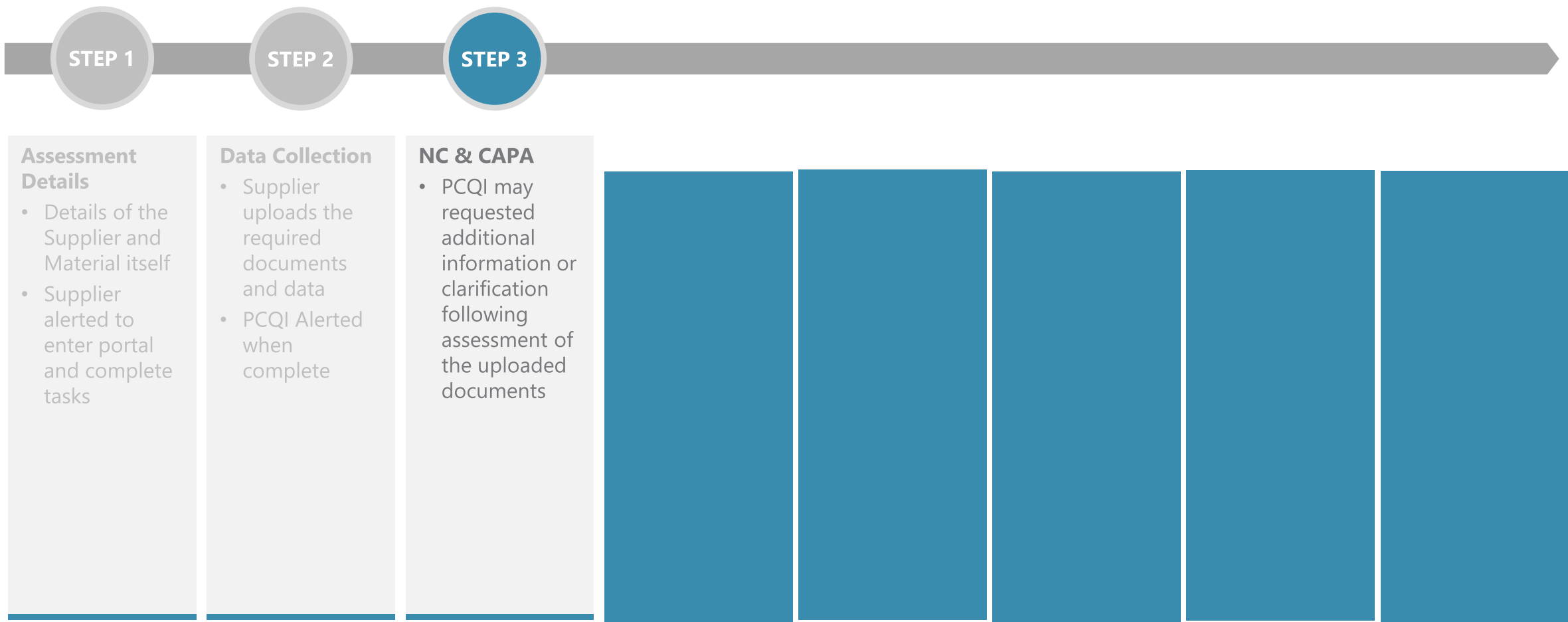
File
The attached document link is here. Click to review the document.

View / Download Document
The Supplier can click this icon to download a standard document to be completed and then re-uploaded

Corrective Action
If more information, document or clarification is required from the supplier the PCQI can click here to generate a corrective action which will be sent to the Supplier's Portal

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STEP 3 :: Corrective Action

Corrective Actions Section. This Section of the workflow is where the PCQI can define who will be responsible for any corrective action generated.

No	Requirement	Comments / Observations	Category	Responsible	Due Date
D030	SVP - Officially recognized or equivalent FSS: Attach documented evidence that the foreign supplier is in good compliance with officially recognized food safety authority	Attached document does not clear state that the company is in full compliance with local regulatory legislation.	Major	Jack Black	02/15/2017

No
The number of the document

Requirement
The Requirement to which the CAPA relates is pulled down from the previous step

Comments / Observations
The comments / observations by the PCQI are also pulled down and can be modified if required

Category
The PCQI can assign a category of Non-conformance

Responsible
The person within the supplier's business is selected here

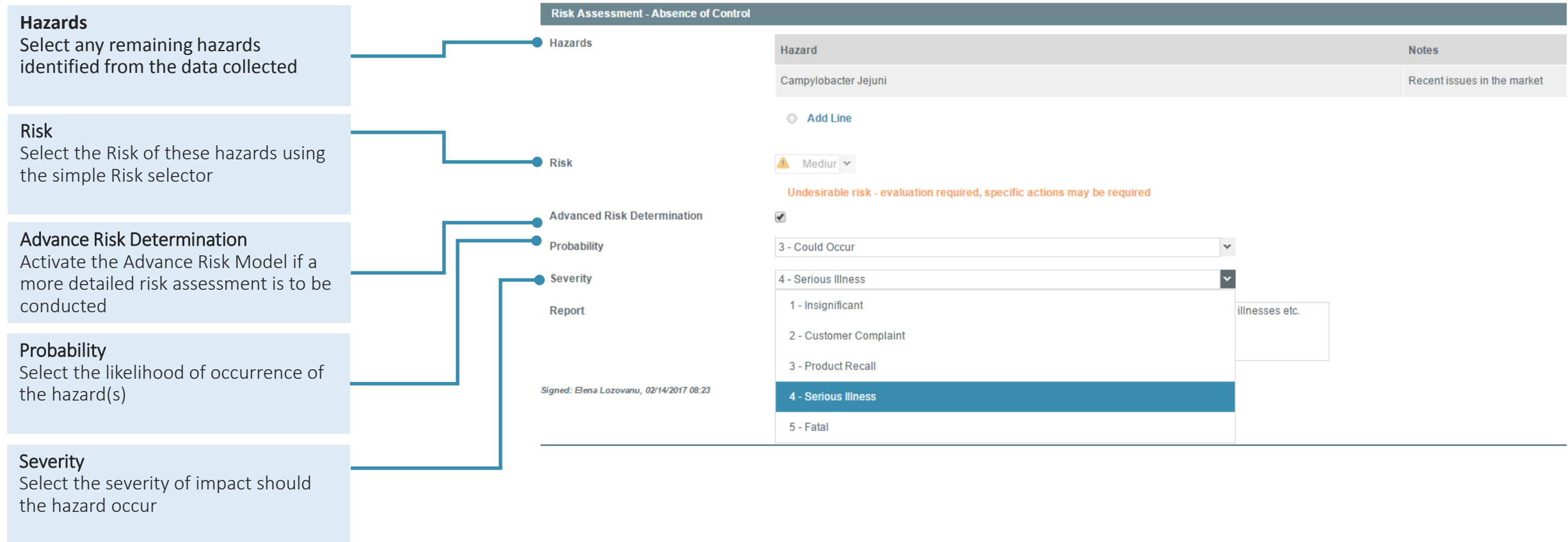
Due Date
The due date for completion of the action

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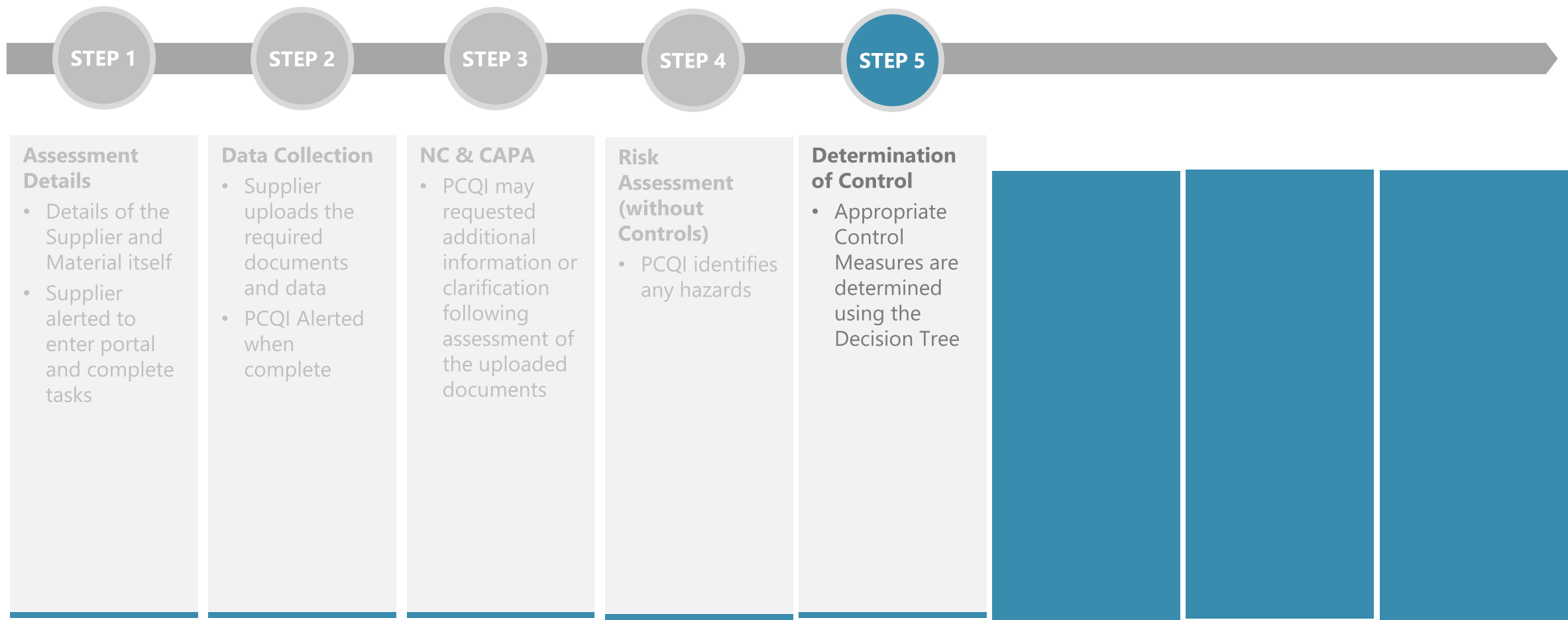


Risk Assessment – Absence of Control Section. Once all the required data and documents have been collected the PCQI is ready to conduct their risk assessment. FSMA requires this is conducted in the absence of controls even where they exist.



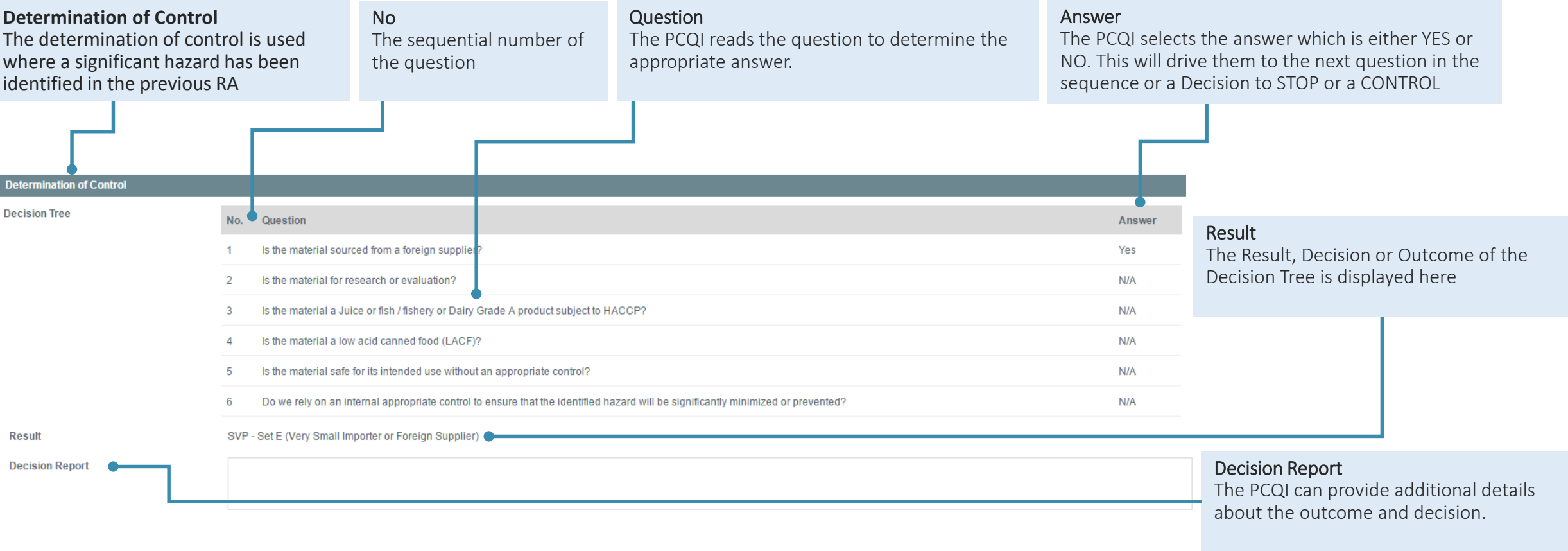
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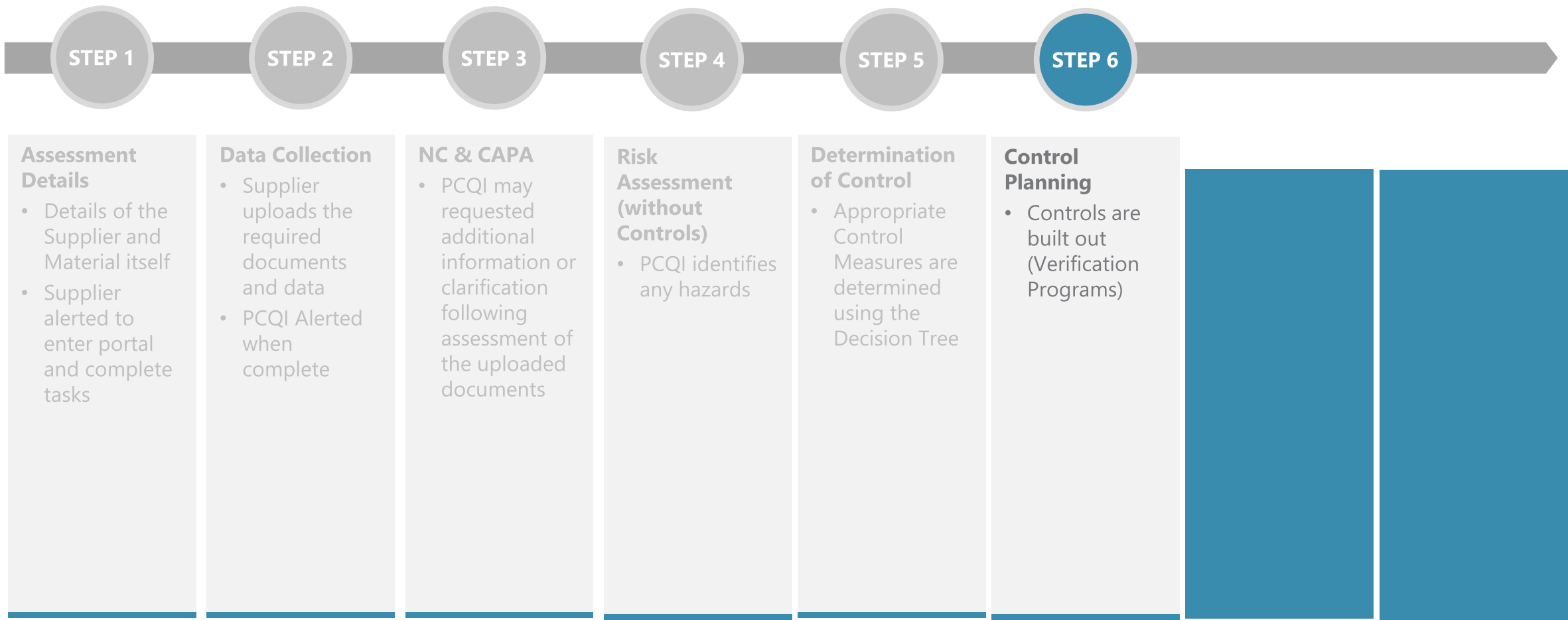
STEP 5 :: Determination of Control – Decision Tree

Determination of Control Section. In this section of the workflow, the PCQI utilizes the decision tree to determine which controls need to be applied. The Decision Tree uses a series of focused questions based on FSMA requirements to determine the appropriate controls. Safefood 360 has already built the appropriate FSMA decision trees into the software to save you time.



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STEP 6 :: Control Planning

Control Planning Section Section. Based on the outcome from the Decision Tree, if a control is required then the PCQI can defined it here. SF360 have built into the software the standard FSMA controls required based on a full review of the legislation.

Control
Enter the name of the control

Control Limit
Define the limit – what is acceptable and not acceptable

How
The procedure or method for control

Responsible
The person responsible

Frequency
How often the control is conducted

Corrective Action
Define clearly the action to be taken if limits are breached

Record
Select the record or program relating to this control

Control	Control Limit	How	Responsible	Frequency	Corrective Action	Record	Verification
Documented Verification	Documentation not available	Obtain documented evidence of eligibility annually (\$500k or less annually in food sales)	Qualified Individual	Initially	Suspend / Reject supply until documented verification is obtained	Cheese Company :: D027 SVP - Very Small Importer or Foreign Supplier Statement	Internal assessment by qualified individual
Documented Verification	Documentation not available	Obtain written assurance of foreign suppliers compliance every 2 years	Qualified Individual	2 Years	Suspend / Reject supply until documented verification is obtained	Cheese Company :: D027 SVP - Very Small Importer or Foreign Supplier Statement	Internal assessment by qualified individual

+

Add Line

+

Add Control

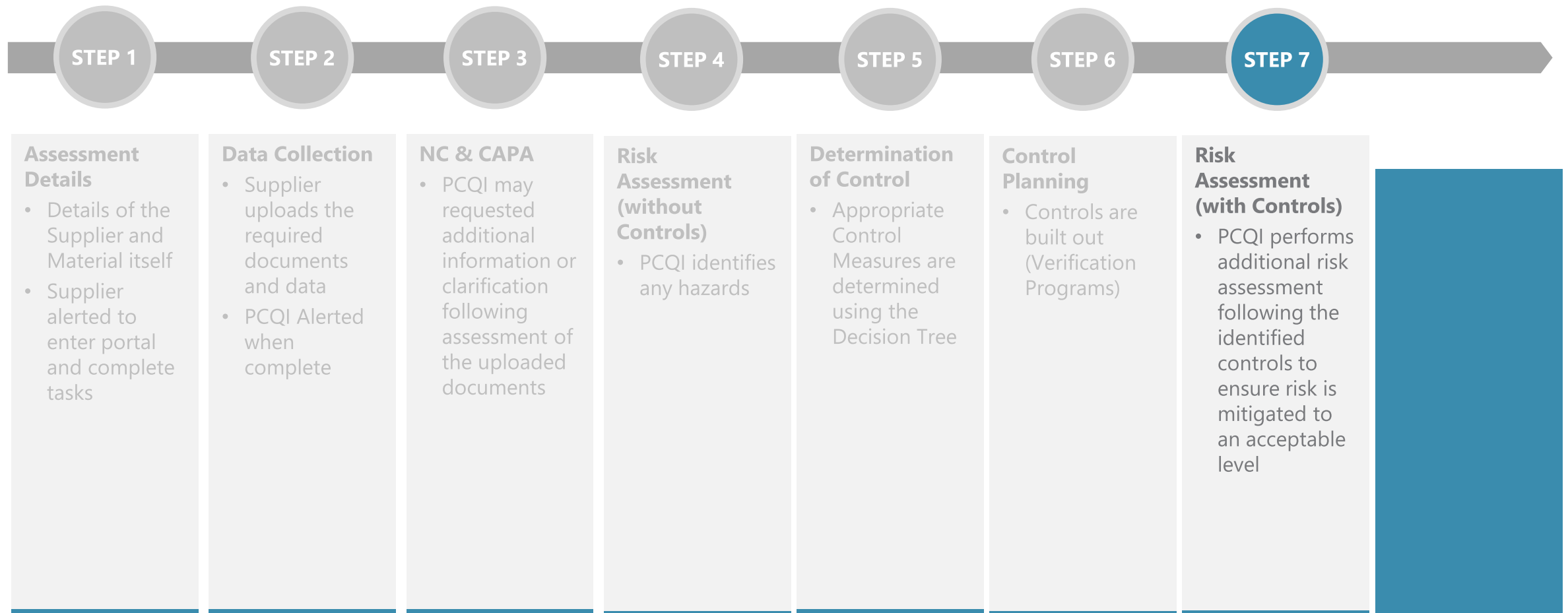
Add Line
You can add additional controls

Add Control
You can select from the SF360 Database select the appropriate control for the final outcome from the Decision Tree. The Table will be populated automatically

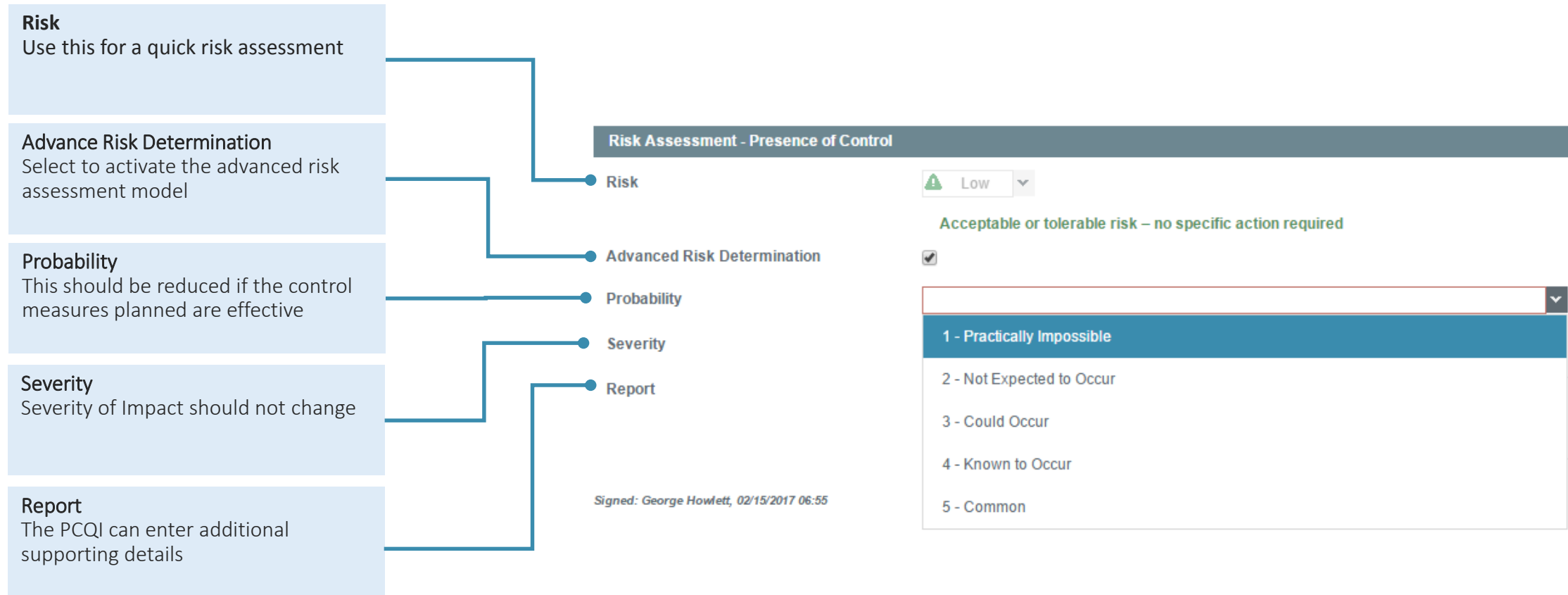
Verification
Define the verification activities for the control e.g. auditing

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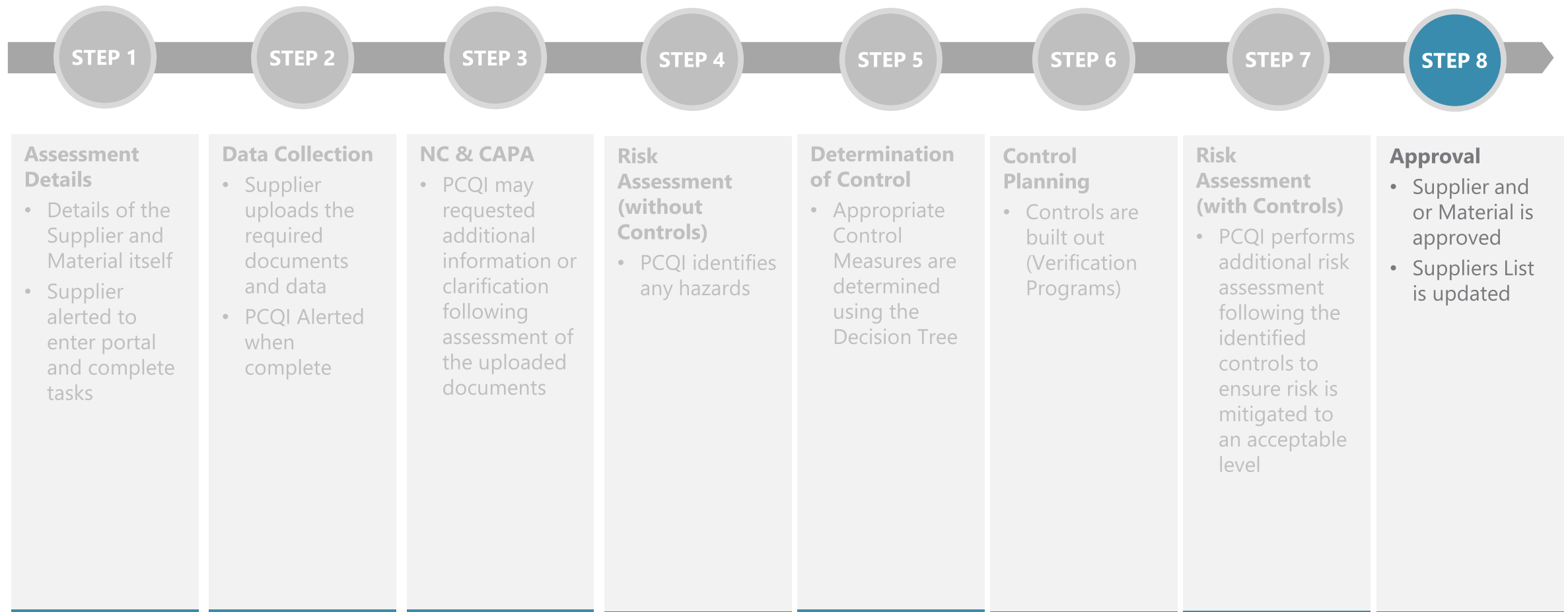


Presence of Control Section. Following the application of control measures, the risks identified should be mitigated. The PCQI should confirm this using the Risk Assessment Presence of Control section. Only the Probability is reduced by control measures.



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Approval Section. In this section the PCQI makes their final determination based on the assessment. Here the status of the supplier or material is defined as either Approved or Not Approved. This is a FSMA requirement.

