This comprehensive Food Safety Management System package contains all the tools you will need to achieve certification to the FSSC 22000 Certification Scheme Version 5.1 November 2020.

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

Click here to order the Assured 22000 Certification Package Now

Step One: ISO 22000 Training for Management

Introduction to ISO 22000

This PowerPoint presentation introduces the ISO 22000 standard to the management team and explains exactly how to start the process of implementing a compliant Food Safety Management System.
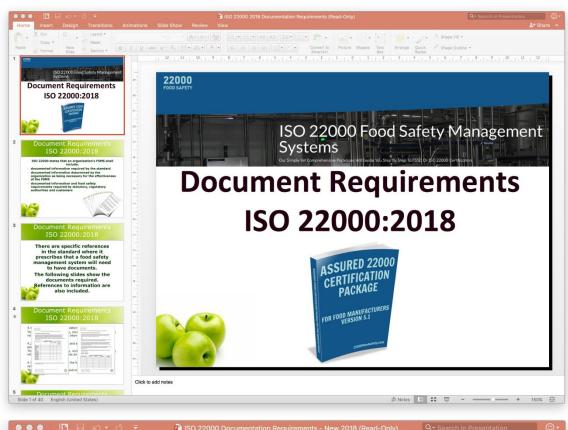
Food Safety Team: ISO 22000 Implementation Guide

The Food Safety Team: ISO 22000 Implementation Guide PowerPoint presentation supplied with the system explains to the Food Safety Team their role in implementing an ISO 22000:2018 compliant Food Safety Management System.

ISO 22000 Document Requirement Guide

The ISO 22000 Document Requirement Guide PowerPoint presentation supplied explains to the Management Team the documentation required in 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.

Top Management FSMS Implementation Meeting

Date/Time

Venue

Agenda

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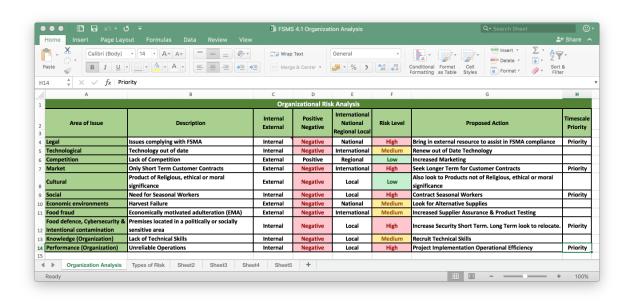
Attendees:

Top Management Team		
Job Title	**Name**	**Role in Team**
Managing Director		Chairman
General Manager		Deputy Chair
Operations Manager		Operations Reporting
Technical Manager		Food Safety and Quality Reporting Management Representative
Planning Manager		Planning and Capacity Reporting
Distribution Manager		Distribution Reporting
Maintenance Manager		Services and Engineering Provision
Finance Manager		Financial Reporting
Human Resources Manager		Resource reporting

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:

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.

Top Management FSMS Implementation Checklist

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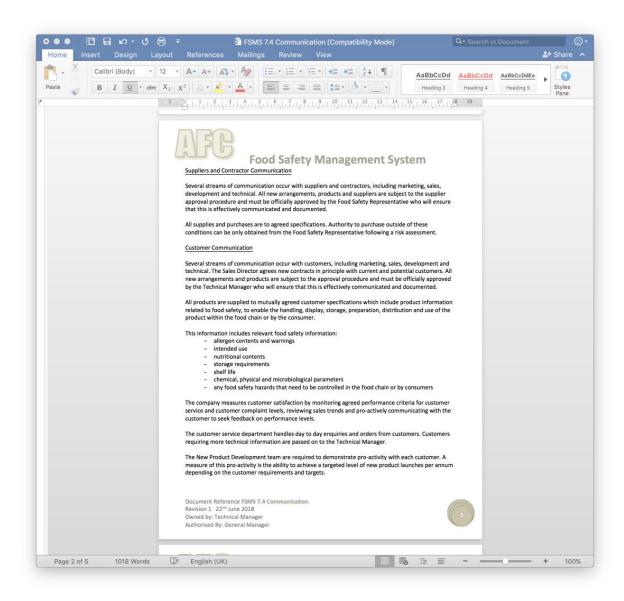
1	Top Management determine external and internal issues that are relevant and affect its ability to achieve the intended result(s) of its FSMS	
	External & Internal Issues	Actions to address risks and opportunities
2	Top Management Determine the interested parties (Customer, Regulatory, Statutory and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

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

| Top management assess plan and establish appropriate internal and external communication (including the food chain) channels		
Communication required	Details	Responsibility

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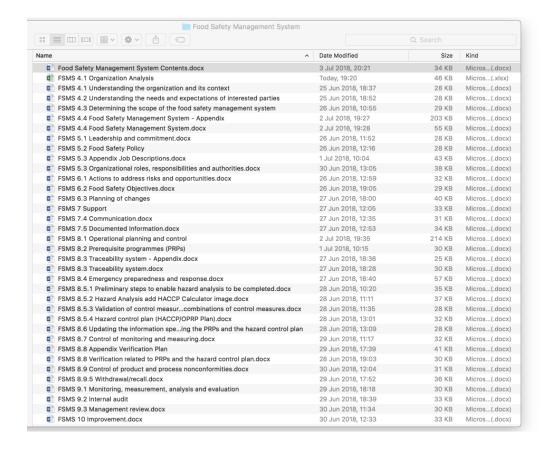
The Food Safety Management System contains a comprehensive ISO 22000 documentation package that you are now ready to implement:

- ✓ 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 Food Safety Management System	
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	
5 Leadership	
FSMS 5.1 Leadership and commitment	
FSMS 5.2 Policy	
FSMS 5.3 Organizational roles, responsibilities and authorities	
6 Planning	
FSMS 6.1 Actions to address risks and opportunities	
FSMS 6.2 Objectives of the food safety management system and planning to achieve them	
FSMS 6.3 Planning of changes	
7 Support	
FSMS 7 Support	7.1 Resources
	7.1.1 General
	7.1.2 People
	7.1.3 Infrastructure
	7.1.4 Work environment
	7.1.5 Externally developed elements of the food safety management system
	7.1.6 Control of externally provided processes, products or services
	7.2 Competence
	7.3 Awareness
FSMS 7.4 Communication	7.4.1 General
	7.4.2 External communication
	7.4.3 Internal communication

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
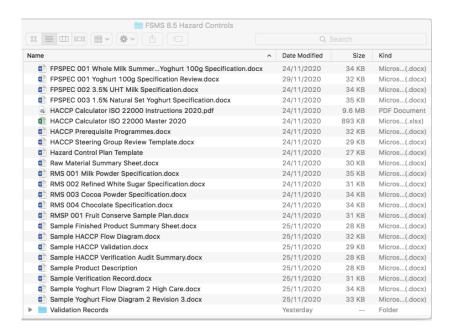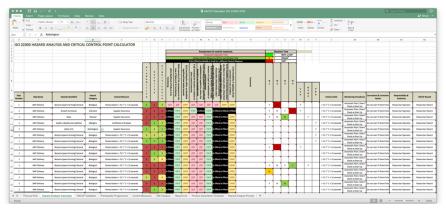
There are also supplementary ISO HACCP Manual documents in the FSMS 8.5 Hazard Controls Folder including the HACCP Calculator ISO 22000 2018 & Instructions:
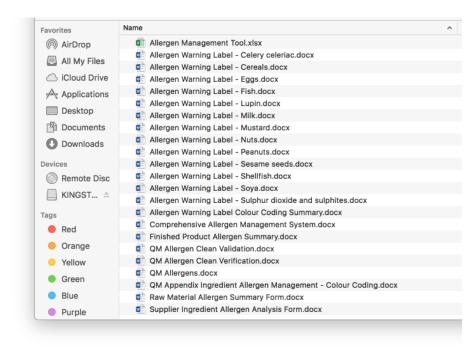
Prerequisite Programmes Manual

Remember there are also supporting supplementary modules:
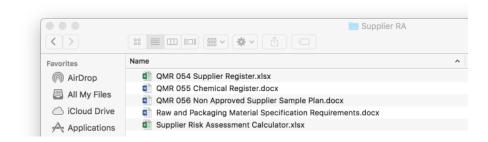
Allergen Management

Product Development

Supplier Risk Assessment

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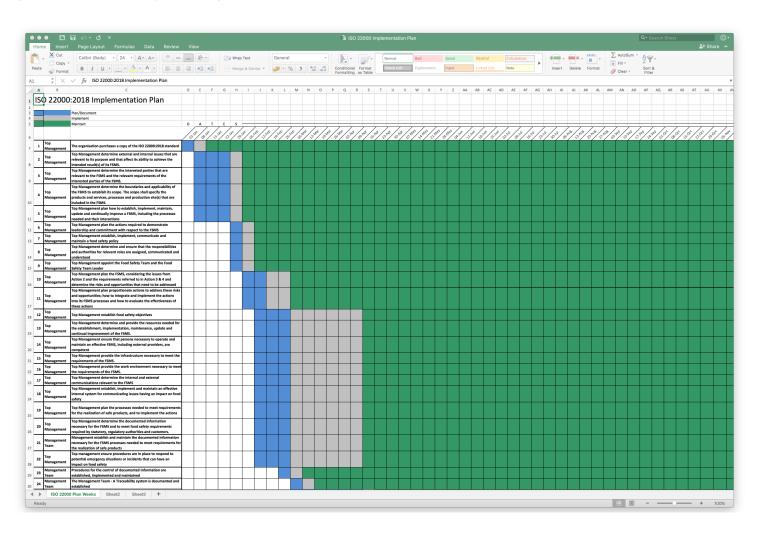
This contains the project tools you will need to achieve FSSC 22000 certification. In this part of the package you will find:

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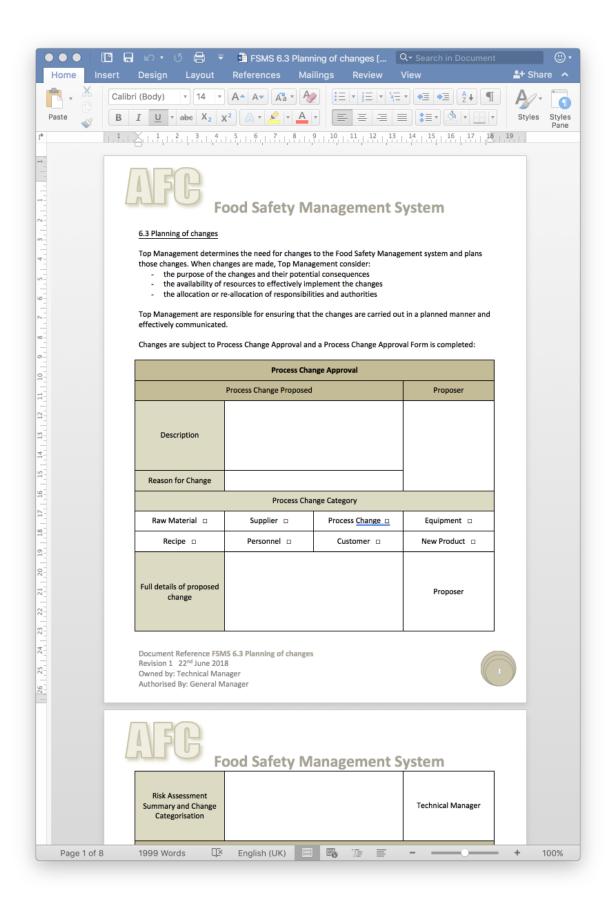
Food Safety Management System Steering Group			
FSMS Team Member	**Name**	**Position**	**Qualification**
FSMS Team Leader			
FSMS Assistant Leader			
FSMS Team Members			

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.

	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**			

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

Food Safety Management System

Risk Assessment Summary and Change Categorisation		Technical Manager

Prerequisite Programme Document Implementation

The Prerequisite Programme documents should be edited and procedures implemented as per the plan and relevant training given. It is advisable that all involved particularly the Food Safety/HACCP Team view the following training presentations first:

Codex GMP & Prerequisite Training

FSMS 8.2 Prerequisite programmes (PRPs)

Food Safety Management System

8.2 Prerequisite programmes (PRPs)

The company has established, implemented, maintains and updates a programme of Prerequisites, which are maintained in order to ensure effective operation of the Food Safety Management system.

Prerequisite programmes (PRPs)

The organization ensures that PRPs are established, implemented, maintained, reviewed, improved and updated to assist in:

- Controlling or preventing the introduction of food safety hazards through the work environment.
- To eliminate, prevent or reduce to an acceptable level the biological, chemical and physical contamination of the product(s) including cross contaminations between products.
- To control, minimize and/or prevent food safety hazard levels in the finished product, ingredients and product processing environment.

All PRP's are approved by the Food Safety Team, their relevance and the reason for their inclusion is documented in the Hazard analysis including details of why the PRP is appropriate to the organisation, the size and type of the operation, the nature of the products being manufactured and/or handled and the control of food safety hazards.

PRP's are implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or process and are categorised into two types:

(i). Infrastructure and Maintenance Programmes

(ii). Operational Prerequisite Programmes

When selecting and designing the PRP's the organisation takes into consideration:
- Known hazards and controls from historic information including complaints
- Customer requirements and codes of practice
- Industry guidelines
- Industry codes of practice
- Regulations
- Appropriate international standards including ISO 22000 and applicable ISO/TS 22002 series
- Codex principles
- GMP guidelines
- The size and type of operation
- Nature of the products

Document Reference **FSMS 8.2 Prerequisite programmes (PRPs)**
Revision 1 22nd June 2018
Owned by: Technical Manager
Authorised By: General Manager

Select, Edit and Implement Relevant Prerequisite Programmes from the PRPs folder:

📁 Prerequisite Programmes

Name	Size	Kind	Date Modified
FSSC 22000 2018 FSMS Prerequisites Manual.docx	29 KB	Micro...(.docx)	24/11/2020
▶ Operational PRPs	--	Folder	26/11/2020
PRP 4.1 Design and Construction of Buildings.docx	26 KB	Micro...(.docx)	26/11/2020
PRP 4.2 Environment Prerequisite Programmes.docx	26 KB	Micro...(.docx)	26/11/2020
PRP 4.3 Site Location and Standards.docx	25 KB	Micro...(.docx)	26/11/2020
PRP 5.1 Layout of Premises and Workspace.docx	26 KB	Micro...(.docx)	26/11/2020
PRP 5.2 Internal Design and Layout.docx	28 KB	Micro...(.docx)	26/11/2020
PRP 5.3 Internal Structure.docx	27 KB	Micro...(.docx)	26/11/2020
PRP 5.4 Equipment Design and Location.docx	26 KB	Micro...(.docx)	26/11/2020
PRP 5.5 Laboratory Facilities.docx	29 KB	Micro...(.docx)	26/11/2020
▶ PRP 5.5 Laboratory Manual	--	Folder	29/11/2020
PRP 5.6 Temporary Structures...Vending Machine Facilities.docx	26 KB	Micro...(.docx)	26/11/2020
PRP 5.7 Storage.docx	31 KB	Micro...(.docx)	27/11/2020
PRP 6.1 Site Services.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 6.2 Control of Water Supply.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 6.3 Control of Boiler Chemicals.docx	26 KB	Micro...(.docx)	27/11/2020
PRP 6.4 Control of Air Supply.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 6.5 Control of Compressed Air and Gases.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 6.6 Lighting.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 7.1 Waste Management.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 7.2 Waste Container Management.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 7.3 Waste Disposal.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 7.4 Drainage Systems.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 8.1 Equipment Prerequisite Programmes.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 8.2 Equipment Hygienic Design.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 8.3 Food Contact Surfaces.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 8.4 Monitoring Equipment.docx	29 KB	Micro...(.docx)	27/11/2020
PRP 8.5 Equipment Cleaning.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 8.6 Appendix Maintenance Procedure.docx	30 KB	Micro...(.docx)	27/11/2020
PRP 8.6 Maintenance Prerequisite Programmes.docx	28 KB	Micro...(.docx)	27/11/2020
▶ PRP 9 Supplier RA	--	Folder	27/11/2020
PRP 9.1 Purchasing Prerequisite Programmes.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 9.2 Supplier Approval and Monitoring.docx	297 KB	Micro...(.docx)	27/11/2020
PRP 9.3 Control of Incoming Materials.docx	31 KB	Micro...(.docx)	27/11/2020
PRP 9.4 Food Fraud Prevention	1.8 MB	Micro...(.docx)	27/11/2020
PRP 9.4A Food Fraud Assessment Tool	34 KB	Micro...(.xlsx)	27/11/2020
PRP 9.4A Food Fraud Raw Material Assessment Tool.xlsx	28 KB	Micro...(.xlsx)	27/11/2020
PRP 10.1 Prevention of Contamination.docx	30 KB	Micro...(.docx)	Yesterday
PRP 10.2 Prevention of Microbiological Contamination.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 10.3 Allergen Control.docx	31 KB	Micro...(.docx)	27/11/2020
▶ PRP 10.3 Allergen Management System	--	Folder	Yesterday
PRP 10.4 Prevention of Physical Contamination.docx	28 KB	Micro...(.docx)	27/11/2020
PRP 11.1 Cleaning Prerequisite Programmes.docx	25 KB	Micro...(.docx)	27/11/2020
PRP 11.2 Cleaning Agents and Equipment.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 11.3 Cleaning Procedures.docx	25 KB	Micro...(.docx)	27/11/2020
PRP 11.4 CIP Systems Prerequisites.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 11.5 Monitoring of Cleaning Effectiveness.docx	26 KB	Micro...(.docx)	27/11/2020
PRP 11.5A Environmental Monitoring Planning.pptx	439 KB	Power...(.pptx)	27/11/2020
PRP 12 Management of Pest Control.docx	38 KB	Micro...(.docx)	27/11/2020
PRP 12.1 Pest Control Prerequisites.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 12.2 Pest Control Programme.docx	28 KB	Micro...(.docx)	27/11/2020
PRP 12.3 Prevention of Pest Access.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 12.4 Prevention of Pest Harbourage.docx	27 KB	Micro...(.docx)	27/11/2020
PRP 12.5 Pest Monitoring.docx	30 KB	Micro...(.docx)	27/11/2020
PRP 12.6 Pest Eradication.docx	28 KB	Micro...(.docx)	27/11/2020
PRP 13 Hygiene Code of Practice.docx	37 KB	Micro...(.docx)	28/11/2020
PRP 13.1 Personal Hygiene an...nnel Facilities Prerequisites.docx	28 KB	Micro...(.docx)	28/11/2020
PRP 13.2 Personnel Hygiene Facilities.docx	25 KB	Micro...(.docx)	28/11/2020
PRP 13.3 Personnel Canteen Facilities.docx	27 KB	Micro...(.docx)	28/11/2020
PRP 13.4 Protective Work Wear.docx	29 KB	Micro...(.docx)	28/11/2020
PRP 13.5 Medical Screening.docx	27 KB	Micro...(.docx)	28/11/2020
PRP 13.6 Illness Reporting Systems.docx	27 KB	Micro...(.docx)	28/11/2020
PRP 13.7 Personal Cleanliness.docx	25 KB	Micro...(.docx)	28/11/2020
PRP 13.8 Personal Behaviour.docx	25 KB	Micro...(.docx)	28/11/2020
PRP 13.9 Control of Visitors and Sub-Contractors.docx	29 KB	Micro...(.docx)	28/11/2020
PRP 14.1 Rework Prerequisite Programmes.docx	25 KB	Micro...(.docx)	28/11/2020
PRP 14.2 Rework Storage Identification and Traceability.docx	28 KB	Micro...(.docx)	28/11/2020
PRP 14.3 Rework Usage Prerequisites.docx	28 KB	Micro...(.docx)	28/11/2020
PRP 15.1 Product Recall Prerequisite Programmes.docx	25 KB	Micro...(.docx)	28/11/2020
PRP 15.2 Product Recall Procedure Prerequisites.docx	29 KB	Micro...(.docx)	28/11/2020
PRP 16.1 Storage Prerequisites.docx	29 KB	Micro...(.docx)	28/11/2020
PRP 16.2 Warehousing Prerequisites.docx	32 KB	Micro...(.docx)	28/11/2020
PRP 16.3 Appendix - Dispatch and Distribution Procedure.docx	26 KB	Micro...(.docx)	28/11/2020
PRP 16.3 Dispatch and Distribution Prerequisites.docx	29 KB	Micro...(.docx)	28/11/2020
PRP 17.1 Product Information Prerequisites.docx	27 KB	Micro...(.docx)	28/11/2020
PRP 17.2 Product Labelling Controls.docx	34 KB	Micro...(.docx)	28/11/2020
PRP 17.2A Label Retention and Check.docx	3.3 MB	Micro...(.docx)	23/11/2020
PRP 18 Food Defence Mitigation Strategies Checklists	45 KB	Micro...(.xlsx)	28/11/2020
PRP 18 Food Threat Assessment & Mitigation Plan Summary	37 KB	Micro...(.xlsx)	28/11/2020
PRP 18.1 Food Defence System.docx	610 KB	Micro...(.docx)	28/11/2020
PRP 18.2 Access Controls.docx	30 KB	Micro...(.docx)	28/11/2020
▶ PRP Verification Records	--	Folder	Yesterday

Step Four: Project 22000 - HACCP Implementation

We will now go through a step by step guide to implementing your HACCP using the HACCP Calculator. It is advisable that all involved particularly the Food Safety/HACCP Team view the following training presentations first:

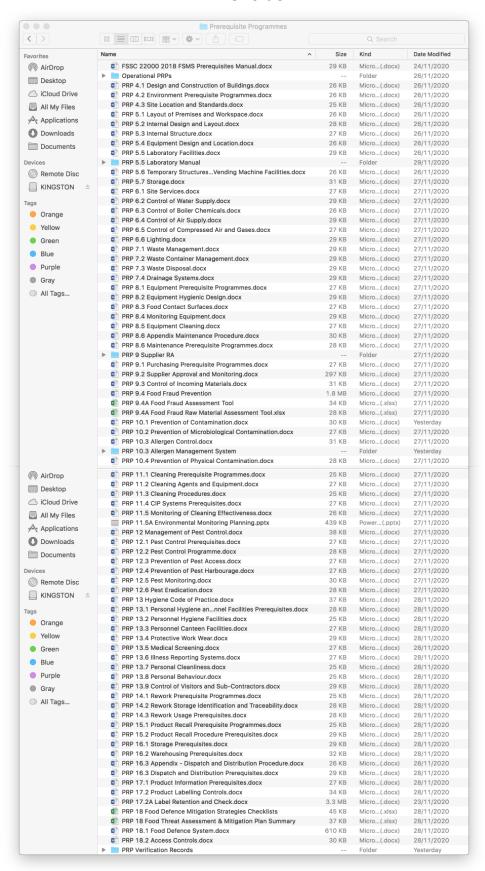Food Safety Team: ISO 22000 Implementation Guide

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
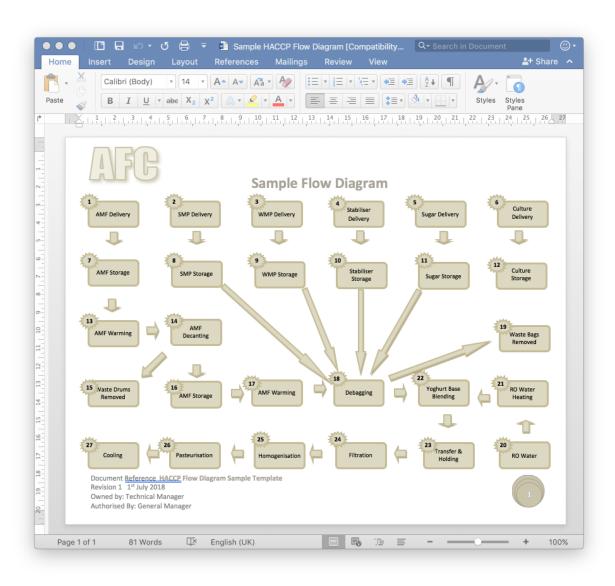FSMS 8.7 Control of monitoring and measuring
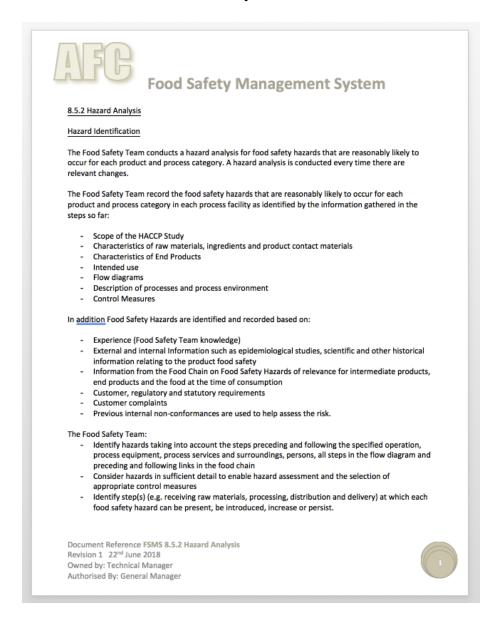FSMS 8.9 Control of product and process nonconformities
FSMS 8.9.5 Withdrawal/recall

There is a Sample HACCP Flow Diagram in the ISO 22000 HACCP Manual as well as a few other useful documents:

Raw Material Summary Sheet
Sample Finished Product Summary Sheet
Sample Product Description
Excel Sheet Product Description in the HACCP Calculator

The Food Safety Team should follow, edit and maintain HACCP document FSMS 8.5.2 Hazard Analysis

AFC

Food Safety Management System

8.5.2 Hazard Analysis

Hazard Identification

The Food Safety Team conducts a hazard analysis for food safety hazards that are reasonably likely to occur for each product and process category. A hazard analysis is conducted every time there are relevant changes.

The Food Safety Team record the food safety hazards that are reasonably likely to occur for each product and process category in each process facility as identified by the information gathered in the steps so far:

- Scope of the HACCP Study
- Characteristics of raw materials, ingredients and product contact materials
- Characteristics of End Products
- Intended use
- Flow diagrams
- Description of processes and process environment
- Control Measures

In addition Food Safety Hazards are identified and recorded based on:

- Experience (Food Safety Team knowledge)
- External and internal Information such as epidemiological studies, scientific and other historical information relating to the product food safety
- Information from the Food Chain on Food Safety Hazards of relevance for intermediate products, end products and the food at the time of consumption
- Customer, regulatory and statutory requirements
- Customer complaints
- Previous internal non-conformances are used to help assess the risk.

The Food Safety Team:
- Identify hazards taking into account the steps preceding and following the specified operation, process equipment, process services and surroundings, persons, all steps in the flow diagram and preceding and following links in the food chain
- Consider hazards in sufficient detail to enable hazard assessment and the selection of appropriate control measures
- Identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist.

Document Reference **FSMS 8.5.2 Hazard Analysis**
Revision 1   22nd June 2018
Owned by: Technical Manager
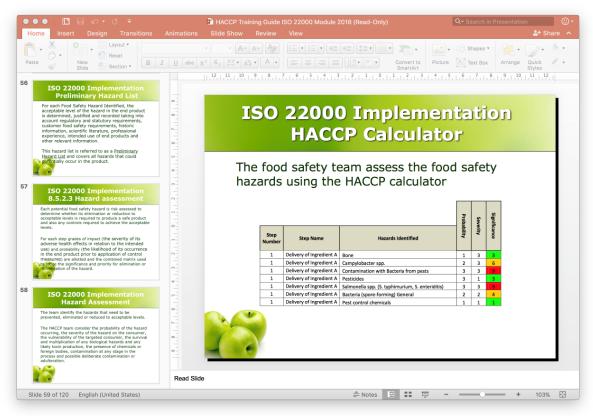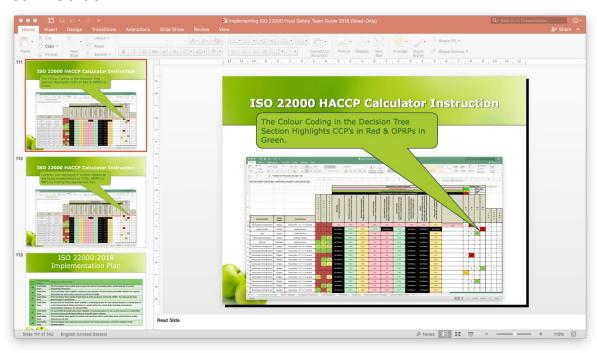Authorised By: General Manager

1

This document covers the following:

Hazard Identification
Food Safety Hazard Analysis Prompt
Determination of Acceptable Levels
Hazard Assessment
Selection and Assessment of Control Measures

There is guidance in HACCP Training Guide ISO 22000 2018 Module

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

There is also guidance in HACCP Calculator ISO 22000 2018 Instructions

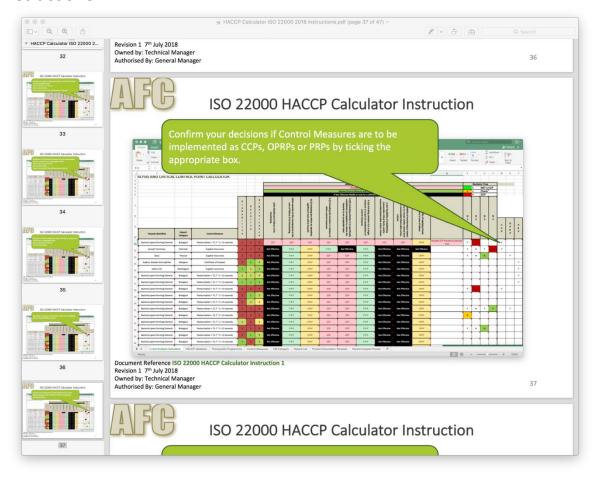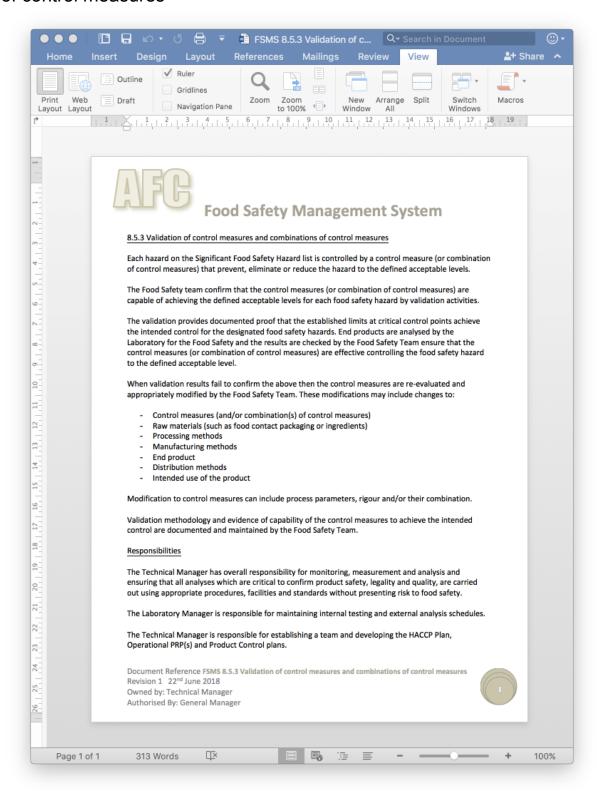The Food Safety Team should follow, edit and maintain HACCP document FSMS 8.5.3 Validation of control measures and combinations of control measures

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

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

AFC 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 2018 Food Safety Team Guide , HACCP Calculator ISO 22000 2018 Instructions and HACCP Training Guide ISO 22000 2018 Module.

At the same time as HACCP Implementation the Management Team will also need to be editing and implementing procedures:
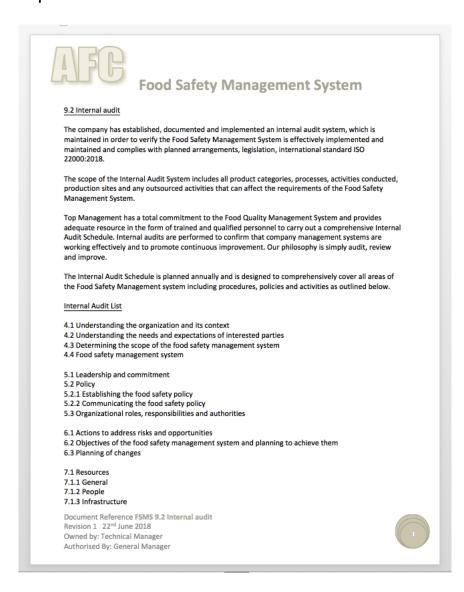
8 Operation
FSMS 8.1 Operational planning and control
FSMS 8.3 Traceability system
FSMS 8.4 Emergency preparedness and response
FSMS 8.7 Control of monitoring and measuring
FSMS 8.9 Control of product and process nonconformities
FSMS 8.9.5 Withdrawal/recall
9 Performance evaluation
FSMS 9.1 Monitoring, measurement, analysis and evaluation
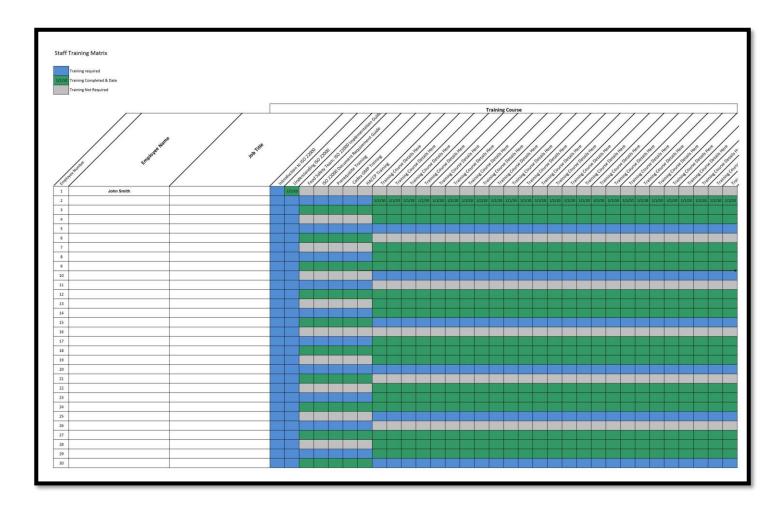FSMS 9.2 Internal audit
FSMS 9.3 Management review
10 Improvement
FSMS 10 Improvement

AFC

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:

QMR 002 Training Record

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Training Record
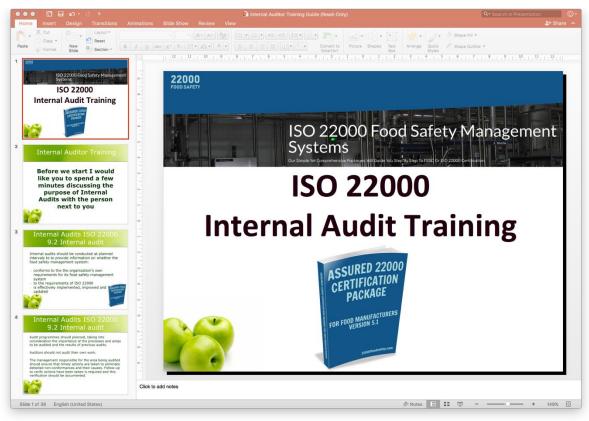
Name:		Employee Number:	
Company Start Date:		Position:	

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
Owned by: Technical Manager
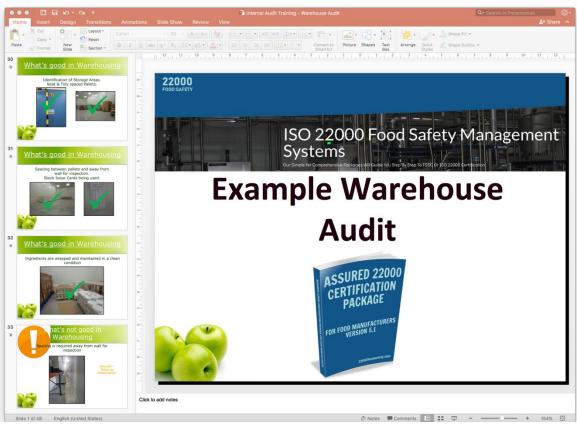Authorised By: General Manager

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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.

Step Five: Internal Auditing & Checklists

There are three PowerPoint Internal Auditor training presentations
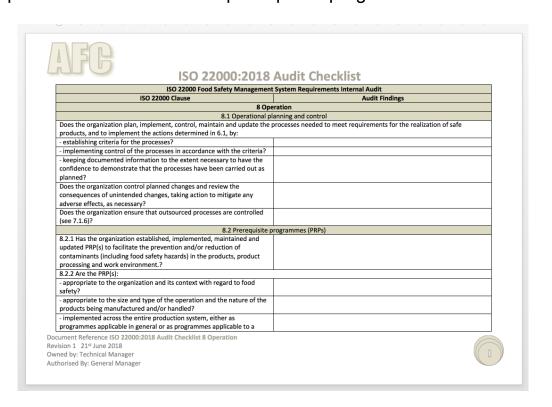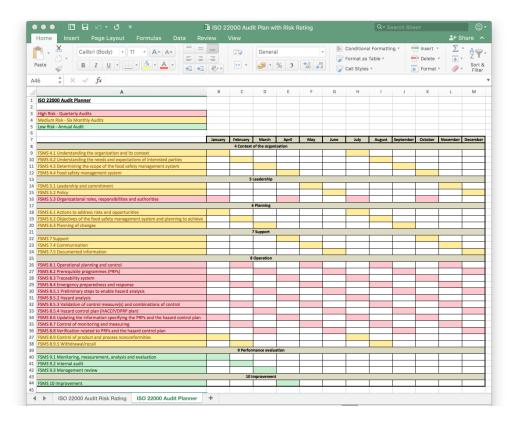
Internal Audit Checklists

There is a checklist for each section of the ISO 22000 standard plus sample verification records for prerequisite programmes.
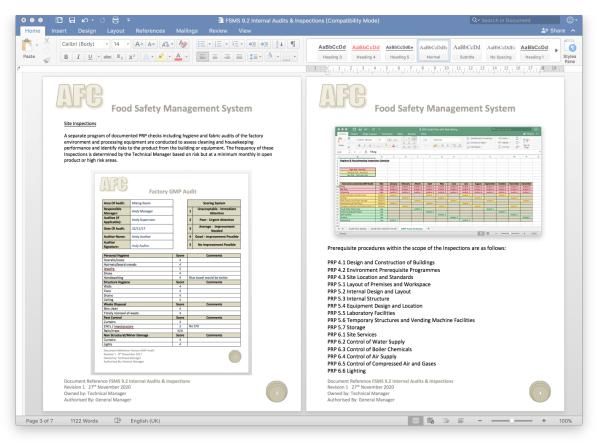
ISO 22000 & ISO 22002-1 Audit Plan with Risk Rating
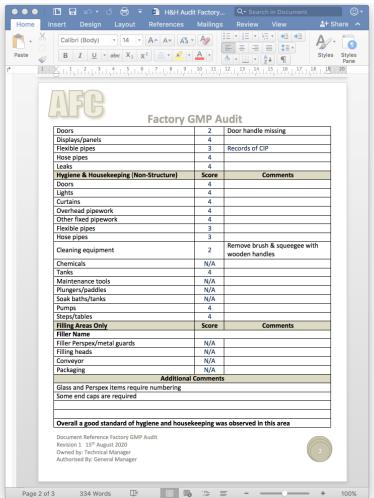
The Food Safety Team Leader should draw up the Internal Audit Schedule based on the following criteria:

- 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

The Food Safety Team Leader should also draw up a Facility Inspection Schedule and maintain routine (e.g. monthly) site inspections/PRP checks to verify that the site (internal and external), production environment and processing equipment are maintained in a suitable condition to ensure food safety. The frequency and content of the site inspections/PRP checks should be based on risk with defined sampling criteria and linked to the relevant technical specification. See Procedure FSMS 9.2 Internal Audits & Inspections and H&H Audit Factory GMP Audit Form.

Food Safety Management System

Site Inspections

A separate program of documented PRP checks including hygiene and fabric audits of the factory environment and processing equipment are conducted to assess cleaning and housekeeping performance and identify risks to the product from the building or equipment. The frequency of these Inspections is determined by the Technical Manager based on risk but at a minimum monthly in open product or high risk areas.

Factory GMP Audit

Area Of Audit:	Mixing Room
Responsible Manager:	Andy Manager
Auditee (If Applicable):	Andy Supervisor
Date Of Audit:	22/11/17
Auditor Name:	Andy Auditor
Auditor Signature:	Andy Auditor

Scoring System

1	Unacceptable - Immediate Attention
2	Poor - Urgent Attention
3	Average - Improvement Needed
4	Good - Improvement Possible
5	No Improvement Possible

Personal Hygiene	Score	Comments
Overals/coats	4	
Hairnets/beard snoods	4	
Jewelry	5	
Shoes	4	
Handwashing	4	Blue towel would be better
Structure Hygiene	**Score**	**Comments**
Walls	4	
Floor	4	
Drains	4	
Ceiling	4	
Waste Disposal	**Score**	**Comments**
Bins clean	4	
Timely removal of waste	4	
Pest Control	**Score**	**Comments**
Curtains	4	
EFK's / insectocutors	3	No EFK
Baits/traps	N/A	
Non Structural/Minor Damage	**Score**	**Comments**
Curtains	4	
Lights	4	

Document Reference Factory GMP Audit
Revision 1 8th November 2017
Owned by: Technical Manager
Authorised By: General Manager

Document Reference FSMS 9.2 Internal Audits & Inspections
Revision 1 27th November 2020
Owned by: Technical Manager
Authorised By: General Manager

Food Safety Management System

Prerequisite procedures within the scope of the Inspections are as follows:

PRP 4.1 Design and Construction of Buildings
PRP 4.2 Environment Prerequisite Programmes
PRP 4.3 Site Location and Standards
PRP 5.1 Layout of Premises and Workspace
PRP 5.2 Internal Design and Layout
PRP 5.3 Internal Structure
PRP 5.4 Equipment Design and Location
PRP 5.5 Laboratory Facilities
PRP 5.6 Temporary Structures and Vending Machine Facilities
PRP 5.7 Storage
PRP 6.1 Site Services
PRP 6.2 Control of Water Supply
PRP 6.3 Control of Boiler Chemicals
PRP 6.4 Control of Air Supply
PRP 6.5 Control of Compressed Air and Gases
PRP 6.6 Lighting

Document Reference FSMS 9.2 Internal Audits & Inspections
Revision 1 27th November 2020
Owned by: Technical Manager
Authorised By: General Manager

Factory GMP Audit

Doors	2	Door handle missing
Displays/panels	4	
Flexible pipes	3	Records of CIP
Hose pipes	4	
Leaks	4	
Hygiene & Housekeeping (Non-Structure)	**Score**	**Comments**
Doors	4	
Lights	4	
Curtains	4	
Overhead pipework	4	
Other fixed pipework	4	
Flexible pipes	3	
Hose pipes	3	
Cleaning equipment	2	Remove brush & squeegee with wooden handles
Chemicals	N/A	
Tanks	4	
Maintenance tools	N/A	
Plungers/paddles	N/A	
Soak baths/tanks	N/A	
Pumps	4	
Steps/tables	4	
Filling Areas Only	**Score**	**Comments**
Filler Name		
Filler Perspex/metal guards	N/A	
Filling heads	N/A	
Conveyor	N/A	
Packaging	N/A	
Additional Comments		
Glass and Perspex items require numbering		
Some end caps are required		
Overall a good standard of hygiene and housekeeping was observed in this area		

Document Reference Factory GMP Audit
Revision 1 15th August 2020
Owned by: Technical Manager
Authorised By: General Manager

Step Six: Review and Updating

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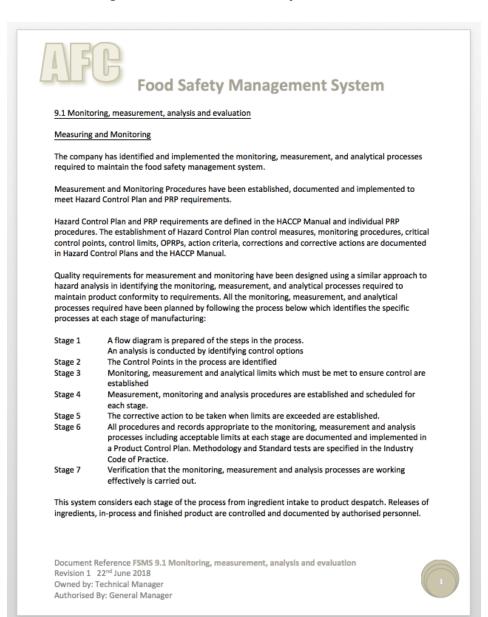**9 Performance evaluation**
FSMS 9.1 Monitoring, measurement, analysis and evaluation
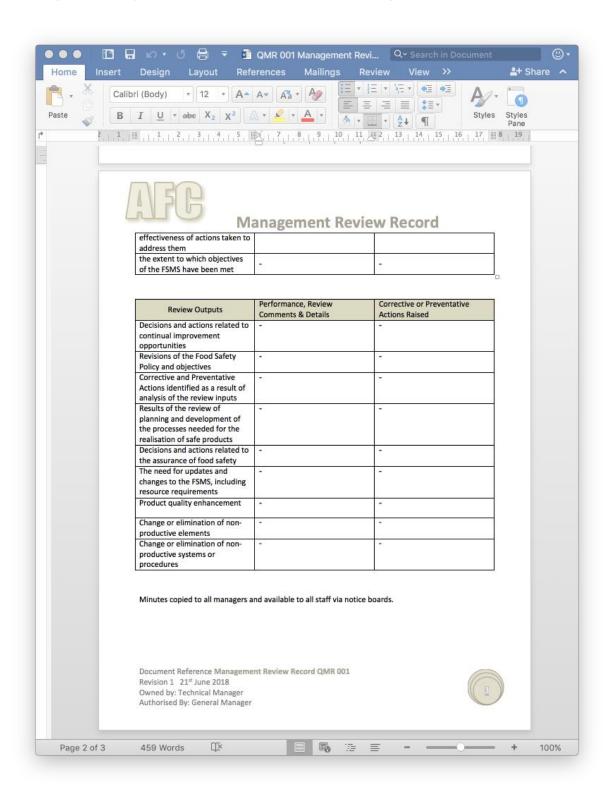FSMS 9.3 Management review
10 Improvement
FSMS 10 Improvement

FSMS 9.1 Monitoring, measurement, analysis and evaluation

AFC **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
Revision 1 22nd June 2018
Owned by: Technical Manager
Authorised By: General Manager

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Top Management should implement actions to improve the Food Safety Management System - outputs from the Management Review:

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
Owned by: Technical Manager
Authorised By: General Manager

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	

• the conditions under which the food will be stored; and			
• the expected length of time before consumption.			
10.3 INSTRUCTION AND SUPERVISION	**Compliant**		**Comments**
	Yes	No	
Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.			
Managers and supervisors of food processes should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.			
10.4 REFRESHER TRAINING	**Compliant**		**Comments**
	Yes	No	
Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.			

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			

Review compliance with FSSC 22000 Certification Scheme Additional Requirements

The Steering Group now need to allocate responsibility to determine how far established procedures meet the Additional Requirements of the FSSC 22000 Certification Scheme and complete the form.

FSSC 22000 Certification Scheme Additional Requirements Version 5.1			
FSSC 22000 Certification Scheme Additional Requirements	**Compliant**		**Comments**
	Yes	**No**	
2.5.1 Management of Services and Purchased Materials – in addition to 7.1.6 Control of externally provided processes, products or services			
Is any analysis critical to the verification and/or validation of food safety conducted by a competent laboratory (including both internal and external laboratories as applicable) that has the capability to produce precise and repeatable test results using validated test methods and best practices. (e.g. successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards such as ISO 17025)?			
Is there a documented procedure for procurement in emergency situations to ensure that products still conform to specified requirements and the supplier has been evaluated?			
Is there a policy for the procurement of animals, fish and seafood that are subject to control of prohibited substances?			
Is there a review process for product specifications to ensure continued compliance with food safety, legal and customer requirements?			
2.5.2 Product Labelling – in addition to 8.5.1.3 Characteristics of end products			

2.5.14 Health Status (Food Chain Category D only)
2.5.15 Requirements for Organizations with Multi-Site Certification (Food Chain Category A, E, FI & G)

Ensure any FSSC/ISO 22000 areas requiring corrective action are addressed

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

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