ISO 22000 Food Safety Management System Implementation Workbook

This comprehensive Food Safety Management System Certification package contains all the tools you will need to achieve ISO 22000:2018 Certification.

This workbook is provided to guide you in the implementation of your Food Safety Management System. The workbook is divided into 7 steps that are designed to assist you in implementing your food safety management system effectively:

- ✓ Step One: ISO 22000 Training for Management
- ✓ Step Two: Top Management Implementation
- ✓ Step Three: Food Safety Management System
- ✓ Step Four: Project 22000 including HACCP Implementation
- ✓ Step Five: Internal Auditing & Checklists
- ✓ Step Six: Review and Updating
- ✓ Step Seven: Final Steps to ISO 22000 Certification

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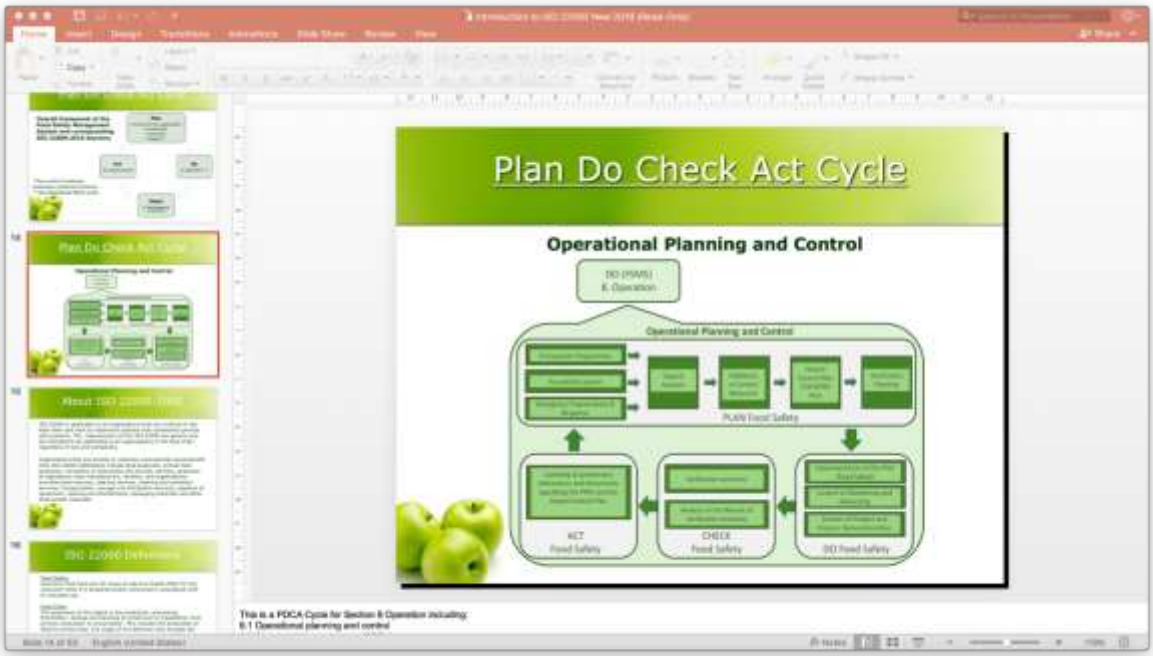
Step One: ISO 22000 Training for Management

Introduction to ISO 22000

This PowerPoint presentation will introduce the ISO 22000 standard to the management team and explain exactly how to start the process of implementing an ISO 22000 compliant Food Safety Management System.



Step Two: Top Management Implementation

Top Management need to start the implementation process.

determine the Context of the organization, how to demonstrate Leadership and Planning establish the Food Safety Management System fundamentals including Food Safety Policies and Objectives ensuring the integration of the FSMS requirements into the organization's business processes.

At this stage, Top Management need to:

- ✓ determine the Context of the organization
- ✓ demonstrate Leadership
- ✓ plan the establishment of the FSMS
- ✓ plan to provide adequate support and resources to establish the FSMS
- ✓ ensure there is adequate infrastructure and work environment
- ✓ allocating responsibility and authority

This stage requires the Top Management to meet and establish the foundations for the Food Safety Management System:

- ✓ Determine external and internal issues that are relevant and affect its ability to achieve the intended result(s) of its FSMS
- ✓ Determine the interested parties (Customer, Regulatory, Statutory and other) that are relevant to the FSMS
- ✓ Determine Customer, Regulatory, Statutory and other relevant Food Safety requirements
- ✓ Define the scope and boundaries of the FSMS
- ✓ Develop a Food Safety Policy
- ✓ Based on the Food Safety Policy establish Food Safety Objectives
- ✓ Plan the establishment of the FSMS using the project planner
- ✓ Provide adequate support to establish the FSMS
- ✓ Ensure there is adequate infrastructure and work environment
- ✓ Allocate responsibility and authority
- ✓ Assess, plan and establish appropriate internal and external communication (including the food chain) channels

A meeting should now be co-ordinated involving all the Top Management Team.

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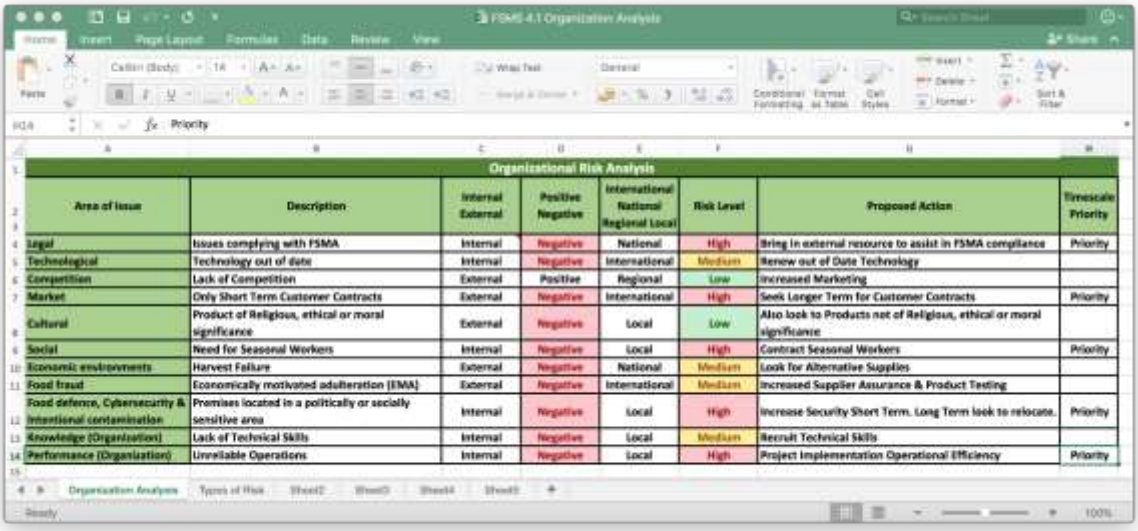
Top Management: Determine external and internal issues that are relevant and affect its ability to achieve the intended result(s) of its FSMS

Top Management need to determine the internal and external issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its FSMS. In order to achieve this aim Top Management should out an Organization Analysis considering external and internal issues, including legal, technological, competitive, market, cultural, social and economic environments, cybersecurity and food fraud, food defence and intentional contamination, knowledge and performance of the organization.

This analysis can be carried out using the FSMS 4.1 Organization Risk Analysis Tool included in the package:



Organizational Risk Analysis

Area of Issue	Description	Internal External	Positive Negative	International National Regional Local	Risk Level	Proposed Action	Timescale Priority
Legal	Issues complying with FSMA	Internal	Negative	National	High	Bring in external resource to assist in FSMA compliance	Priority
Technological	Technology out of date	Internal	Negative	International	Medium	Renew out of Date Technology	
Competition	Lack of Competition	External	Positive	Regional	Low	Increased Marketing	
Market	Only Short Term Customer Contracts	External	Negative	International	High	Seek Longer Term for Customer Contracts	Priority
Cultural	Product of Religious, ethical or moral significance	External	Negative	Local	Low	Also look to Products not of Religious, ethical or moral significance	
Social	Need for Seasonal Workers	Internal	Negative	Local	High	Contract Seasonal Workers	Priority
Economic environments	Harvest Failure	External	Negative	National	Medium	Look for Alternative Supplies	
Food fraud	Economically motivated adulteration (EMA)	External	Negative	International	Medium	Increased Supplier Assurance & Product Testing	
Food defence, Cybersecurity & Intentional contamination	Premises located in a politically or socially sensitive area	Internal	Negative	Local	High	Increase Security Short Term. Long Term look to relocate.	Priority
Knowledge (Organization)	Lack of Technical Skills	Internal	Negative	Local	Medium	Recruit Technical Skills	
Performance (Organization)	Unreliable Operations	Internal	Negative	Local	High	Project Implementation Operational Efficiency	Priority

The FSMS 4.1 Organization Risk Analysis Tool allows Top Management to summarise the Analysis by Area of Issue; Description of Issue; Whether Internal or External; Whether Positive or Negative; Whether International, National, Regional or Local; Risk Level; Proposed Action; Timescale and Priority.

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Top Management FSMS Implementation Checklist

The Top Management FSMS Implementation Meeting should follow the guidelines of the Top Management Implementation Checklist:

1	Top Management determine external and internal issues that are relevant and affect its ability to achieve the intended result(s) of its FSMS	
	External & Internal Issues	Actions to address risks and opportunities
2	Top Management Determine the interested parties (Customer, Regulatory, Statutory and Other) that are relevant to the FSMS.	
	Interested Parties (Customer, Regulatory, Statutory and Other)	Details

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* When determining this scope, Top Management consider the external and internal issues, the interested parties and applicable statutory, regulatory and customer requirements.
** Top Management ensure that the food safety policy and the objectives of the FSMS are established and are compatible with the strategic direction of the organization
*** Top Management ensure the integration of the FSMS requirements into the organization's business processes
**** Top Management also need to ensure the importance of effective food safety management and conforming to the FSMS requirements, applicable statutory and regulatory requirements, and mutually agreed customer requirements related to food safety is communicated effectively.

The outputs from this meeting will be:

- ✓ Food Safety Policy
- ✓ Food Safety Objectives
- ✓ Defined Scope
- ✓ A Developed Project Planner
- ✓ Support Plan for Implementation/Training
- ✓ Plans for Infrastructure/Work Environment
- ✓ Allocation of Responsibility/Authority
- ✓ Defined Communication Channels

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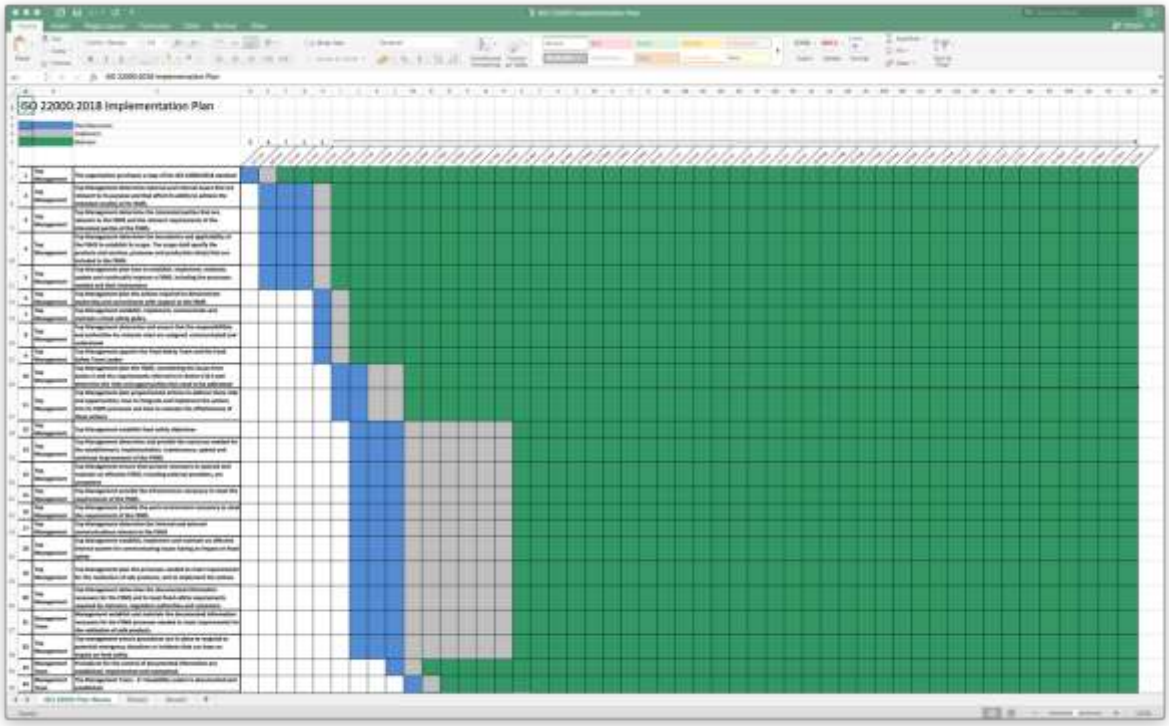
Top Management Establish the Project Plan

Using the Excel Project Planner Top Management adapt the template supplied with the system to establish a Project Plan.



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ISO 22000:2018 Implementation Plan

Step	Responsible Team	Implementation Task
1	Top Management	The organisation purchases a copy of the ISO 22000:2018 standard
2	Top Management	Top Management determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its FSMS.
3	Top Management	Top Management determine the interested parties that are relevant to the FSMS and the relevant requirements of the interested parties of the FSMS.
4	Top Management	Top Management determine the boundaries and applicability of the FSMS to establish its scope. The scope shall specify the products and services, processes and production site(s) that are included in the FSMS.
5	Top Management	Top Management plan how to establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions
6	Top Management	Top Management plan the actions required to demonstrate leadership and commitment with respect to the FSMS
7	Top Management	Top Management establish, implement, communicate and maintain a food safety policy
8	Top Management	Top Management determine and ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood
9	Top Management	Top Management appoint the Food Safety Team and the Food Safety Team Leader
10	Top Management	Top Management plan the FSMS, considering the issues from Action 2 and the requirements referred to in Action 3 & 4 and determine the risks and opportunities that need to be addressed
11	Top Management	Top Management plan proportionate actions to address these risks and opportunities; how to integrate and implement the actions into its FSMS processes and how to evaluate the effectiveness of these actions
12	Top Management	Top Management establish food safety objectives
13	Top Management	Top Management determine and provide the resources needed for the establishment, implementation, maintenance, update and continual improvement of the FSMS.

Document Reference FSMS 8 ISO 22000:2018 Implementation Plan
Revision 1 22nd June 2018
Owned by: Production Manager
Authorised By: Technical Manager

Top Management provide adequate support to establish the FSMS

Top management establish and provide adequate support to establish the FSMS including the resource required to complete the implementation plan, establish, implement and maintain the Food Safety Management System, conduct Internal Audits and Monitor & Measure.

8	Top management provide adequate support to establish the FSMS	
	Resource requirement	Details
	Food Safety Team Leader	
	Food Safety Team	
	FSMS Steering Group	
	Trainers	
	Internal Auditors	

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- External communication and liaison regarding the management systems.

Site and Departmental Annual Objectives and targets are agreed and documented in the Management Review minutes.

Objectives of the food safety management system and planning to achieve them

For Objectives Top Management need to define:

- what will be done
- what resources will be required
- who will be responsible
- when it will be completed
- how the results will be evaluated.

Key Personnel and Nominated Deputies

Job Title	Job Holder	Nominated Deputy
Emergency Response Coordinator		
General Manager		
Operations Manager		
Production Manager		
Warehouse Manager		
Maintenance Manager		
Factory Safety Manager		
Human Resource Manager		
Quality Manager		
Packing Manager		
Technical Manager (Food Safety Team Leader)		
Goods Receipt Manager		
Design and Development Manager		
Planning Manager		
Customer Service Manager		
Laboratory Manager		
Distribution Manager		

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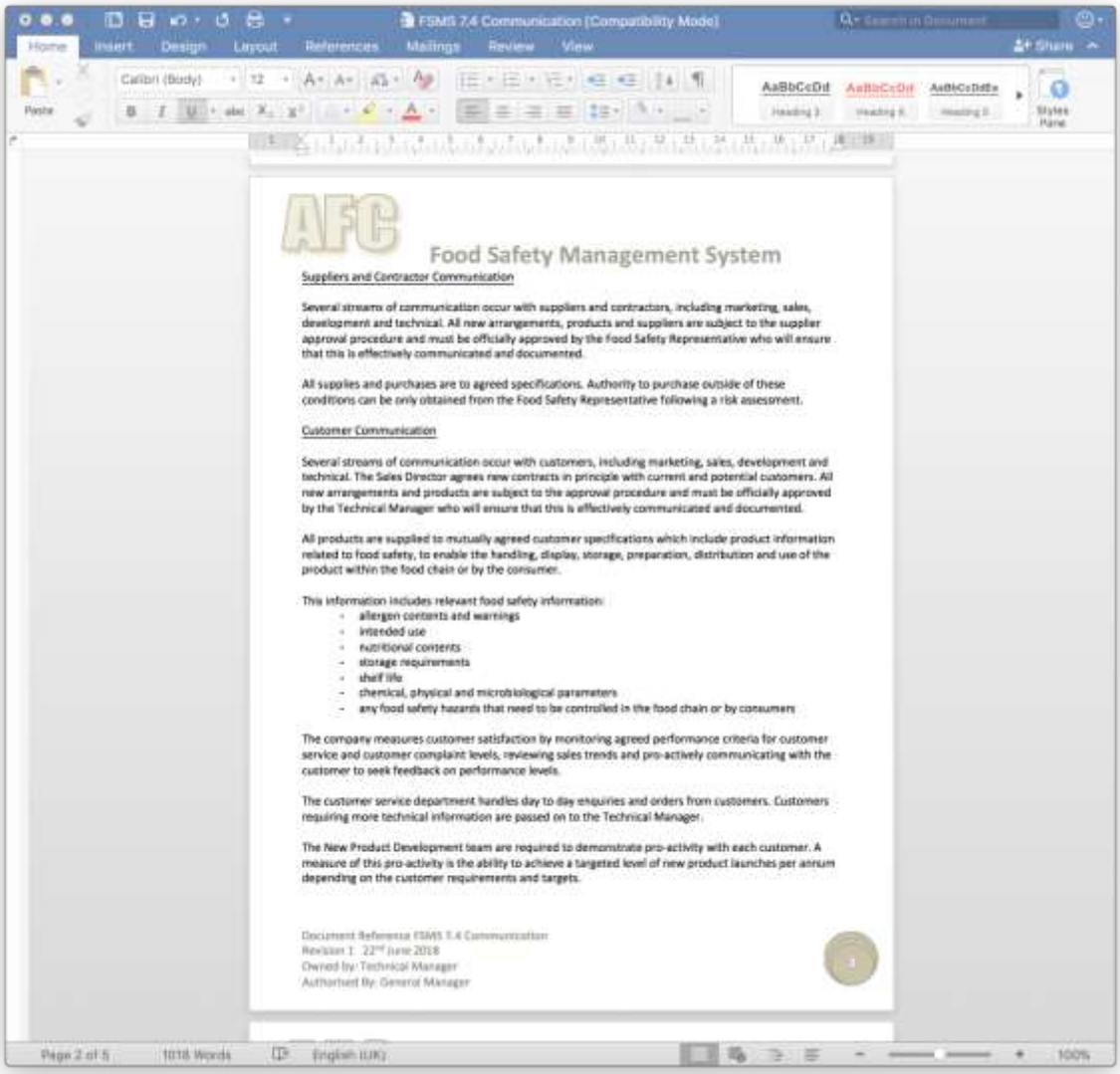
Top Management establish Communication Channels

Top Management must establish and document clear levels of communication for suppliers, contractors, customers, food authorities and staff within the food safety management system. Detailed communication arrangements and food safety communication responsibilities for all levels of management should contained in the food safety and quality manual. The communication procedures should apply to all members of staff, both full time and temporary.

Procedures should be in place to address communication including:

Suppliers and Contractor Communication
Customer Communication
Food Authority Communication



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Food Safety Management System

Suppliers and Contractor Communication

Several streams of communication occur with suppliers and contractors, including marketing, sales, development and technical. All new arrangements, products and suppliers are subject to the supplier approval procedure and must be officially approved by the Food Safety Representative who will ensure that this is effectively communicated and documented.

All supplies and purchases are to agreed specifications. Authority to purchase outside of these conditions can be only obtained from the Food Safety Representative following a risk assessment.

Customer Communication

Several streams of communication occur with customers, including marketing, sales, development and technical. The Sales Director agrees new contracts in principle with current and potential customers. All new arrangements and products are subject to the approval procedure and must be officially approved by the Technical Manager who will ensure that this is effectively communicated and documented.

All products are supplied to mutually agreed customer specifications which include product information related to food safety, to enable the handling, display, storage, preparation, distribution and use of the product within the food chain or by the consumer.

This information includes relevant food safety information:

- allergen contents and warnings
- intended use
- nutritional contents
- storage requirements
- shelf life
- chemical, physical and microbiological parameters
- any food safety hazards that need to be controlled in the food chain or by consumers

The company measures customer satisfaction by monitoring agreed performance criteria for customer service and customer complaint levels, reviewing sales trends and pro-actively communicating with the customer to seek feedback on performance levels.

The customer service department handles day to day enquiries and orders from customers. Customers requiring more technical information are passed on to the Technical Manager.

The New Product Development team are required to demonstrate pro-activity with each customer. A measure of this pro-activity is the ability to achieve a targeted level of new product launches per annum depending on the customer requirements and targets.

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Step Three: Food Safety Management System

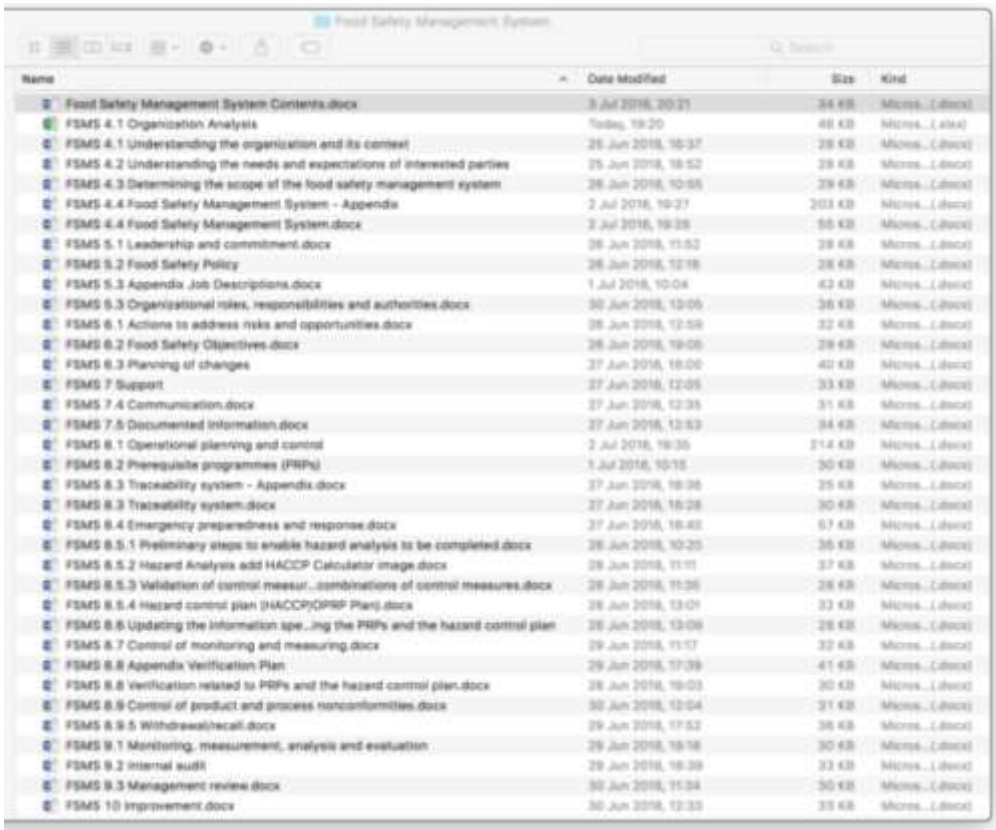
The Food Safety Management System contains a comprehensive ISO 22000 documentation package that you are now ready to implement:

- ✓ Food Safety Manual containing a set comprehensive procedures and record templates.
- ✓ HACCP manual containing food safety procedures and our unique HACCP Calculator.
- ✓ Laboratory manual including sample procedures and records.
- ✓ Prerequisite Programmes manual.

At this stage, you can choose to totally implement the procedures supplied or pick those that are applicable to your process.

Food Safety Manual

The Food Safety Management System folder contains comprehensive top level procedures templates that match the clauses of the ISO 22000:2018 standard and form the foundations of your Food Safety Management System so you don't have to spend 1,000's of hours writing compliant procedures:

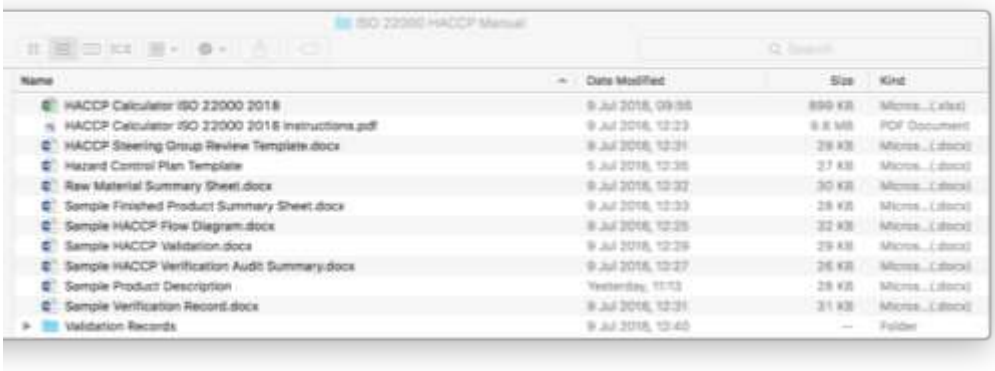


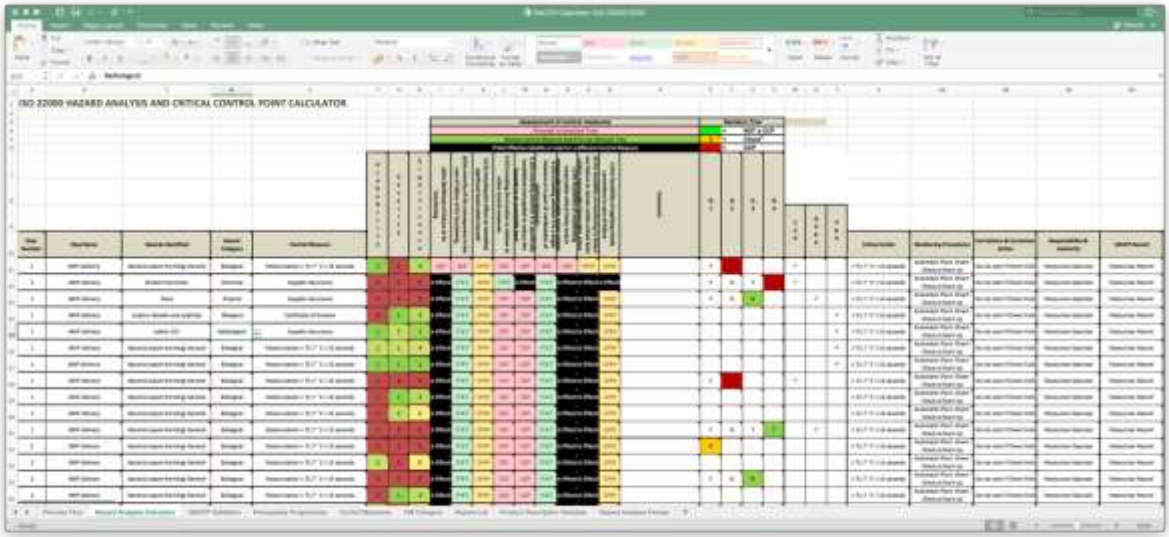
ISO 22000 HACCP Manual containing the HACCP Calculator

The HACCP System is defined in the following Food Safety Management System documents:

FSMS 8.5.1 Preliminary steps to enable hazard analysis
FSMS 8.5.2 Hazard analysis
FSMS 8.5.3 Validation of control measure(s) and combinations of control measures
FSMS 8.5.4 Hazard control plan (HACCP/OPRP plan)
FSMS 8.6 Updating the information specifying the PRPs and the hazard control plan
FSMS 8.7 Control of monitoring and measuring
FSMS 8.8 Verification related to PRPs and the hazard control plan

There are also supplementary ISO HACCP Manual documents including the HACCP Calculator ISO 22000 2018 & Instructions:





Prerequisite Programmes Manual

A comprehensive set of prerequisite programme templates compliant with TECHNICAL ISO/TS SPECIFICATION 22002-1 Prerequisite programmes on food safety — Part 1: Food manufacturing:

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Step Four: Project 22000

This contains the project tools you will need to achieve ISO 22000 certification. In this part of the package you will find:

- ✓ Steering Group are established and briefed
- ✓ The Steering Group take control of the Project Plan established by Top Management
- ✓ The documents described previously are implemented as part of the Project Plan

Food Safety Management System Steering Group			
FSMS Team Member	**Name**	**Position**	**Qualification**
FSMS Team Leader			
FSMS Assistant Leader			
FSMS Team Members			

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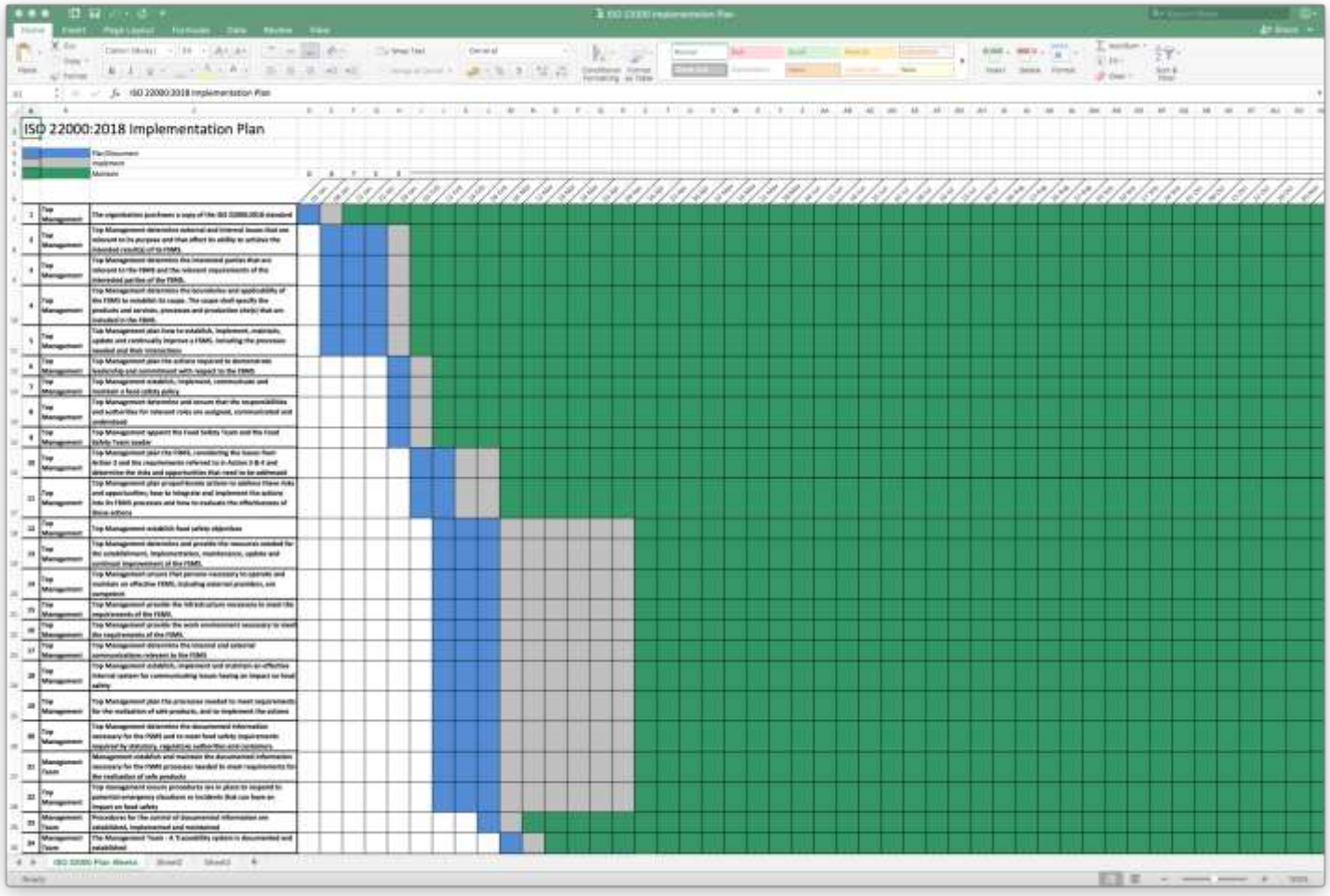
Project Plan

The Steering Group use the Excel Project Plan developed by Top Management as a step by step guide to implementing the Food Safety Management System.



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Project Planning Tasks		Responsibility	Comments	Due Date for Completion	Date Completed
1	**The organisation purchases a copy of the ISO 22000:2018 standard**	**Top Management**			
2	**Top Management determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its FSMS.**	**Top Management**			
3	**Top Management determine the interested parties that are relevant to the FSMS and the relevant requirements of the interested parties of the FSMS.**	**Top Management**			
4	**Top Management determine the boundaries and applicability of the FSMS to establish its scope. The scope shall specify the products and services, processes and production site(s) that are included in the FSMS.**	**Top Management**			
5	**Top Management plan how to establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions**	**Top Management**			
6	**Top Management plan the actions**	**Top Management**			

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Food Safety Management System Document Implementation

The Food Safety Management System (FSMS) documents should be edited and procedures implemented as per the plan and relevant training given.

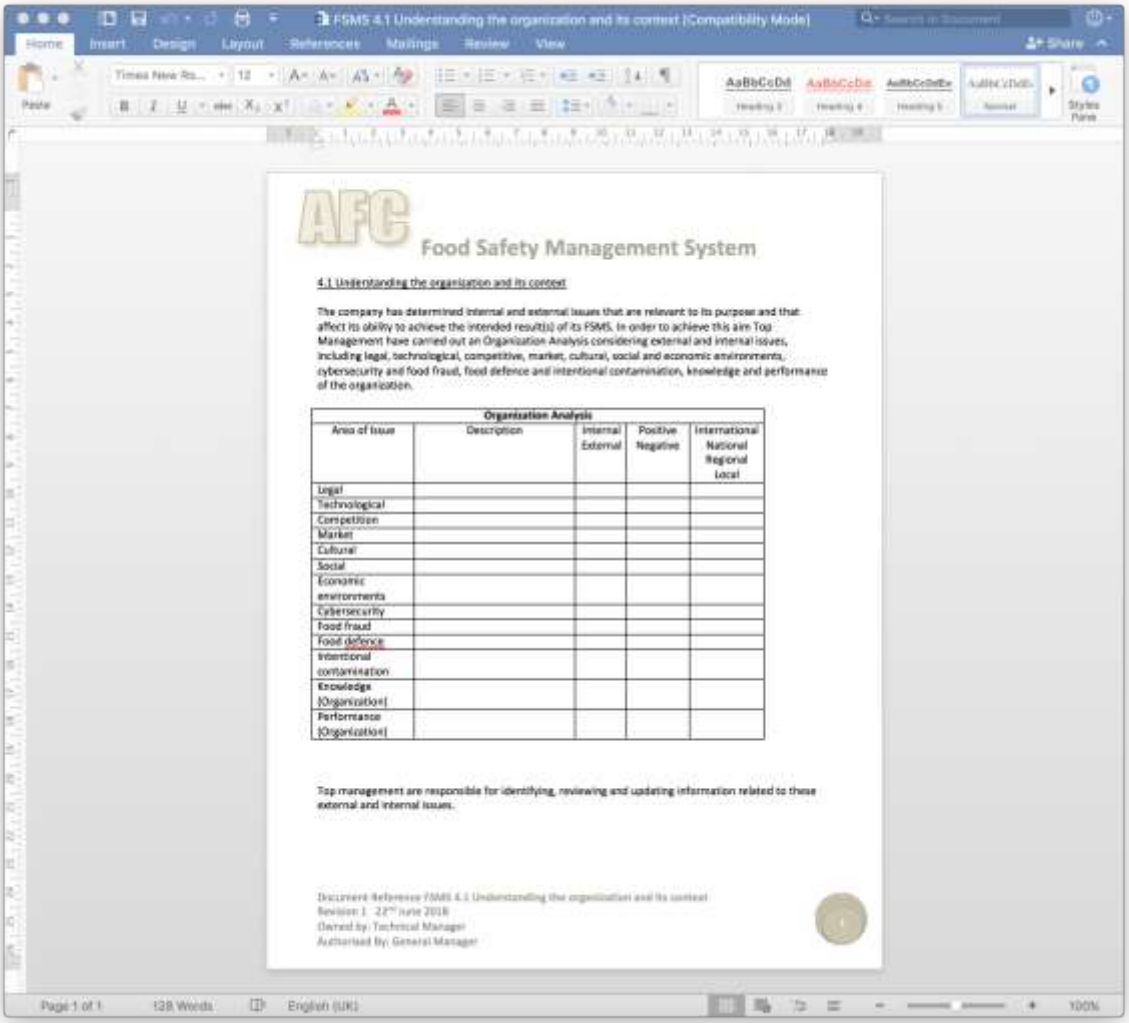
4 Context of the organization

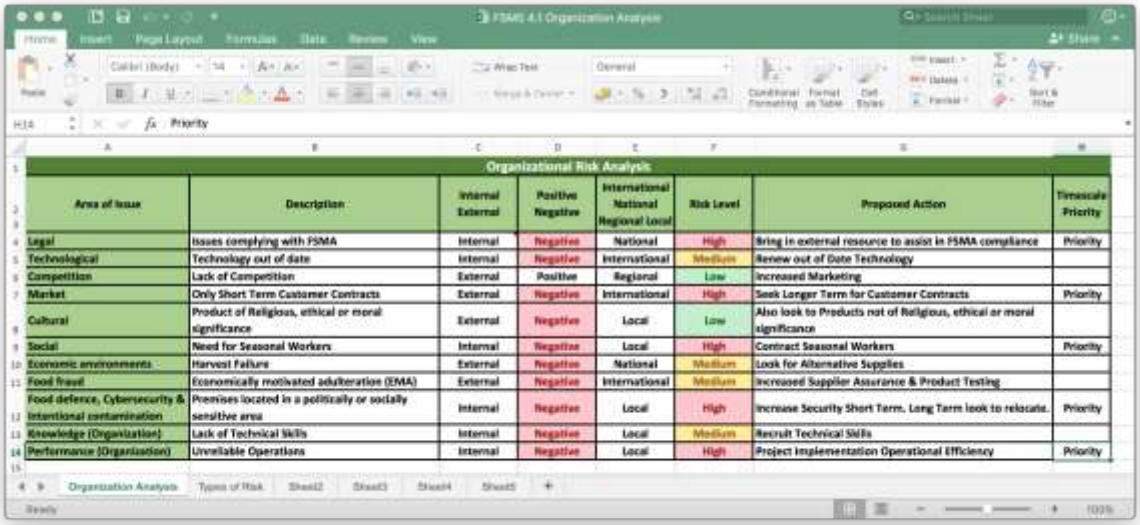
FSMS 4.1 Understanding the organization and its context

FSMS 4.2 Understanding the needs and expectations of interested parties

FSMS 4.3 Determining the scope of the food safety management system

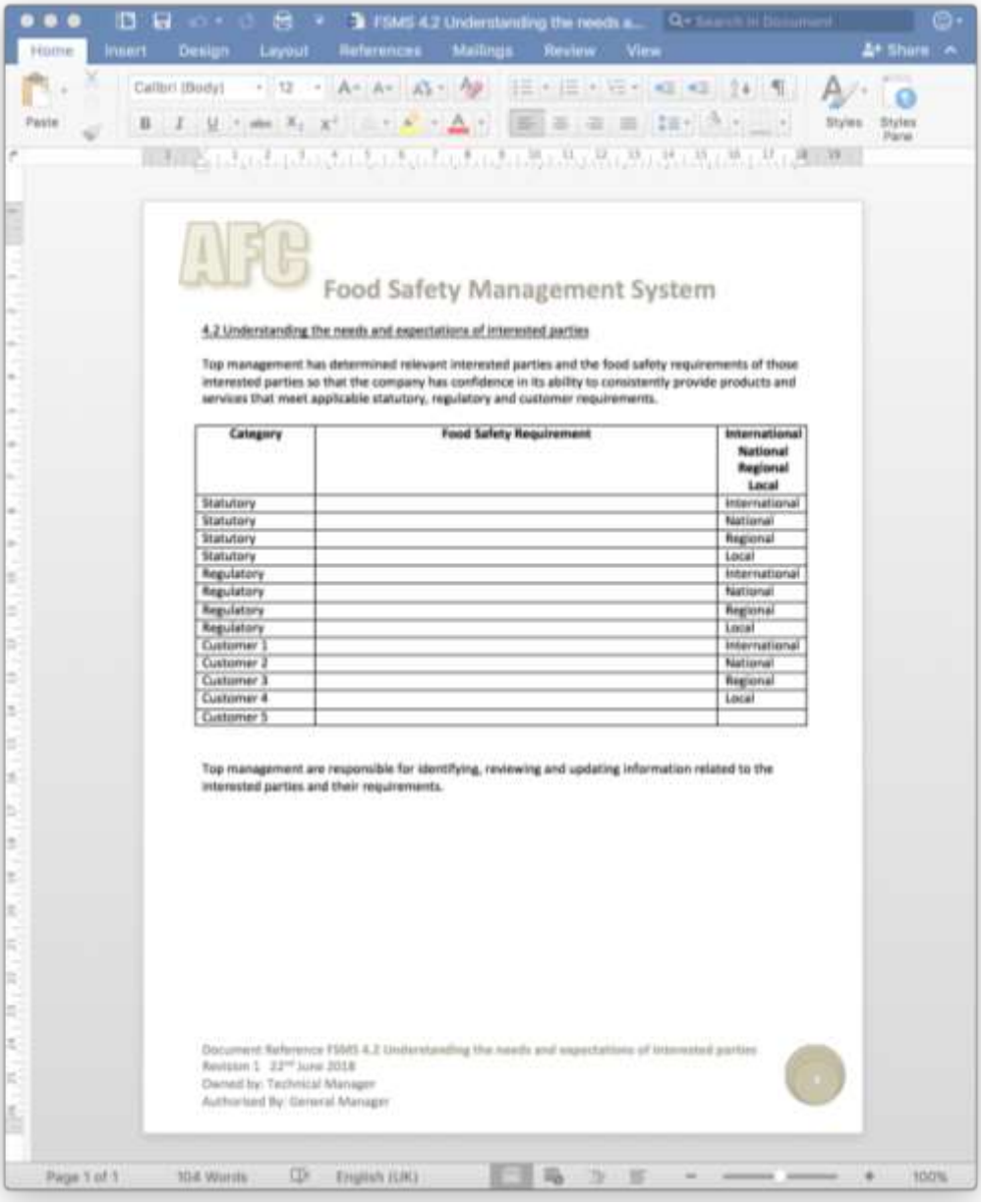
FSMS 4.4 Food safety management system





Organizational Risk Analysis

Area of Issue	Description	Internal External	Positive Negative	International National Regional Local	Risk Level	Proposed Action	Timescale Priority
Legal	Issues complying with FSMA	Internal	Negative	National	High	Bring in external resource to assist in FSMA compliance	Priority
Technological	Technology out of date	Internal	Negative	International	Medium	Renew out of Date Technology	
Competition	Lack of Competition	External	Positive	Regional	Low	Increased Marketing	
Market	Only Short Term Customer Contracts	External	Negative	International	High	Seek Longer Term for Customer Contracts	Priority
Cultural	Product of Religious, ethical or moral significance	External	Negative	Local	Low	Also look to Products not of Religious, ethical or moral significance	
Social	Need for Seasonal Workers	Internal	Negative	Local	High	Contract Seasonal Workers	Priority
Economic environments	Harvest Failure	External	Negative	National	Medium	Look for Alternative Supplies	
Food fraud	Economically motivated adulteration (EMA)	External	Negative	International	Medium	Increased Supplier Assurance & Product Testing	
Food defence, Cybersecurity & Intentional contamination	Premises located in a politically or socially sensitive area	Internal	Negative	Local	High	Increase Security Short Term. Long Term look to relocate.	Priority
Knowledge (Organization)	Lack of Technical Skills	Internal	Negative	Local	Medium	Recruit Technical Skills	
Performance (Organization)	Unreliable Operations	Internal	Negative	Local	High	Project Implementation Operational Efficiency	Priority



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Food Safety Management System

4.2 Understanding the needs and expectations of interested parties

Top management has determined relevant interested parties and the food safety requirements of those interested parties so that the company has confidence in its ability to consistently provide products and services that meet applicable statutory, regulatory and customer requirements.

Category	Food Safety Requirement	International National Regional Local
Statutory		International
Statutory		National
Statutory		Regional
Statutory		Local
Regulatory		International
Regulatory		National
Regulatory		Regional
Regulatory		Local
Customer 1		International
Customer 2		National
Customer 3		Regional
Customer 4		Local
Customer 5		

Top management are responsible for identifying, reviewing and updating information related to the interested parties and their requirements.

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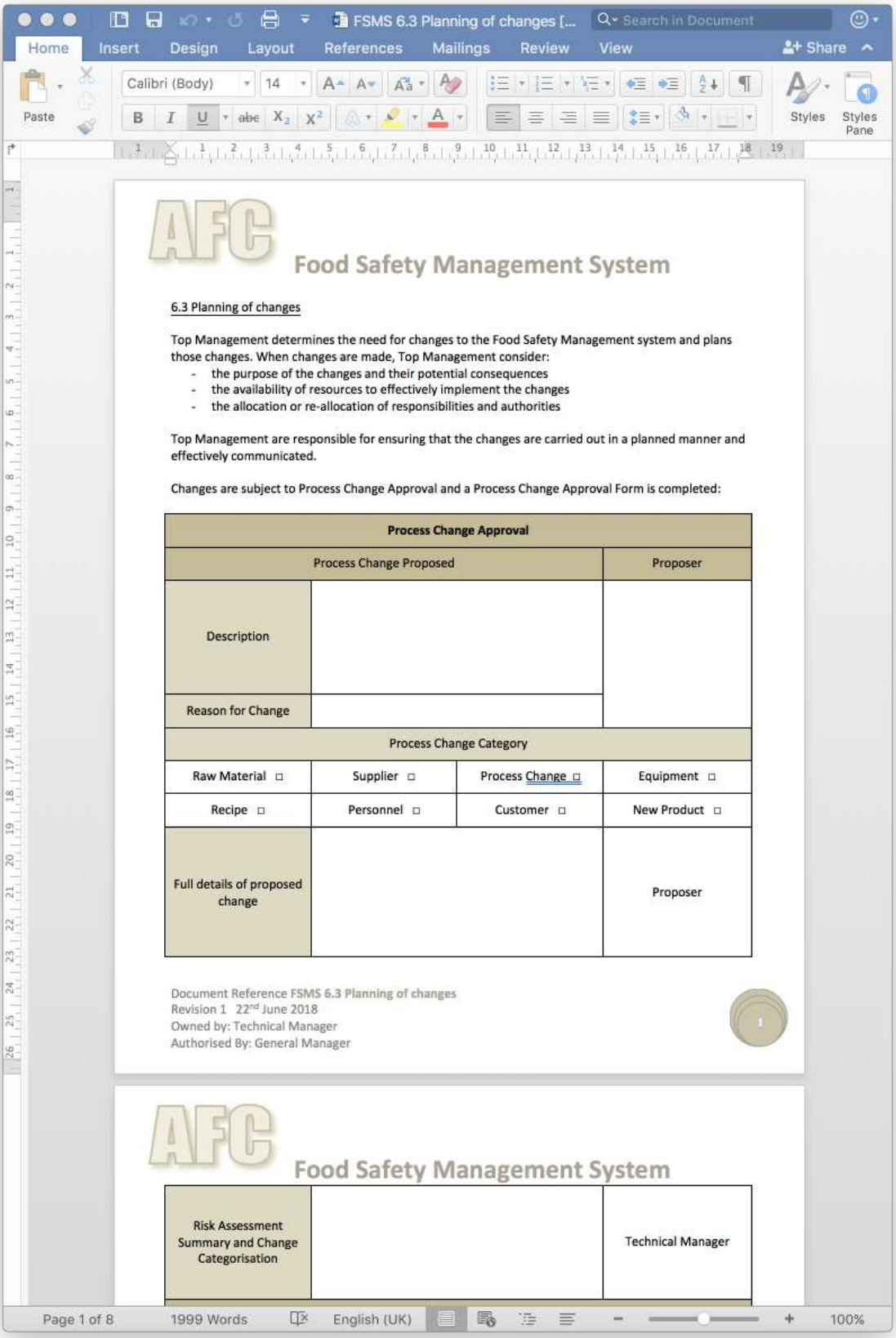

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Food Safety Management System

6.3 Planning of changes

Top Management determines the need for changes to the Food Safety Management system and plans those changes. When changes are made, Top Management consider:

- the purpose of the changes and their potential consequences
- the availability of resources to effectively implement the changes
- the allocation or re-allocation of responsibilities and authorities

Top Management are responsible for ensuring that the changes are carried out in a planned manner and effectively communicated.

Changes are subject to Process Change Approval and a Process Change Approval Form is completed:

Process Change Approval			
Process Change Proposed			Proposer
Description			
Reason for Change			
Process Change Category			
Raw Material ☐	Supplier ☐	Process Change ☐	Equipment ☐
Recipe ☐	Personnel ☐	Customer ☐	New Product ☐
Full details of proposed change			Proposer

Document Reference FSMS 6.3 Planning of changes
Revision 1 22nd June 2018
Owned by: Technical Manager
Authorised By: General Manager

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Food Safety Management System

Risk Assessment Summary and Change Categorisation		Technical Manager

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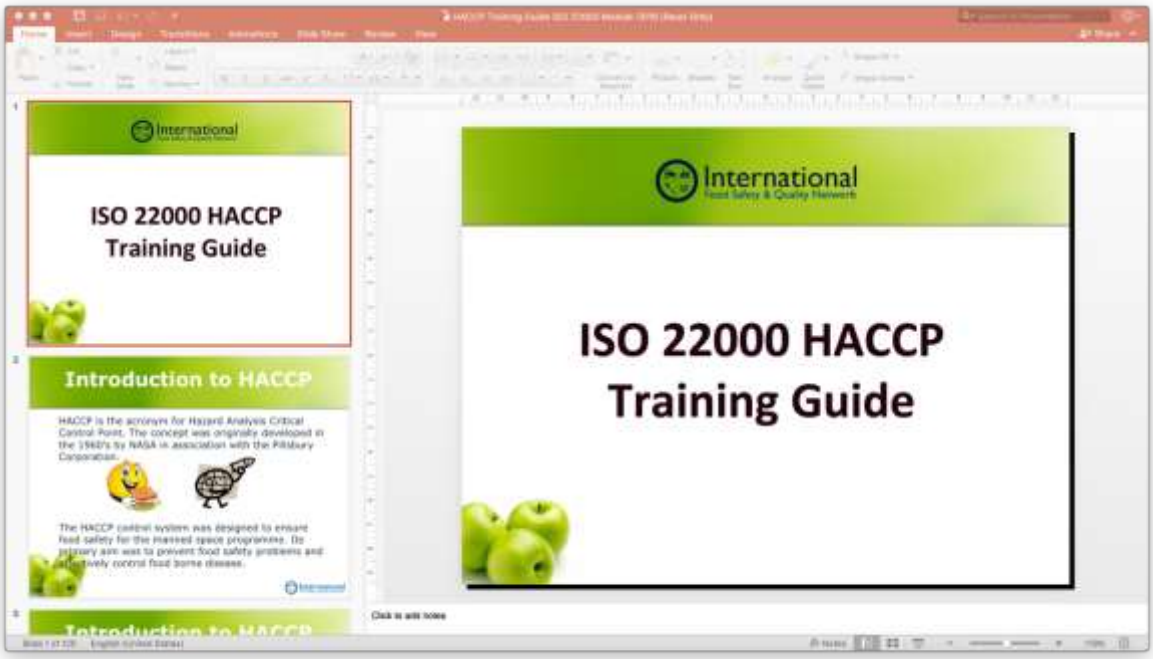
HACCP Training

An illustrated PowerPoint HACCP training presentation is supplied to train your food safety team.



The HACCP documents should be edited and procedures implemented by the Food Safety Team as per the plan.

8.5 Hazard control
FSMS 8.5.1 Preliminary steps to enable hazard analysis
FSMS 8.5.2 Hazard analysis
FSMS 8.5.3 Validation of control measure(s) and combinations of control measures
FSMS 8.5.4 Hazard control plan (HACCP/OPRP plan)
FSMS 8.6 Updating the information specifying the PRPs and the hazard control plan
FSMS 8.8 Verification related to PRPs and the hazard control plan

The Management Team will also be editing implementing procedures:
FSMS 8.1 Operational planning and control
FSMS 8.3 Traceability system
FSMS 8.4 Emergency preparedness and response
FSMS 8.7 Control of monitoring and measuring
FSMS 8.9 Control of product and process nonconformities
FSMS 8.9.5 Withdrawal/recall

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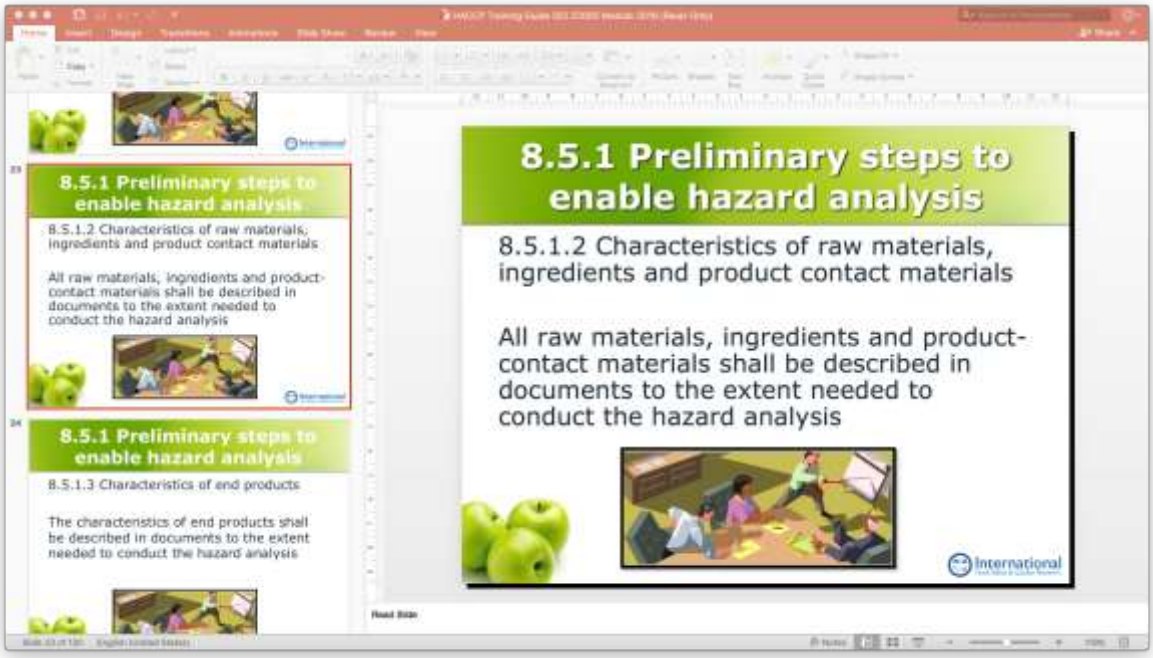
There is guidance in HACCP Training Guide ISO 22000 Module 2018



There is also guidance in Implementing ISO 22000 Food Safety Team Guide 2018

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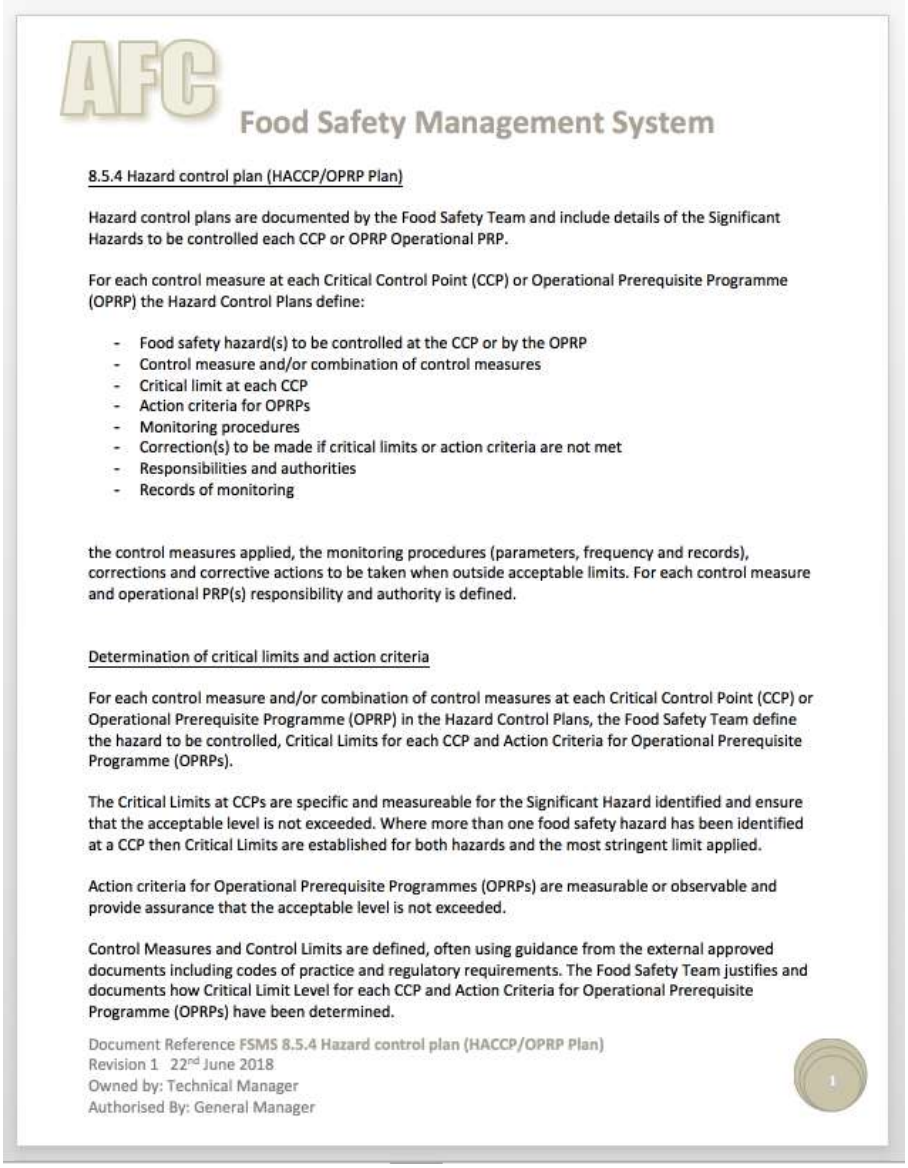
The Food Safety Team should follow, edit and maintain HACCP document FSMS 8.5.4 Hazard control plan (HACCP/OPRP Plan)



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Food Safety Management System

8.5.4 Hazard control plan (HACCP/OPRP Plan)

Hazard control plans are documented by the Food Safety Team and include details of the Significant Hazards to be controlled each CCP or OPRP Operational PRP.

For each control measure at each Critical Control Point (CCP) or Operational Prerequisite Programme (OPRP) the Hazard Control Plans define:

- Food safety hazard(s) to be controlled at the CCP or by the OPRP
- Control measure and/or combination of control measures
- Critical limit at each CCP
- Action criteria for OPRPs
- Monitoring procedures
- Correction(s) to be made if critical limits or action criteria are not met
- Responsibilities and authorities
- Records of monitoring

the control measures applied, the monitoring procedures (parameters, frequency and records), corrections and corrective actions to be taken when outside acceptable limits. For each control measure and operational PRP(s) responsibility and authority is defined.

Determination of critical limits and action criteria

For each control measure and/or combination of control measures at each Critical Control Point (CCP) or Operational Prerequisite Programme (OPRP) in the Hazard Control Plans, the Food Safety Team define the hazard to be controlled, Critical Limits for each CCP and Action Criteria for Operational Prerequisite Programme (OPRPs).

The Critical Limits at CCPs are specific and measureable for the Significant Hazard identified and ensure that the acceptable level is not exceeded. Where more than one food safety hazard has been identified at a CCP then Critical Limits are established for both hazards and the most stringent limit applied.

Action criteria for Operational Prerequisite Programmes (OPRPs) are measurable or observable and provide assurance that the acceptable level is not exceeded.

Control Measures and Control Limits are defined, often using guidance from the external approved documents including codes of practice and regulatory requirements. The Food Safety Team justifies and documents how Critical Limit Level for each CCP and Action Criteria for Operational Prerequisite Programme (OPRPs) have been determined.

Document Reference FSMS 8.5.4 Hazard control plan (HACCP/OPRP Plan)
Revision 1 22nd June 2018
Owned by: Technical Manager
Authorised By: General Manager

This document covers the following:

Determination of critical limits and action criteria
Monitoring systems at CCPs and for OPRPs
Actions when critical limits or action criteria are not met
Implementation of the hazard control plan

There is guidance in Implementing ISO 22000 Food Safety Team Guide 2018, HACCP Calculator ISO 22000 2018 Instructions and HACCP Training Guide ISO 22000 Module 2018.

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At the same time as HACCP Implementation the Management Team will also need to be editing and implementing procedures:

8 Operation

FSMS 8.1 Operational planning and control
FSMS 8.3 Traceability system
FSMS 8.4 Emergency preparedness and response
FSMS 8.7 Control of monitoring and measuring
FSMS 8.9 Control of product and process nonconformities
FSMS 8.9.5 Withdrawal/recall

9 Performance evaluation

FSMS 9.1 Monitoring, measurement, analysis and evaluation
FSMS 9.2 Internal audit
FSMS 9.3 Management review

10 Improvement

FSMS 10 Improvement

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Food Safety Management System

9.2 Internal audit

The company has established, documented and implemented an internal audit system, which is maintained in order to verify the Food Safety Management System is effectively implemented and maintained and complies with planned arrangements, legislation, international standard ISO 22000:2018.

The scope of the Internal Audit System includes all product categories, processes, activities conducted, production sites and any outsourced activities that can affect the requirements of the Food Safety Management System.

Top Management has a total commitment to the Food Quality Management System and provides adequate resource in the form of trained and qualified personnel to carry out a comprehensive Internal Audit Schedule. Internal audits are performed to confirm that company management systems are working effectively and to promote continuous improvement. Our philosophy is simply audit, review and improve.

The Internal Audit Schedule is planned annually and is designed to comprehensively cover all areas of the Food Safety Management system including procedures, policies and activities as outlined below.

Internal Audit List

4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Determining the scope of the food safety management system
4.4 Food safety management system

5.1 Leadership and commitment
5.2 Policy
5.2.1 Establishing the food safety policy
5.2.2 Communicating the food safety policy
5.3 Organizational roles, responsibilities and authorities

6.1 Actions to address risks and opportunities
6.2 Objectives of the food safety management system and planning to achieve them
6.3 Planning of changes

7.1 Resources
7.1.1 General
7.1.2 People
7.1.3 Infrastructure

Document Reference FSMS 9.2 Internal audit
Revision 1 22nd June 2018
Owned by: Technical Manager
Authorised By: General Manager

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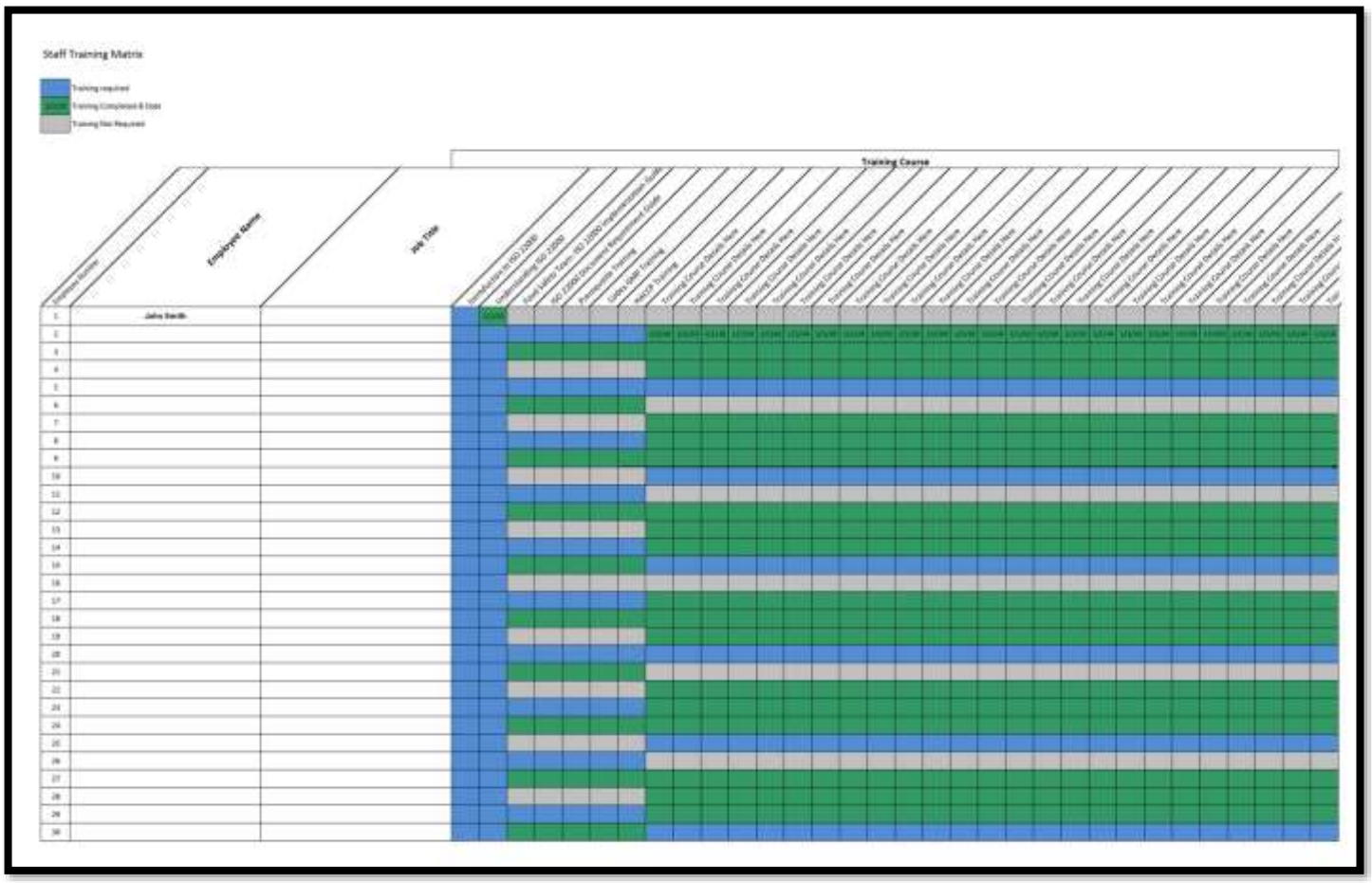
Project 22000 - Staff Training

A significant part of the implementation process is training. Job Descriptions should be available for all staff and they should be briefed and aware of their food safety responsibilities.

A training matrix and plans should be drawn up for all staff and the relevant training given based on responsibility and authority.



We have provided a Staff Training Matrix Template in Microsoft Excel Format.

For each employee and individual training record should be completed. QMR 002 Training Record is provided in the documentation pack as a template:

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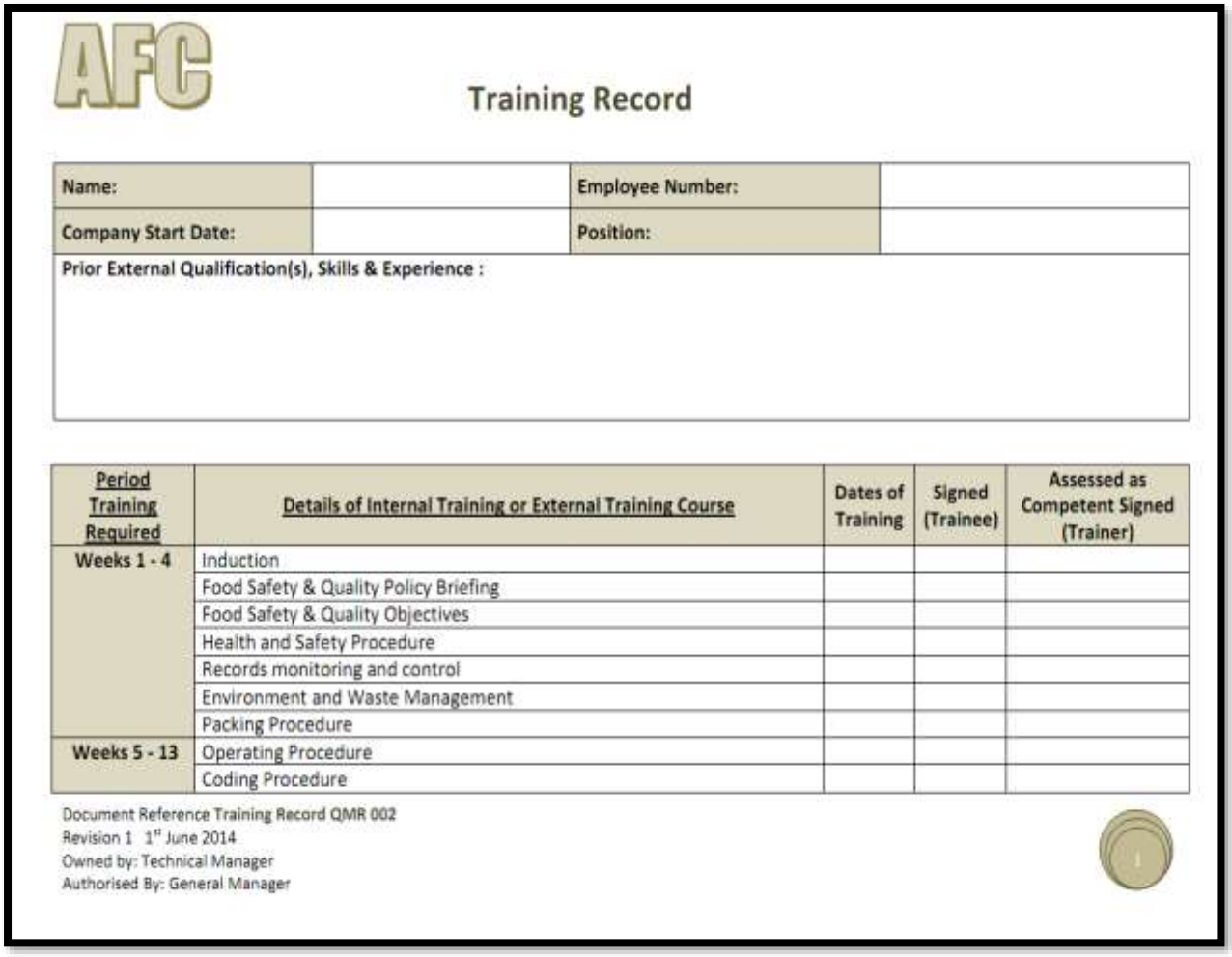
QMR 002 Training Record



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Training Record

Name:		**Employee Number:**	
Company Start Date:		**Position:**	

Prior External Qualification(s), Skills & Experience :

Period Training Required	Details of Internal Training or External Training Course	Dates of Training	Signed (Trainee)	Assessed as Competent Signed (Trainer)
Weeks 1 - 4	Induction			
	Food Safety & Quality Policy Briefing			
	Food Safety & Quality Objectives			
	Health and Safety Procedure			
	Records monitoring and control			
	Environment and Waste Management			
	Packing Procedure			
Weeks 5 - 13	Operating Procedure			
	Coding Procedure			

Document Reference Training Record QMR 002
Revision 1 1st June 2014
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Remember

Now that the Prerequisite Programmes, and Hazard Control Plans all staff should be trained in the appropriate procedures, limits, corrective actions, and record completion.

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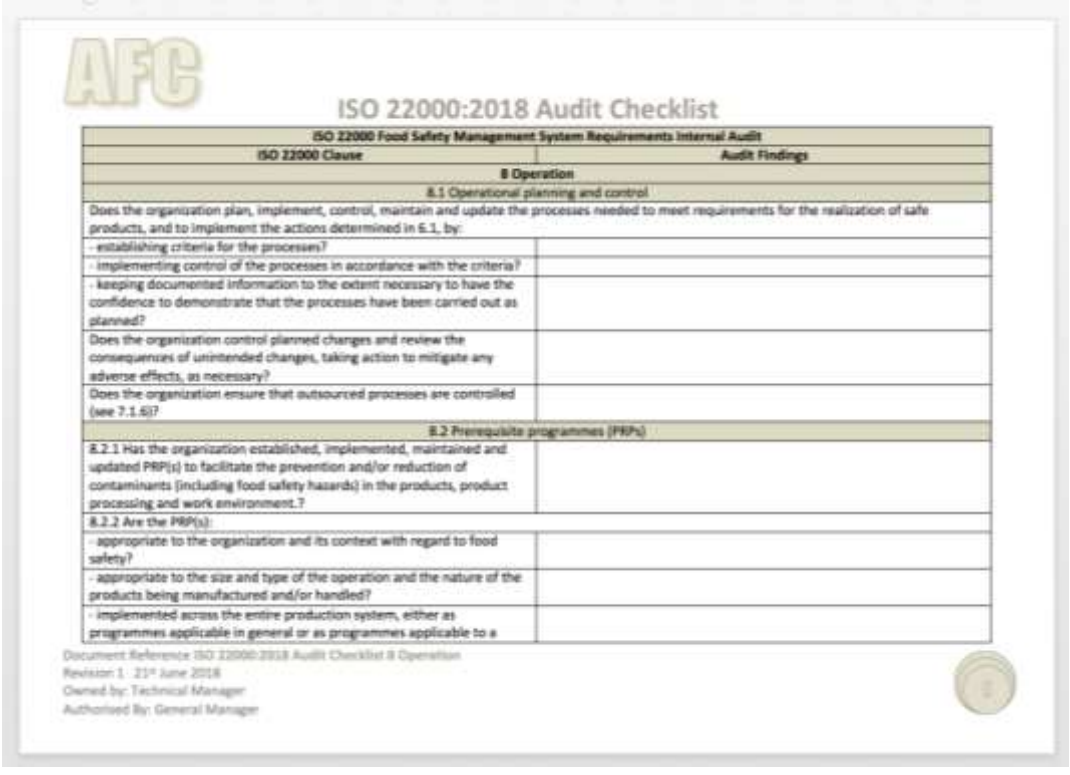
Step Five: Internal Auditing & Checklists

There is a PowerPoint Internal Auditor training presentation

Internal Audit Checklists

There is a checklist for each section of the ISO 22000 standard plus sample verification records for prerequisite programmes.



ISO 22000:2018 Audit Checklist

ISO 22000 Food Safety Management System Requirements Internal Audit	
ISO 22000 Clause	Audit Findings
8 Operation	
8.1 Operational planning and control	
Does the organization plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products, and to implement the actions determined in 6.1, by:	
- establishing criteria for the processes?	
- implementing control of the processes in accordance with the criteria?	
- keeping documented information to the extent necessary to have the confidence to demonstrate that the processes have been carried out as planned?	
Does the organization control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary?	
Does the organization ensure that outsourced processes are controlled (see 7.1.6)?	
8.2 Prerequisite programmes (PRPs)	
8.2.1 Has the organization established, implemented, maintained and updated PRP(s) to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment.?	
8.2.2 Are the PRP(s):	
- appropriate to the organization and its context with regard to food safety?	
- appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled?	
- implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a	

Document Reference ISO 22000:2018 Audit Checklist 8 Operation
Revision 1 - 21st June 2018
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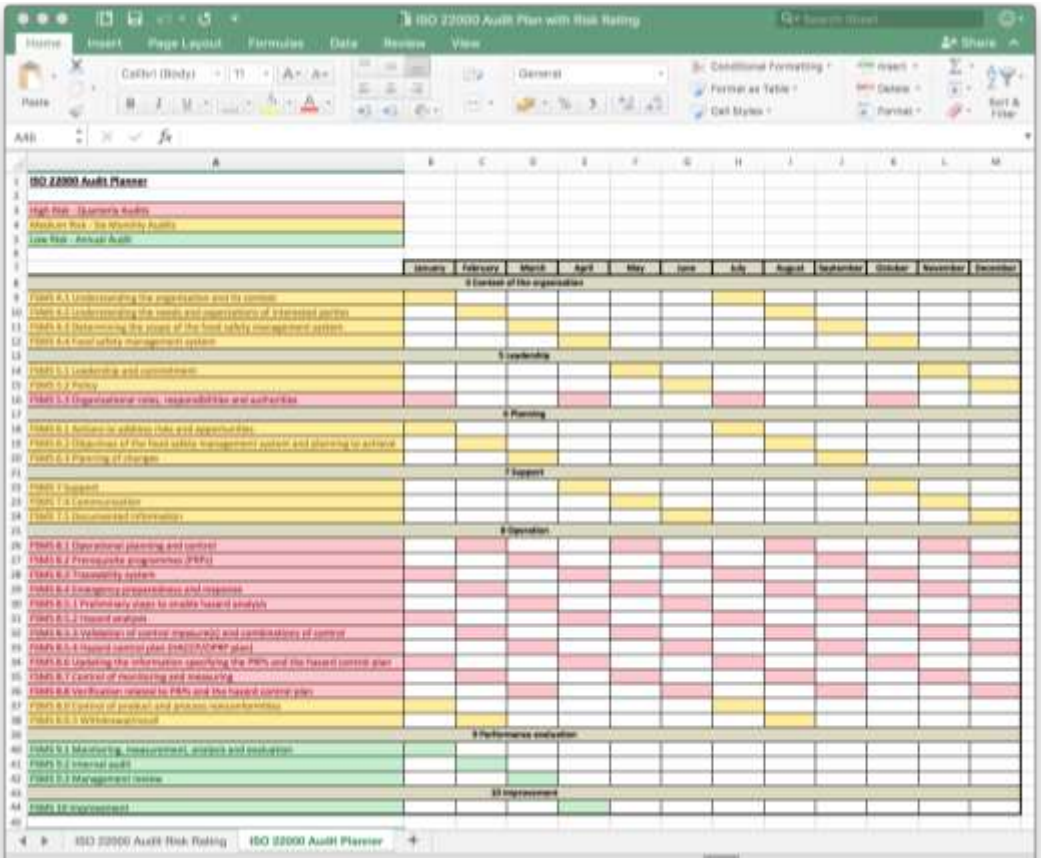
ISO 22000 Audit Plan with Risk Rating



The Food Safety Team Leader should draw up the Internal Audit Schedule based on the following criteria:

- Importance of the processes concerned
- Changes in the FSMS
- Results of monitoring, measurement
- Risk associated with the procedure or activity
- Results of Previous audits
- Number of Corrective and/or Preventive Actions raised or outstanding
- Customer Complaint Analysis
- Results of the Management Review

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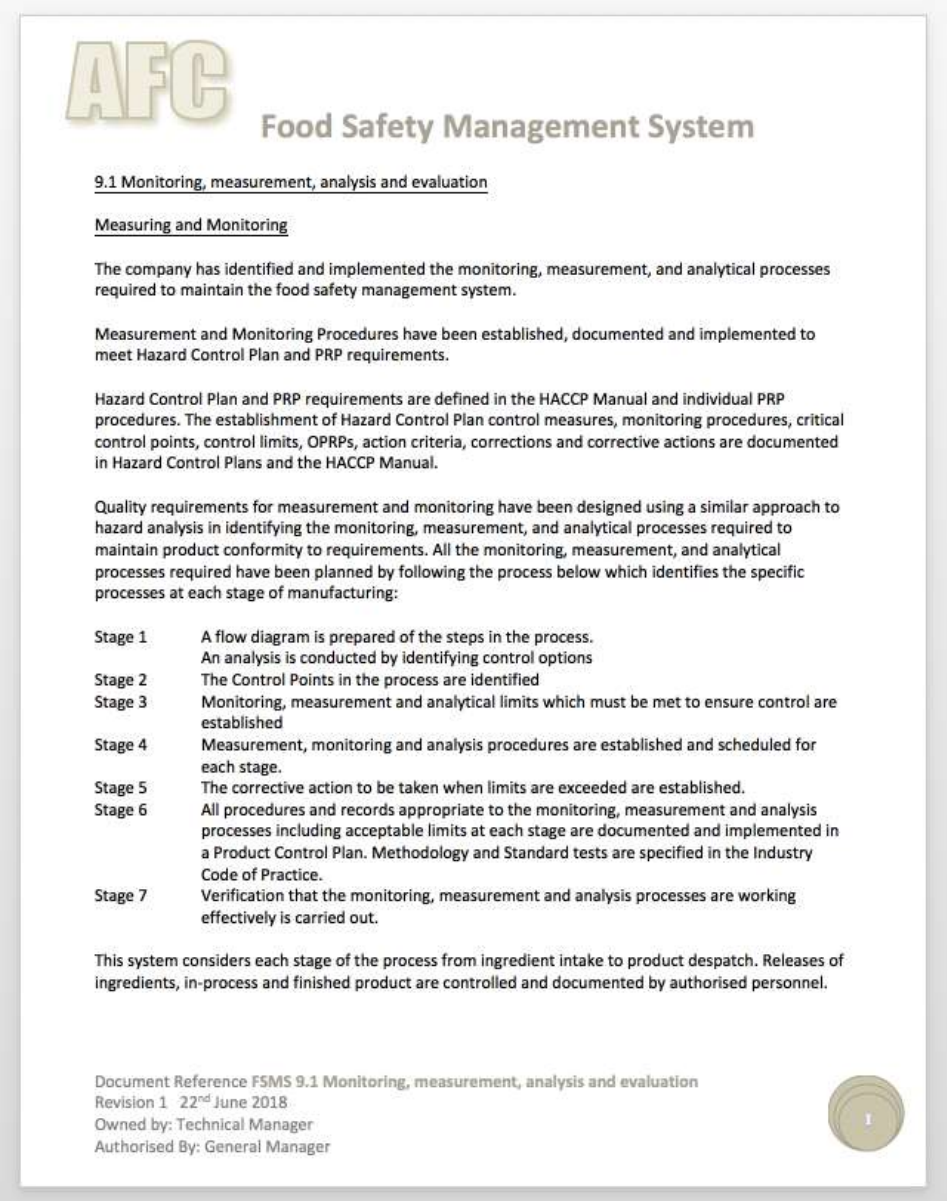
Step Six: Review and Updating

Top Management and the Management Team follow procedures:
9 Performance evaluation
FSMS 9.1 Monitoring, measurement, analysis and evaluation
FSMS 9.3 Management review
10 Improvement
FSMS 10 Improvement

FSMS 9.1 Monitoring, measurement, analysis and evaluation



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Food Safety Management System

9.1 Monitoring, measurement, analysis and evaluation

Measuring and Monitoring

The company has identified and implemented the monitoring, measurement, and analytical processes required to maintain the food safety management system.

Measurement and Monitoring Procedures have been established, documented and implemented to meet Hazard Control Plan and PRP requirements.

Hazard Control Plan and PRP requirements are defined in the HACCP Manual and individual PRP procedures. The establishment of Hazard Control Plan control measures, monitoring procedures, critical control points, control limits, OPRPs, action criteria, corrections and corrective actions are documented in Hazard Control Plans and the HACCP Manual.

Quality requirements for measurement and monitoring have been designed using a similar approach to hazard analysis in identifying the monitoring, measurement, and analytical processes required to maintain product conformity to requirements. All the monitoring, measurement, and analytical processes required have been planned by following the process below which identifies the specific processes at each stage of manufacturing:

Stage 1	A flow diagram is prepared of the steps in the process. An analysis is conducted by identifying control options
Stage 2	The Control Points in the process are identified
Stage 3	Monitoring, measurement and analytical limits which must be met to ensure control are established
Stage 4	Measurement, monitoring and analysis procedures are established and scheduled for each stage.
Stage 5	The corrective action to be taken when limits are exceeded are established.
Stage 6	All procedures and records appropriate to the monitoring, measurement and analysis processes including acceptable limits at each stage are documented and implemented in a Product Control Plan. Methodology and Standard tests are specified in the Industry Code of Practice.
Stage 7	Verification that the monitoring, measurement and analysis processes are working effectively is carried out.

This system considers each stage of the process from ingredient intake to product despatch. Releases of ingredients, in-process and finished product are controlled and documented by authorised personnel.

Document Reference FSMS 9.1 Monitoring, measurement, analysis and evaluation
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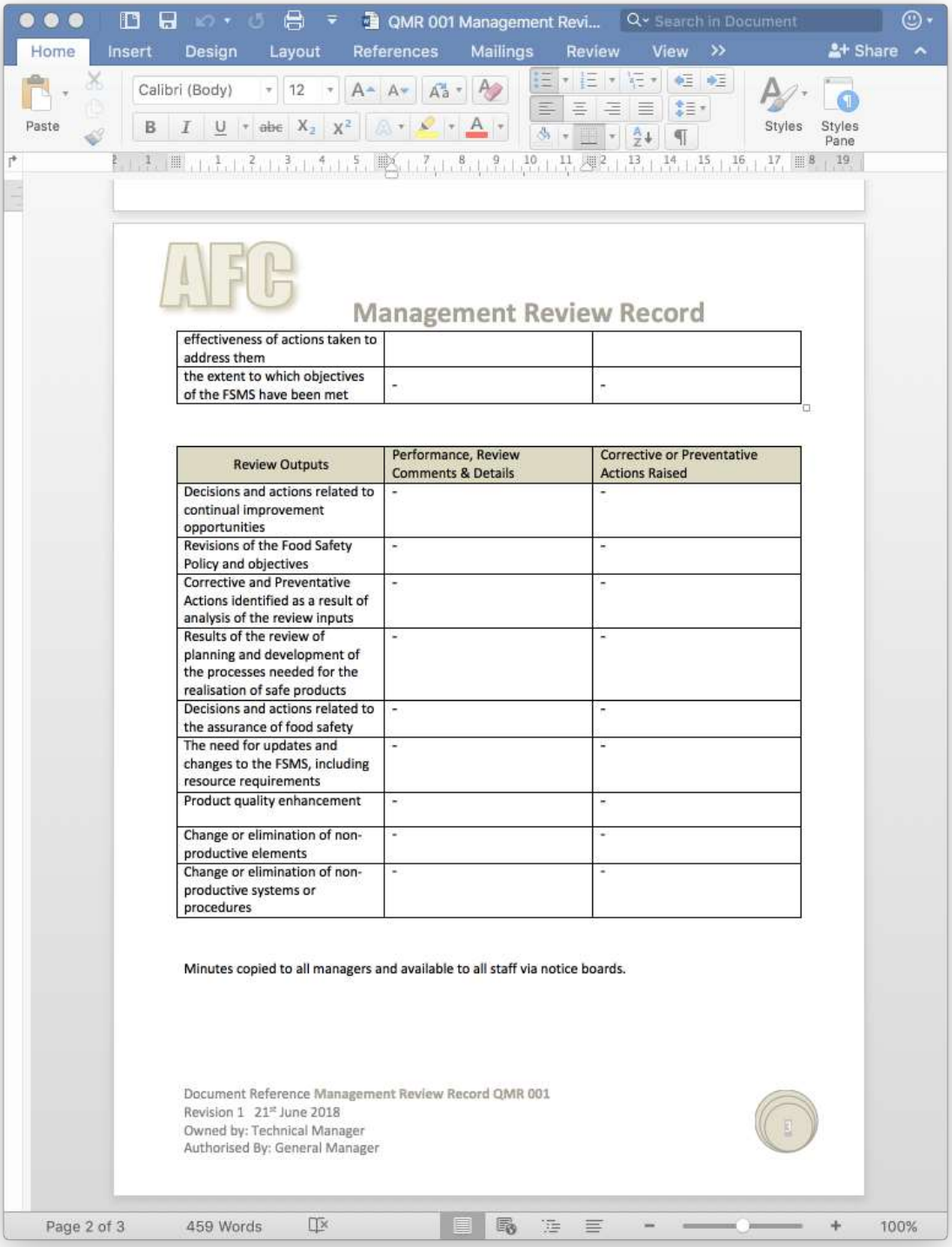
Top Management should implement actions to improve the Food Safety Management System - outputs from the Management Review:



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Management Review Record

effectiveness of actions taken to address them		
the extent to which objectives of the FSMS have been met	-	-

Review Outputs	Performance, Review Comments & Details	Corrective or Preventative Actions Raised
Decisions and actions related to continual improvement opportunities	-	-
Revisions of the Food Safety Policy and objectives	-	-
Corrective and Preventative Actions identified as a result of analysis of the review inputs	-	-
Results of the review of planning and development of the processes needed for the realisation of safe products	-	-
Decisions and actions related to the assurance of food safety	-	-
The need for updates and changes to the FSMS, including resource requirements	-	-
Product quality enhancement	-	-
Change or elimination of non-productive elements	-	-
Change or elimination of non-productive systems or procedures	-	-

Minutes copied to all managers and available to all staff via notice boards.

Document Reference Management Review Record QMR 001
Revision 1 21st June 2018
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Authorised By: General Manager

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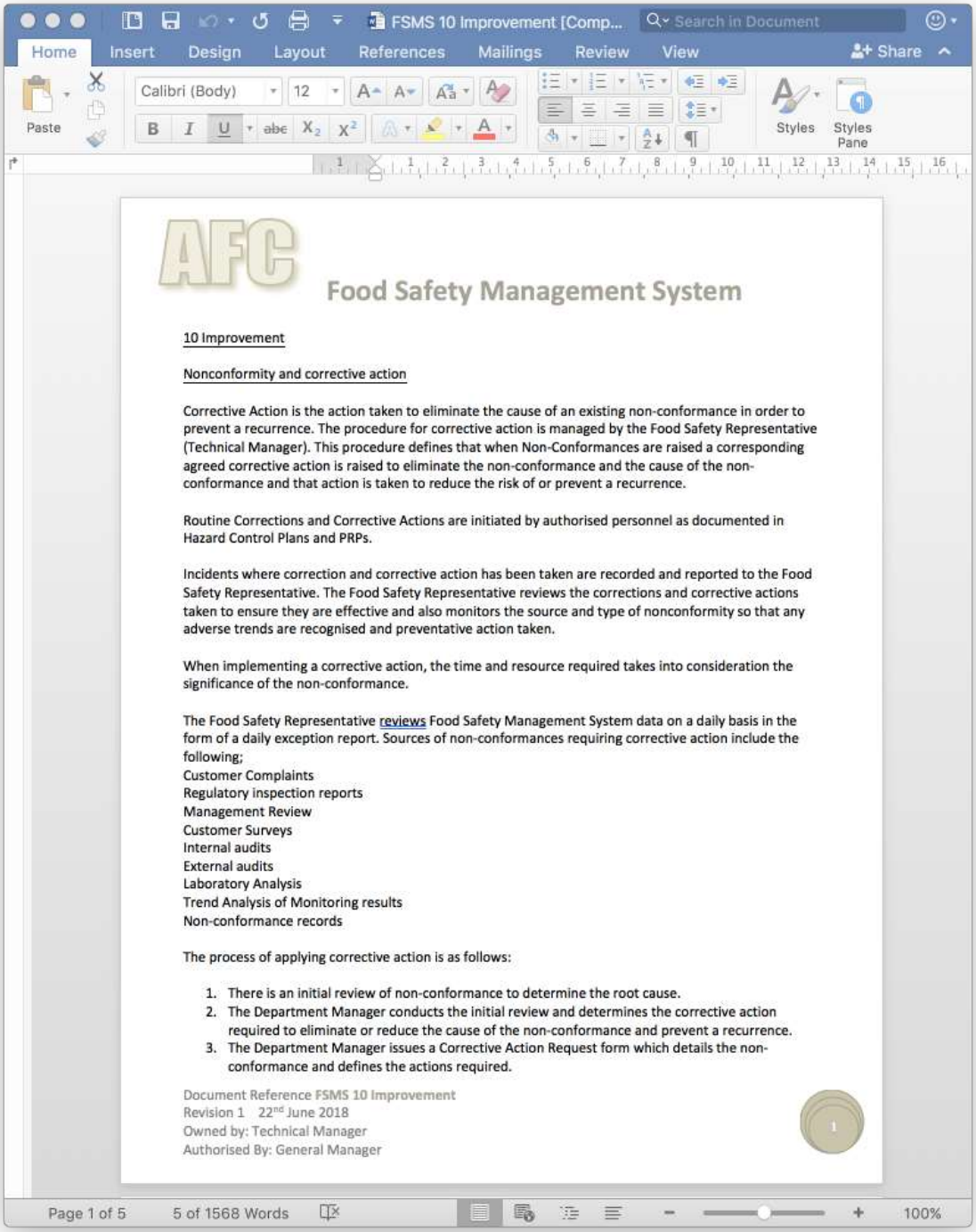
The Top management team implement actions continually improve the suitability, adequacy and effectiveness of the FSMS

Implement document FSMS 10 Improvement

Nonconformity and corrective action
Preventative Action
Continual Improvement
Customer Satisfaction
Food Safety Management System Updating



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Food Safety Management System

10 Improvement

Nonconformity and corrective action

Corrective Action is the action taken to eliminate the cause of an existing non-conformance in order to prevent a recurrence. The procedure for corrective action is managed by the Food Safety Representative (Technical Manager). This procedure defines that when Non-Conformances are raised a corresponding agreed corrective action is raised to eliminate the non-conformance and the cause of the non-conformance and that action is taken to reduce the risk of or prevent a recurrence.

Routine Corrections and Corrective Actions are initiated by authorised personnel as documented in Hazard Control Plans and PRPs.

Incidents where correction and corrective action has been taken are recorded and reported to the Food Safety Representative. The Food Safety Representative reviews the corrections and corrective actions taken to ensure they are effective and also monitors the source and type of nonconformity so that any adverse trends are recognised and preventative action taken.

When implementing a corrective action, the time and resource required takes into consideration the significance of the non-conformance.

The Food Safety Representative reviews Food Safety Management System data on a daily basis in the form of a daily exception report. Sources of non-conformances requiring corrective action include the following;
Customer Complaints
Regulatory inspection reports
Management Review
Customer Surveys
Internal audits
External audits
Laboratory Analysis
Trend Analysis of Monitoring results
Non-conformance records

The process of applying corrective action is as follows:

1. There is an initial review of non-conformance to determine the root cause.
2. The Department Manager conducts the initial review and determines the corrective action required to eliminate or reduce the cause of the non-conformance and prevent a recurrence.
3. The Department Manager issues a Corrective Action Request form which details the non-conformance and defines the actions required.

Document Reference FSMS 10 Improvement
Revision 1 22nd June 2018
Owned by: Technical Manager
Authorised By: General Manager

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Stage 8 Final Steps to ISO 22000 Certification

There a few final steps to achieving ISO 22000 Certification:

- ✓ Carry out an assessment of your system to make sure that it meets the requirements of the certification scheme using the checklists provided
- ✓ Ensure any areas requiring corrective action are addressed
- ✓ Choose your Certification Body
- ✓ Make contact with the Certification Body
- ✓ Pre-assessment
- ✓ Formal assessment
- ✓ Certification
- ✓ Celebrate!
- ✓ Communicate your success!

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Assess the Food Safety Management System

The Steering Group need to allocate responsibility to assess if the established Food Safety Management System meets the requirements of the ISO 22000 standard, TS ISO 22002 and CODEX Guidelines using the checklists provided.

ISO 22000 Food Safety Management System Requirements Internal Audit	
ISO 22000 Clause	**Audit Findings**
4 Context of the organization	
4.1 Understanding the organization and its context	
Has the organization determined external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its Food Safety Management System?	
Has the organization identified, reviewed and updated information related to these external and internal issues (legal, technological, competitive, market, cultural, social and economic environments, cybersecurity and food fraud, food defence and intentional contamination, knowledge and performance of the organization)? *See notes from the standard.*	
4.2 Understanding the needs and expectations of interested parties	
To ensure that the organization has the ability to consistently provide products and services that meet applicable statutory, regulatory and customer requirements with regard to food safety, has the organization determined:	
- the interested parties that are relevant to the Food Safety Management System?	
- the relevant requirements of the interested parties of the Food Safety Management System?	
Does the organization identify, review and update information related to the interested parties and their requirements?	
4.3 Determining the scope of the food safety management system	

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hazards to be effectively controlled.			
4.1 LOCATION			
4.1.1 Establishments	Compliant		Comments
	Yes	No	
Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:			
• environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;			
• areas subject to flooding unless sufficient safeguards are provided;			
• areas prone to infestations of pests;			
• areas where wastes, either solid or liquid, cannot be removed effectively.			
4.1.2 Equipment			
Equipment should be located so that it:			
• permits adequate maintenance and cleaning;			
• functions in accordance with its intended use; and			
• facilitates good hygiene practices, including monitoring.			
4.2 PREMISES AND ROOMS			
4.2.1 Design and layout	Compliant		Comments
	Yes	No	
Where appropriate, the internal design and layout of food establishments should permit good food hygiene practices, including protection against cross-contamination between and during operations by foodstuffs.			
4.2.2 Internal structures and fittings			
Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:			
• the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;			
• walls and partitions should have a smooth surface up to a height appropriate to the operation;			

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11. Cleaning And Sanitizing			
ISO 22002 Requirements	Compliant		Comments
	Yes	No	
11.1 General requirements			
11.2 Cleaning and sanitizing agents and tools			
11.3 Cleaning and sanitizing programmes			
11.4 Cleaning in place (CIP) systems			
11.5 Monitoring sanitation effectiveness			
12. Pest Control			
ISO 22002 Requirements	Compliant		Comments
	Yes	No	
12.1 General requirements			
12.2 Pest control programmes			
12.3 Preventing access			
12.4 Harbourage and infestations			

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Ensure any ISO 22000 areas requiring corrective action are addressed

The non-compliances identified in the assessment of compliance with ISO 22000 should be logged by the Food Safety Team Leader and the appropriate corrective action allocated and taken:

Date	ISO 22000 Clause	Details of Non-Conformance	Identified by:	Corrective Action Required	Responsibility	Target completion Date	Date Completed

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Prerequisite Corrective Actions

The non-compliances identified in the assessment of compliance with the prescribed prerequisite programmes should be logged by the Food Safety Team Leader and the appropriate corrective action allocated and taken:

Date	Prerequisite Clause	Details of Non-Conformance	Identified by:	Corrective Action Required	Responsibility	Target completion Date	Date Completed

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