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. In addition, this 2022 version has been updated in accordance with CODEX Recommended International Code of Practice General Principles of Food Hygiene 2020 Edition HACCP System and Guidelines for its Application.

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
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:

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Name</th>
<th>Role in Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managing Director</td>
<td></td>
<td>Chairman</td>
</tr>
<tr>
<td>General Manager</td>
<td></td>
<td>Deputy Chair</td>
</tr>
<tr>
<td>Operations Manager</td>
<td></td>
<td>Operations Reporting</td>
</tr>
<tr>
<td>Technical Manager</td>
<td></td>
<td>Food Safety and Quality Reporting</td>
</tr>
<tr>
<td>Planning Manager</td>
<td></td>
<td>Planning and Capacity Reporting</td>
</tr>
<tr>
<td>Distribution Manager</td>
<td></td>
<td>Distribution Reporting</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td></td>
<td>Services and Engineering Provision</td>
</tr>
<tr>
<td>Finance Manager</td>
<td></td>
<td>Financial Reporting</td>
</tr>
<tr>
<td>Human Resources Manager</td>
<td></td>
<td>Resource reporting</td>
</tr>
</tbody>
</table>
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.
The Top Management FSMS Implementation Meeting should follow the guidelines of the Top Management Implementation Checklist:

<table>
<thead>
<tr>
<th></th>
<th>Top Management determine external and internal issues that are relevant and affect its ability to achieve the intended result(s) of its FSMS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>External &amp; Internal Issues</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Top Management Determine the interested parties (Customer, Regulatory, Statutory and Other) that are relevant to the FSMS.</td>
</tr>
<tr>
<td></td>
<td>Interested Parties (Customer, Regulatory, Statutory and Other)</td>
</tr>
</tbody>
</table>
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.
Top Management establish and provide Infrastructure and Work Environment Requirements

Top Management provides the Infrastructure and Work Environment required to establish the Food Safety Management System.

Infrastructure

Infrastructure within the scope of this procedure includes:
- buildings including temporary buildings
- workspace layout
- process equipment
- tools
- supporting services
- information systems

Work Environment

Work environment areas, including conditions under which work is performed, within the scope of this procedure include:
- legislation
- external environment
- buildings including temporary buildings
- layout of facilities
- plant equipment
- pest control
- waste control
- health screening
- laundry and work wear
- cleaning processes
- noise
- temperature
- humidity
- lighting
- weather

The Senior Management team identify and provide the work environment required to:
- Maintain quality systems and food safety systems
- Comply with site policies
- Meet site objectives
- Meet customer requirements
- Promotion of the awareness of customer requirements throughout the company.
- 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

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Job Holder</th>
<th>Nominated Deputy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Response Coordinator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operations Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Production Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warehouse Manager</td>
<td></td>
<td></td>
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<tr>
<td>Maintenance Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factory Safety Manager</td>
<td></td>
<td></td>
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<tr>
<td>Human Resource Manager</td>
<td></td>
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<tr>
<td>Packing Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical Manager (Food Safety Team Leader)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design and Development Manager</td>
<td></td>
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<tr>
<td>Planning Manager</td>
<td></td>
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<tr>
<td>Customer Service Manager</td>
<td></td>
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<tr>
<td>Laboratory Manager</td>
<td></td>
<td></td>
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<tr>
<td>Distribution Manager</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Top Management Establish Food Safety Management System Steering Group

<table>
<thead>
<tr>
<th>FSMS Team Member</th>
<th>Name</th>
<th>Position</th>
<th>Qualification</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSMS Team Leader</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSMS Assistant Leader</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSMS Team Members</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Top Management Establish a Food Safety Team

<table>
<thead>
<tr>
<th>Food Safety Team</th>
<th>Name</th>
<th>Position</th>
<th>Qualification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
Top Management Establish a Product Recall/Crisis Management Team

<table>
<thead>
<tr>
<th>Crisis</th>
<th>Name</th>
<th>Crisis Coordinator</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire or Site evacuation</td>
<td></td>
<td>Health and Safety Manager</td>
<td></td>
</tr>
<tr>
<td>Utility Supply failure</td>
<td></td>
<td>Maintenance Manager</td>
<td></td>
</tr>
<tr>
<td>IT systems failure</td>
<td></td>
<td>Operations Manager</td>
<td></td>
</tr>
<tr>
<td>Water Supply Contamination</td>
<td></td>
<td>Technical Manager</td>
<td></td>
</tr>
<tr>
<td>Breaches of security</td>
<td></td>
<td>General Manager</td>
<td></td>
</tr>
<tr>
<td>Distribution Failure</td>
<td></td>
<td>Distribution Manager</td>
<td></td>
</tr>
<tr>
<td>Bomb Threat or similar</td>
<td></td>
<td>General Manager</td>
<td></td>
</tr>
<tr>
<td>Bioterrorism</td>
<td></td>
<td>Managing Director</td>
<td></td>
</tr>
<tr>
<td>Extortion or Sabotage</td>
<td></td>
<td>General Manager</td>
<td></td>
</tr>
<tr>
<td>Product quality or safety</td>
<td></td>
<td>Technical Manager</td>
<td></td>
</tr>
</tbody>
</table>
## Top Management Establish Food Safety Responsibility & Authority Levels

<table>
<thead>
<tr>
<th>Process</th>
<th>Responsible Persons</th>
<th>Activity</th>
</tr>
</thead>
</table>
| Purchases                    | Purchasing Manager                       | Purchase ingredients from approved and certified sources  
Ensure purchase orders comply with applicable specifications                                                        |
|                              | Technical Manager                        | Ensure adequate information on supply application form  
Ensure suppliers adhere to supply handling practices  
Perform suppliers audit or review supply status where necessary                                                        |
| Receiving and warehousing    | QA/QC & Store Executives                 | Compare Purchase Order and Delivery Note or check contracts as per Suppliers Specifications criteria (if applicable)  
Check receiving temperature, pest infestations, quality, packing conditions and truck hygiene.  
Observe unloading practices  
Handle incoming goods as per documented procedures  
Ensure Good Storage Practices and FIFO/FEFO rotation principles                                                       |
| Preparation of Ingredients   | QA/QC, Production Manager & Production Executive | Follow safe food preparation and handling practices  
Check environmental hygiene and safety  
Check equipment process performance and maintenance  
Check water quality and safety  
Check raw materials identification and traceability                                                                         |
| Production                   | QC/QC, Production Manager, Supervisor & Operators | Maintain product recipes and characteristics  
Do not modify recipes prior to approval from top management  
Follow safe food handling practices  
Ensure Good Manufacturing Practices are adhered to  
Follow cleaning and sanitation standards and procedures  
Follow the handling standards of raw and processed foods                                                                   |
| Holding and Filling of Processed Food | Production Supervisor & Operators | Follow safe food holding procedures  
Hold foods outside the range of danger zone  
Follow safe food filling procedures into primary packaging                                                            |
| Capping, coding and packing  | Production Supervisor & Operators        | Follow safe capping procedures  
Ensure food in primary packaging are hygienically located  
Ensure coding for traceability is performed to procedures  
Follow secondary packaging procedures to protect                                                                   |
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
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

<table>
<thead>
<tr>
<th>FSMS 4.1 Understanding the organization and its context</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSMS 4.2 Understanding the needs and expectations of interested parties</td>
</tr>
<tr>
<td>FSMS 4.3 Determining the scope of the food safety management system</td>
</tr>
<tr>
<td>FSMS 4.4 Food safety management system</td>
</tr>
</tbody>
</table>

## 5 Leadership

<table>
<thead>
<tr>
<th>FSMS 5.1 Leadership and commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSMS 5.2 Policy</td>
</tr>
<tr>
<td>FSMS 5.3 Organizational roles, responsibilities and authorities</td>
</tr>
</tbody>
</table>

## 6 Planning

<table>
<thead>
<tr>
<th>FSMS 6.1 Actions to address risks and opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSMS 6.2 Objectives of the food safety management system and planning to achieve them</td>
</tr>
<tr>
<td>FSMS 6.3 Planning of changes</td>
</tr>
</tbody>
</table>

## 7 Support

### FSMS 7 Support

<table>
<thead>
<tr>
<th>7.1 Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1.1 General</td>
</tr>
<tr>
<td>7.1.2 People</td>
</tr>
<tr>
<td>7.1.3 Infrastructure</td>
</tr>
<tr>
<td>7.1.4 Work environment</td>
</tr>
<tr>
<td>7.1.5 Externally developed elements of the food safety management system</td>
</tr>
<tr>
<td>7.1.6 Control of externally provided processes, products or services</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.2 Competence</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3 Awareness</td>
</tr>
</tbody>
</table>

### FSMS 7.4 Communication

<table>
<thead>
<tr>
<th>7.4.1 General</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4.2 External communication</td>
</tr>
</tbody>
</table>
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 & Instructions:

This package has been updated in accordance with CODEX Recommended International Code of Practice General Principles of Food Hygiene 2020 Edition HACCP System and Guidelines for its Application and a New 2022 Decision Tree.
A.1. “Example of a CCP Decision Tree - Apply to each step where a specified significant hazard is identified.”

Q1. Can the significant hazard be controlled to an acceptable level at this step by prerequisite programs (e.g. GHPs)?

   Yes → This step is not a CCP.

   No →

Q2. Do specific control measures for an identified significant hazard exist at this step?

   Yes →

Q3. Will a subsequent step prevent or eliminate the identified significant hazard or reduce it to an acceptable level?

   Yes → That subsequent step should be a CCP.

   No →

Q4. Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level? ***

   Yes →

   No → Modify the step, process or product to implement a control measure ****

This step is a Critical Control Point (CCP)

* Consider the significance of the hazard (i.e., the likelihood of occurrence in the absence of control and the severity of impact of the hazard) and whether it could be sufficiently controlled by prerequisite programs such as GHPs. GHPs could be routine GHPs or GHPs that require greater attention to control the hazard (e.g. monitoring and recording).

** If a CCP is not identified at questions 2-4, the process or product should be modified to implement a control measure and a new hazard analysis should be conducted.

***Consider whether the control measure at this step works in combination with a control measure at another step to control the same hazard, in which case both steps should be considered as CCPs.

****Return to the beginning of the decision tree after a new hazard analysis.
Prerequisite Programmes Manual

Remember there are also supporting supplementary modules:

Allergen Management

Product Development

Supplier Risk Assessment
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.
<table>
<thead>
<tr>
<th>Project Planning Tasks</th>
<th>Responsibility</th>
<th>Comments</th>
<th>Due Date for Completion</th>
<th>Date Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The organisation purchases a copy of the ISO 22000:2018 standard</td>
<td>Top Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>Top Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Top Management determine the interested parties that are relevant to the FSMS and the relevant requirements of the interested parties of the FSMS.</td>
<td>Top Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>Top Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Top Management plan how to establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions</td>
<td>Top Management</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6 Top Management plan the actions</td>
<td>Top Management</td>
<td></td>
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</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Area of Issue</th>
<th>Description</th>
<th>Internal</th>
<th>Positive</th>
<th>Negative</th>
<th>International</th>
<th>National</th>
<th>Regional</th>
<th>Local</th>
<th>Risk Level</th>
<th>Proposed Action</th>
<th>Tenable Priority</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant</td>
<td>Issues complying with FSMA</td>
<td>Internal</td>
<td>Positive</td>
<td>Negative</td>
<td>International</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>High</td>
<td>Bring in external resource to assist in FSMA compliance</td>
<td>Priority</td>
<td></td>
</tr>
<tr>
<td>Technological</td>
<td>Technology</td>
<td>Internal</td>
<td>Positive</td>
<td>Negative</td>
<td>International</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>Medium</td>
<td>Revise out of date Technology</td>
<td>Priority</td>
<td></td>
</tr>
<tr>
<td>Competition</td>
<td>Lack of Competitiveness</td>
<td>External</td>
<td>Positive</td>
<td>Negative</td>
<td>International</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>High</td>
<td>Increased Marketing</td>
<td>Priority</td>
<td></td>
</tr>
<tr>
<td>Market</td>
<td>Daily Short Term Customer Contracts</td>
<td>Internal</td>
<td>Positive</td>
<td>Negative</td>
<td>International</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>Medium</td>
<td>Seek Longer Term for Customer Contracts</td>
<td>Priority</td>
<td></td>
</tr>
<tr>
<td>Cultural</td>
<td>Product of Religious, ethical or moral significance</td>
<td>Internal</td>
<td>Negative</td>
<td>Positive</td>
<td>International</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>Low</td>
<td>Also look to Products not of Religious, ethical or moral significance</td>
<td>Priority</td>
<td></td>
</tr>
<tr>
<td>Solid</td>
<td>Need for Seasonal Workers</td>
<td>Internal</td>
<td>Negative</td>
<td>Positive</td>
<td>Local</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>High</td>
<td>Contract Seasonal Workers</td>
<td>Priority</td>
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<tr>
<td>Economic</td>
<td>Economic Environment</td>
<td>Internal</td>
<td>Negative</td>
<td>Positive</td>
<td>International</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>Medium</td>
<td>Look for Alternative Supplies</td>
<td>Priority</td>
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</tr>
<tr>
<td>Good Health</td>
<td>Economic and Economic Environment</td>
<td>Internal</td>
<td>Negative</td>
<td>Positive</td>
<td>International</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>Medium</td>
<td>Increased Supplier Assurance &amp; Product Testing</td>
<td>Priority</td>
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<td>Food Defence</td>
<td>Food Defence</td>
<td>Internal</td>
<td>Negative</td>
<td>Positive</td>
<td>Local</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>High</td>
<td>Increase Security Short Term, Long Term task to relocate</td>
<td>Priority</td>
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</tr>
<tr>
<td>Knowledge</td>
<td>Knowledge (Organizational)</td>
<td>Internal</td>
<td>Negative</td>
<td>Positive</td>
<td>Local</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>Medium</td>
<td>Increase Technical Skills</td>
<td>Priority</td>
<td></td>
</tr>
<tr>
<td>Performance</td>
<td>Performance (Organizational)</td>
<td>Internal</td>
<td>Negative</td>
<td>Positive</td>
<td>Local</td>
<td>National</td>
<td>Regional</td>
<td>Local</td>
<td>High</td>
<td>Project Implementation Operational Efficiency</td>
<td>Priority</td>
<td></td>
</tr>
</tbody>
</table>

### AFC 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.

<table>
<thead>
<tr>
<th>Category</th>
<th>Food Safety Requirement</th>
<th>International</th>
<th>National</th>
<th>Regional</th>
<th>Local</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statutory</td>
<td></td>
<td>International</td>
<td>National</td>
<td>Regional</td>
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<tr>
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<td>National</td>
<td>Regional</td>
<td>Local</td>
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<tr>
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<tr>
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<td>National</td>
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<td>Local</td>
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<tr>
<td>Regulatory</td>
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<td>Regional</td>
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<tr>
<td>Customer 1</td>
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<td>Customer 2</td>
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<td>Customer 3</td>
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<tr>
<td>Customer 4</td>
<td></td>
<td>Local</td>
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</tbody>
</table>

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

New Good Hygienic Practice Training

Prerequisite Programme Training
FSMS 8.2 Prerequisite programmes (PRPs)

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

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 products/including cross contamination between products.
- To control, minimize and/or prevent food safety hazard levels in the finished product, ingredients and product processing environment.

All PRPs 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.

PRPs 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:

1. Infrastructure and Maintenance Programmes
2. Operational Prerequisite Programmes

When selecting and designing the PRPs 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
Select, Edit and Implement Relevant Prerequisite Programmes
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
8.5 Hazard control

The Food Safety Team should follow, edit and maintain HACCP document FSMS 8.5.1 Preliminary steps to enable hazard analysis.

This document covers the following:

HACCP (Food Safety) Team
HACCP Scope
Characteristics of raw materials, ingredients and product contact materials
Characteristics of End Products
Intended Use
Preparation of the flow diagrams

The flow chart is confirmed physically on site by the Food Safety team who conduct a walk through verifying all steps in the process flow chart. Description of processes and process environment.
There is guidance in HACCP Training Guide ISO 22000 Module

There is also guidance in Implementing ISO 22000 Food Safety Team Guide
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
There is guidance in HACCP Training Guide ISO 22000 Module.
There is guidance in HACCP Training Guide ISO 22000 Module

There is also guidance in Implementing ISO 22000 Food Safety Team Guide
There is also guidance in HACCP Calculator ISO 22000 Instructions.
There is also guidance in HACCP Calculator ISO 22000 Instructions

**ISO 22000 HACCP Calculator Instruction**

**Selection and Categorisation of Control Measures**

Selection and categorization of control measures includes the following assessments in the Hazard Analysis Calculator worksheet:

For each of the control measures selected, there is an assessment of:
- the likelihood of failure of its functioning
- the severity of the consequence in the case of failure of its functioning
- (i) including the effect on identified significant food safety hazards
- (ii) including the location in relation to other control measures
- (iii) including whether it is specifically established and applied to reduce the hazards to an acceptable level
- (iv) including whether it is a single measure or is part of combination of control measures
- c) the feasibility of establishing measurable critical limits and/or measurable/observable action criteria
- d) the feasibility of monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria
- e) the feasibility of applying timely corrections in case of failure

The Control Measure Assessment section of the Hazard Analysis Calculator is Colour Coded. Control Measures that are Not likely to be Effective are highlighted by a Black Box. Control Measures that are likely to be PRPs are highlighted by a Green Box. Control Measures that are likely to be Operational PRPs are highlighted by a Orange Box.

If all Boxes are Red after Assessment the team are to continue and use the Decision Tree Section.
If a mixture of Red and Orange Boxes are highlighted then the HACCP team consider if to proceed to the Decision Tree Section or implement as an Operational PRP.

Significant Hazards which proceed to the Decision Tree Section are Categorised as Critical Control Points if they are highlighted in Red by the Hazard Analysis Calculator otherwise they are implemented as Operational PRPs.
There is also guidance in HACCP Calculator ISO 22000 Instructions

ISO 22000 HACCP Calculator Instruction

a) What is the likelihood of failure of its functioning?
Consider if:
Never fails
Slight risk of failure
Possible failure
Likely failure
Guaranteed failure

Based on the above select from the drop-down list if it is likely to be a CCP, OPRP, PRP or Not Effective.
If Not Effective Modify or look for a different Control Measure

ISO 22000 HACCP Calculator Instruction

b) What is the severity of the consequences in the case of failure in its functioning?
Consider would failure mean a:
Very severe life-threatening event
Severe injury or trauma requiring urgent hospital treatment
Immobilising injury or trauma requiring hospital treatment
Non-immobilising injury or trauma but requiring hospital treatment
Minor non-immobilising injury or trauma not requiring hospital treatment

Based on the above select from the drop-down list if it is likely to be a CCP, OPRP, PRP or Not Effective.
If Not Effective Modify or look for a different Control Measure
There is also guidance in HACCP Calculator ISO 22000 Instructions

**ISO 22000 HACCP Calculator Instruction**

e) What is the feasibility of applying timely corrections in case of failure?

Timely corrections can be applied 100% of the time
Timely corrections can be applied most of the time
Timely corrections can be applied some of the time
Timely corrections can’t be applied

Based on the above select from the drop-down list if it is likely to be a CCP, OPRP, PRP or Not Effective.

If Not Effective Modify or look for a different Control Measure

**ISO 22000 HACCP Calculator Instruction**

Make notes of your findings from Assessment of Control Measures
There is also guidance in HACCP Calculator ISO 22000 Instructions.
There is also guidance in HACCP Calculator ISO 22000 Instructions.

Question 1: Can the significant hazard be controlled to an acceptable level at this step by prerequisite programs (e.g. GHPs)?
   Enter Y for Yes or N for No
   Do not leave blank
   Stop at this point if the cell turns Orange.
   This step is not a CCP.
   If No, the cell turns Green. Proceed to Question 2.

Question 2: Do specific control measures for an identified significant hazard exist at this step?
   Enter Y for Yes or N for No
   Do not leave blank
   Stop at this point if the cell turns Orange.
   This step is not a CCP.
   Subsequent steps should be evaluated for a CCP***
   If Yes, the cell turns Green. Proceed to Question 3.
There is also guidance in HACCP Calculator ISO 22000 Instructions

Refer to the FSSC 22000 HACCP Calculator Instructions 2022 pdf for more details.
The Food Safety Team should follow, edit and maintain HACCP document FSMS 8.5.3 Validation of control measures and combinations of control measures.

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.
AFC

Factory GMP Audit

Doors 2
Door handle missing

Display/paints 4

Flexible pipes 3
Records of CIP

Heater pipes 4
Leaks 4

Hygiene & Housekeeping (Non-Structure) Score Comments

Doors 4

Lights 4

Laminates 4
Overhead pipework 4

Cleaner Floor pipework 4
Flexible pipes 3

Cleaning equipment 2
Remove brush & squeegee with wooden handles

Chemicals N/A

Toilets 4

Maintenance tools N/A

Flanges/couplings N/A

Soak baths/tanks N/A

Turnips 4

Steps/stairs 4

Overall score: 2

Comments: Good standard of hygiene and housekeeping was observed in this area.
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

### 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, OP RP Ps, 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 chart 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 dispatch. Releases of ingredients, in-process and finished product are controlled and documented by authorised personnel.
Top Management Review QMR 001 Management Review Record can be used to record the details of Management Review.
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
The food safety team update the FSMS as necessary by reviewing data collected and information.

The food safety team evaluate the Food Safety Management System at planned intervals and consider whether it is necessary to review the hazard analysis, the established hazard control plan and the established PRPs.
Stage 8 Final Steps to ISO 22000 Certification

There are 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!
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 FSSC 22000 Certification Scheme Additional Requirements using the checklists provided.

<table>
<thead>
<tr>
<th>ISO 22000 Food Safety Management System Requirements Internal Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 22000 Clause</td>
</tr>
<tr>
<td>4 Context of the organization</td>
</tr>
<tr>
<td>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?</td>
</tr>
<tr>
<td>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)?</td>
</tr>
<tr>
<td>4.2 Understanding the needs and expectations of interested parties</td>
</tr>
<tr>
<td>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:</td>
</tr>
<tr>
<td>- the interested parties that are relevant to the Food Safety Management System?</td>
</tr>
<tr>
<td>- the relevant requirements of the interested parties of the Food Safety Management System?</td>
</tr>
<tr>
<td>Does the organization identify, review and update information related to the interested parties and their requirements?</td>
</tr>
<tr>
<td>4.3 Determining the scope of the food safety management system</td>
</tr>
</tbody>
</table>
Review ISO 22002 prerequisite programs (PRPs) to control food safety hazards

The Steering Group now need to allocate responsibility to determine how far established prerequisite programmes meet the requirements of ISO 22002-1. Using the checklist below and a copy of Technical Specification ISO 22002-1 the delegated person should read the requirements in the relevant section of ISO 22002 and complete the form.

<table>
<thead>
<tr>
<th>ISO 22002 CONFORMANCE ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Construction and Layout of Buildings</td>
</tr>
<tr>
<td>ISO 22002 Requirements</td>
</tr>
<tr>
<td>4.1 General requirements</td>
</tr>
<tr>
<td>4.2 Environment</td>
</tr>
<tr>
<td>4.3 Locations of establishments</td>
</tr>
</tbody>
</table>

<p>| 5. Layout of Premises Workspace |
| ISO 22002 Requirements | Compliant | Comments |
|  | Yes | No |</p>
<table>
<thead>
<tr>
<th>16.3 Vehicles, conveyances and containers</th>
<th></th>
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<tbody>
<tr>
<td><strong>17. Product Information/Consumer Awareness</strong></td>
<td></td>
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</tr>
<tr>
<td>ISO 22002 Requirements</td>
<td>Compliant</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>17.1 Product information</td>
<td></td>
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<tr>
<td>17.2 Labelling of pre-packaged foods</td>
<td></td>
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<tr>
<td><strong>18. Food Defence, Biovigilance And Bioterrorism</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISO 22002 Requirements</td>
<td>Compliant</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>18.1 General requirements</td>
<td></td>
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<tr>
<td>18.2 Access controls</td>
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</tbody>
</table>
**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.

<table>
<thead>
<tr>
<th>FSSC 22000 Certification Scheme Additional Requirements</th>
<th>Compliant</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.5.1 Management of Services and Purchased Materials</strong> – in addition to 7.1.6 Control of externally provided processes, products or services</td>
<td></td>
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<tr>
<td>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)?</td>
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<tr>
<td>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?</td>
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<tr>
<td>Is there a policy for the procurement of animals, fish and seafood that are subject to control of prohibited substances?</td>
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<tr>
<td>Is there a review process for product specifications to ensure continued compliance with food safety, legal and customer requirements?</td>
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</tbody>
</table>

**2.5.2 Product Labelling** – in addition to 8.5.1.3 Characteristics of end products
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:

<table>
<thead>
<tr>
<th>Date</th>
<th>ISO/FSSC 22000 Clause</th>
<th>Details of Non-Conformance</th>
<th>Identified by:</th>
<th>Corrective Action Required</th>
<th>Responsibility</th>
<th>Target completion Date</th>
<th>Date Completed</th>
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