

Insert Company Logo

# Food Safety Management System Manual

## Document Control

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## Revision History

Version	Date	Author	Brief Description of Changes
1	Insert Revision Date	Insert Author	First Version

## 1. Scope

Write a paragraph here to clearly identify the scope of your system. Include the products, product categories, processes, and production sites in your system.

## 2. References

ISO 22000:2018 Food Safety Management Systems – Includes requirements for any organization in the food chain.

ISO/TS 22002-2 Prerequisite programs on food safety

List other references used in the development of your system.

## 3. Terms and definitions

List terms that you use and must be defined.

### Instructions for this Manual:

Use the ISO 22000 Standard and the appropriate ISO/TS 22002.

Replace the words **Insert Company Name** with your company name. Delete or remove any **Red text** (instructional). Review and adapt all text to your Food Safety Management System.

The headers are in the following Microsoft Word Styles associated with this document:

**Section Heading (followed by the tab to bring the line to the page edge)**

**Heading 2**

Body Text

*Heading 3*

Body Text

## 4. Context of the Organization

### 4.1 Understanding the organization and its context

**Insert Company Name** has identified relevant internal and external issues to our purpose. Such could impact our capacity to attain desired results in achieving an FSMS. We review and use information from these issues to our risk-based thinking and decision-making processes.

### 4.2 Understanding the needs and expectations of interested parties

**Insert Company Name** has identified interested third parties that are relevant to the FSMS and its requirements. We review, update, and use this information when reviewing and making decisions related to our FSMS.

### 4.3 Determining the scope of the food safety management system

We have considered the information from internal and external issues, and requirements of the interested third parties as we identified the scope of our FSMS. We have defined our scope to cover products, services, processes, and production sites included in the FSMS. The scope of our Food Safety Management System is:

**Insert your scope**

### 4.4 Food safety management system

**Insert Company Name's** Food Safety Management System ensures the provision of safe, quality products to our customers. The FSMS has been built and implemented based upon the principles and requirements in ISO 22000 and ISO/TS 22002-2. This system is maintained and updated per the ISO 22000 Certification scheme. The FSMS guarantees the identification, evaluation, and control of food safety hazards to prevent safety problems from happening.

Communication channels have been created for information concerning product safety issues. This includes information for the development, implementation, and updating of our FSMS. The system is evaluated and updated to ensure that activities are accurately reflected. This also adds the most recent information on food safety hazards into the system.

**Insert Company Name** controls all outsourced processes according to our FSMS.

## 5. Leadership

### 5.1 Leadership and commitment

The top management has involvement in the development and implementation of **Insert Company Name's** FSMS. It commits to maintaining and continually improving the FSMS' effectiveness. Top Management ensures that the organization communicates the importance of meeting requirements. This includes requirements of ISO 22000 and all regulatory, statutory, and customer requirements. Our Leadership Procedure defines and documents management's role in the FSMS.

## 5.2 Food Safety Policy

### 5.2.1 Establishing the food safety policy

Management has formulated the Food Safety Policy. It also established **Insert Company Name's** business objectives to support food safety.

**Insert Company Name's** food safety policy is:

**State the food safety policy or put it in its own document. You may make it an attachment to the management responsibility procedure. Make sure it is a controlled document and that approval by top management is clear. Provide proof that top management established it.**

### 5.2.2 Communicating the food safety policy

This policy is communicated, implemented, and maintained throughout the organization. Regular reviews guarantee the policy continues to be suitable for the organization.

## 5.3 Organizational roles, responsibilities and authorities

### 5.3.1 Responsibility and authority

The Organizational Chart, Job Descriptions, Procedures, and Work Instructions define and document system responsibilities and authorities for all FSMS activities to ensure the system's effective operation. All employees must report problems with the FSMS. Our Correction and Corrective Action Procedure specifies responsibility for initiating and recording actions.

**You may insert the organizational chart here. Reference it here if you choose to keep it somewhere else.**

### 5.3.2 Food safety team leader

**Insert Company Name** has designated a Food Safety Team Leader, who is documented on our organizational chart. He or she manages the food safety team, organizes work, and ensures all members have relevant training and education. The team leader ensures the updating and maintenance of the FSMS. The team leader reports to top management about the system's effectiveness and suitability.

## 6. Planning

### 6.1 Actions to address risks and opportunities

**Insert Company Name** considers the issues and requirements of interested parties in determining and addressing the risks and opportunities. This ensures an effective FSMS will obtain its intended results, as well as continue to improve.

**Insert Company Name** has planned and developed processes to provide safe products. Our FSMS documents these processes. All planned activities are done within the control of our FSMS. This ensures the effectiveness of activities and any changes to the activities.

### 6.2 Objectives of the Food Safety Management System and planning to achieve them

Objectives are established for the FSMS and support the food safety policy. They are communicated and implemented throughout the organization. They are also measured and monitored to inform management of the performance of the FSMS.

Planning for objectives includes identification of what will be done, the necessary resources, responsibilities, goals for completion, and evaluation of performance results.

### 6.3 Planning of changes

There are various ways to identify necessary changes to the FSMS. This may cover the management review or review of the HACCP plan. It may also come as the result of internal audits or corrective actions, as well as external information or other sources of information. Carry out and communicate changes in a planned manner.

## 7. Support

### 7.1 Resources

#### 7.1.1 General

**Insert Company Name** commits to the FSMS and provides the resources needed to maintain the effectiveness and make updates to the system. Resources include Human resources, Infrastructure, and Work Environment.

#### 7.1.2 People

**Insert Company Name** assigns qualified people to activities affecting food safety. Human Resources ensures that the person has the appropriate education, skills, training, and experience for their position. The top management designed qualified individuals to form the food safety team.

External experts are used when expertise is not available within **Insert Company Name**. Records are maintained to define an external expert's authority and responsibility.

#### 7.1.3 Infrastructure

Infrastructure is recognized as an integral part of food safety. **Insert Company Name** provides the resources needed to establish and maintain our infrastructure needed to comply with the requirements of our FSMS and the ISO 22000 Standard.

#### 7.1.4 Work environment

Work Environment is also recognized to be an important part of food safety. **Insert Company Name** provides the relevant resources to maintain a work environment that lets us comply with the requirements of our FSMS and the ISO 22000 Standard.

#### 7.1.5 Externally developed elements of the food safety management system

If **Insert Company Name** uses externally developed elements of the FSMS, the management ensures that they are in conformance with the standard's requirements, apply to our products, processes, and sites. The food safety team adapts the elements to our own processes and products. As part of the FSMS, they are implemented, maintained, and retained as documented information.

#### 7.1.6 Control of externally provided processes, products or services

For products or services provided by external parties, **Insert Company Name** manages them according to the procedures for Management of Services and Management of Supplied Materials. This ensures that the products or services do not impact the ability to meet the requirements of the FSMS.

## 7.2 Competence

**Insert Company Name** has identified the competencies needed for all personnel in Job Descriptions. The procedure, Competence, Awareness, and Training defines the process for qualification and training of personnel to fulfill all requirements. The procedure includes a process for evaluating the implementation and effectiveness of all of the training and qualification activities.

## 7.3 Awareness

Personnel is trained on the food safety policy, as well as on the importance of their activities on the safety of the products. Training covers their responsibility to report problems with the FSMS, and on the requirements for effective communication. Maintain records of training.

## 7.4 Communication

### 7.4.1 General

**Insert Company Name** has implemented internal and external communication systems for information relating to the FSMS. These include methods to identify what must be communicated, when and how to communicate, and who is responsible for various communications. Responsibilities are documented in procedures and work instructions as well as in job descriptions.

### 7.4.2 External communication

**Insert Company Name** ensures effective communication throughout the food chain by communicating with suppliers, contractors, customers, consumers, statutory and regulatory authorities. **Insert Company Name** also communicates with others that have an impact on or will be affected by the status of our FSMS. Our communication gives information about our product. This includes food safety issues and hazards that must be controlled by others in the food chain.

Our Competence, Awareness and Communication Procedure defines responsibilities and authorities. It also documents our system for making safety requirements available and providing information on food safety. It includes information obtained for system updating and management review.

### 7.4.3 Internal communication

Internal communication processes, documented in our Communication Procedure, have been implemented to effectively communicate food safety issues within **Insert Company Name**. The process ensures the Food Safety Team's awareness about changes that have an impact on the FSMS. The team must include information obtained in Management Review and update the FSMS.

## 7.5 Documented information

### 7.5.1 General

Our FSMS is documented in this FSMS Manual, Procedures, Work Instructions, and Records. These include documented statements of our Food Safety Policy and Objectives.

### 7.5.2 Creating and updating

Identify, review, and approve documents before release for use.

### 7.5.3 Control of documented information

**Insert Company Name's** document control process ensures that all of the FSMS documents are controlled. All proposed changes are reviewed for their effect on food safety and the FSMS. They are also approved before implementation. This process is documented in our Control of Documents and Records Procedure.

The procedure defines document control including document approval, review, update and re-approval of documents, identification of changes and current revision, availability of current documents at the point of use, legibility, and identification of documents, control of documents of external origin and prevention of unintended use of obsolete documents.

This process addresses the steps in establishing and preserving our records to show conformance to our FSMS requirements, as well as regulatory requirements. The procedure defines identification, storage, protection, retrieval, retention time, and disposition methods.

## 8. Operation

### 8.1 Operational planning and control

**Insert Company Name** has planned for and developed processes to provide safe products. These processes are documented as our FSMS. All planned activities are done within the control of our FSMS. This ensures the effectiveness of activities and any changes to the activities.

### 8.2 Prerequisite programs (PRPs)

Prerequisite programs provide a foundation for our HACCP program. PRPs help control the risk of introducing food safety hazards. The PRPs have been implemented according to our Prerequisite Program procedure.

The procedure documents requirements for the PRPs and defines appropriate programs for **Insert Company Name's** food safety needs, size, products, as well as applicable statutory and regulatory requirements. The food safety team approved the PRPs before the implementation across the entire production system.

**Insert Company Name** considers all appropriate information in the establishment of PRPs. This includes statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) **principles, and other applicable standards. Personalize this list to include items applicable to your organization. Do not include those that do not and will not apply to you.**

The procedure identifies the specific information that must be considered when establishing PRPs. This also covers the process for verifications and modifications, how the activities are managed, and what records must be maintained.

### 8.3 Traceability system

Our traceability system lets us trace the product from raw materials to delivery. Each product lot can be matched to batches of raw material, processing, and delivery records. The system identifies incoming material from suppliers and the end product's distribution. We maintain records for system assessment, handling of unsafe products, and product recall. The traceability system is documented in the procedure Traceability.

## 8.4 Emergency preparedness and response

Our Emergency Preparedness Procedure has been established to manage potential emergencies or accidents that could impact food safety.

## 8.5 Hazard control

### 8.5.1 Preliminary steps to enable hazard analysis

**Insert Company Name** uses a Hazard Analysis Critical Control Point (HACCP) system to ensure product safety. Information needed to conduct this analysis is collected, maintained, updated and documented according to our Information for Hazard Analysis Procedure.

Materials that come in contact with the product or are used in the product, such as ingredients or raw materials, are described to allow hazard analysis. These are documented and updated descriptions that relate to statutory and regulatory food safety requirements.

**Insert Company Name** documents descriptions of end products to allow hazard analysis. The descriptions are kept up to date and all related statutory and regulatory food safety requirements are identified.

The intended use of each end product is defined, along with possible misuse or mishandling of the product. Users of the product are identified, along with any groups especially vulnerable to a food safety hazard.

Flow diagrams serve as a basis for evaluating food safety hazards. The preparation each product or process category in the FSMS. The Food Safety Team does on-site check to verify the accuracy of the diagrams.

The flow diagrams identify the current control measures, process parameters, or procedures that influence food safety and relevant external requirements.

### 8.5.2 Hazard Analysis

The Food Safety Team conducts the Hazard Analysis to determine what hazards to control, to what degree, and in what combination they are needed to ensure the product's safety. The process is documented in the HACCP procedure.

For each type of product and process, the Hazard Analysis identifies the expected safety hazards and the step where the hazard is introduced. This is based on the collected preliminary information, experience, external information, and information from the food chain.

During the analysis, we consider the steps and links in the food chain preceding and following the operations. This also applies to equipment, services, and surroundings.

The analysis considers statutory and regulatory requirements, customer requirements, the intended use, and other relevant data. If possible, it determines an acceptable level of the food safety hazard in the end product.

Each identified food safety hazard is assessed to determine if elimination or reduction is necessary for a safe product, and if it must be controlled to meet acceptable levels. The team evaluates the hazards based on the severity and likelihood of adverse health effects.

The team identifies appropriate preventive controls to avoid, eliminate, or reduce the food safety hazards to the defined acceptable levels. Existing control measures are reviewed for effectiveness against the safety hazard.

### 8.5.3 Validation of control measure and combinations of control measures

Before implementing control measures, and after any change in the HACCP plan, the effectiveness of control measures is validated. Validation must show that the control measures can achieve and ensure acceptable control of the hazard they are designed to protect against.

Modifications are made and control measures reassessed if validation is unsuccessful. **Insert Company Name's** validation process, requirements, and responsibilities are documented in the HACCP Procedure.

### 8.5.4 Hazard control plan (HACCP/OPRP plan)

**Insert Company Name** has established and documented a HACCP plan. The plan identifies the hazards to be controlled at each control point, the control measures used, critical limits, the monitoring procedures, the corrections, and corrective actions to be taken if limits are exceeded. The HACCP procedure documents the responsibilities, authorities, and records relating to the HACCP Plan.

Determine a critical limit for each monitoring point. The rationale for that limit is documented. The critical limit ensures that an acceptable level of the hazard is not exceeded.

A monitoring system is designed and documented for each CCP to show that the CCP is in control. This system includes procedures and work instructions. It also covers records defining the measurements or observations, timeframes, monitoring devices, calibration methods, frequency, and responsibilities and authorities.

The monitoring systems identify when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

**Insert Company Name's** HACCP Plan identifies what corrections or corrective actions must be done when results exceed critical limits. The cause of the nonconformity is identified. The out of control parameter is brought back under control. Preventive action ensures that the nonconformity does not happen again.

The Nonconforming Product procedure details the procedure for handling of potentially unsafe products, so the products are not released until they are evaluated.

## 8.6 Updating the information specifying the PRPs and hazard control plan

**Insert Company Name** updates process information as necessary. This includes product characteristics, intended use, flow diagrams, process steps, and control measures. The HACCP plan and procedures specifying PRPs are amended as needed.

## 8.7 Control of monitoring and measuring

**Insert Company Name** follows the Control of Monitoring and Measuring Procedure to ensure that the monitoring and measuring methods and equipment are adequate to meet the requirements. The procedure outlines the process used for calibration of measuring equipment if the equipment is found to be nonconforming. The capability of software used for measuring and monitoring is confirmed according to the procedure and reconfirmed as necessary.

## 8.8 Verification related to PRPs and the hazard control plan

### 8.8.1 Verification

Carry out verification activities according to the HACCP plan. The food safety team reviews the results.

### 8.8.2 Analysis of results of verification activities

The food safety team also reviews the results of verifications such as internal and external audits. It ensures that overall system performance meets planned arrangements and management system requirements. The review is also used to identify the need to update or improve the FSMS. It identifies trends indicating higher incidents of potentially unsafe products. The review also establishes information for planning the internal audit program, as well as show evidence of effective corrections and corrective action.

We document the results of the analysis, which also serve as an input to management review.

## 8.9 Control of product and process nonconformities

### 8.9.2 Corrections

Products are identified and controlled whenever preventive control parameters are not met, CCPs are exceeded, or there is a loss of control of operational PRPs. The correction process is detailed in procedure Hazard Analysis and HACCP Plan. It includes the identification and assessment of affected end products and reviews of the corrections. Products manufactured under conditions where critical limits have been exceeded are handled according to this procedure. They are evaluated, and evaluations are subsequently recorded. The responsible person approves all corrections and records information on the nonconformance's cause and consequence for traceability.

### 8.9.3 Corrective actions

The food safety manager reviews data from the operational PRPs and CCPs to start corrective actions. Corrective actions are done if critical limits are exceeded or when there is nonconformance with operational PRPs.

### 8.9.4 Handling of potentially unsafe products

The handling of potentially unsafe products is under procedure. This procedure defines the necessary actions that can prevent any nonconforming product from entering the food chain, unless the reduction of food safety to acceptable levels has been identified. In other cases, the product meets acceptable levels despite the nonconformity.

Products that may have been affected by a nonconformity are held under control until they have been evaluated. Initiate a recall if any product has left control of **Insert Company Name**.

A product that is affected by nonconformities will only be released as safe after the evaluation's completion. The evaluation must show evidence other than monitoring demonstrates that the control has been effective. The combined effect of control measures for that product complies with performance intended. It must show results of sampling, analysis, or other verification that the product complies with acceptable levels for the hazard.

Handling of product that is not acceptable for release is in accordance with the Control of Nonconforming Product procedure. The procedure defines the process for reprocessing or further processing to ensure the elimination or reduction of nonconformance to acceptable levels. It also identifies methods for the destruction or disposal of the product.

### 8.9.5 Withdrawal/recall

**Insert Company Name** has a documented procedure for withdrawing an end product. This is used whenever a product is identified as unsafe. (Control of Nonconforming Product). This procedure defines responsibility for and the process for executing the withdrawal. It covers notification of relevant parties,

handling of withdrawn products and affected lots of products in stock, and the sequence of actions to be taken.

Secure withdrawn product until it is destroyed or dispositioned according to the procedure. Record the cause, extent, and result of withdrawals. Report these to the management. Verify the effectiveness of the withdrawal process.

## 9. Performance evaluation

### 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

The FSMS documentation identifies the need for monitoring, measurement, analysis, and evaluation. The documentation defines what needs monitoring and measuring, the methods, frequency and the analysis, and evaluation of results. Document, maintain, and use the results to evaluate the effectiveness of the performance of the FSMS.

#### 9.1.2 Analysis and evaluation.

A designed individual or the Food Safety Team analyzes data from the monitoring and measuring. The team evaluates the results of verification activities for PRPs, the HACCP Plan, and internal and external audits. The team determines if the system's performance meets the objectives and identifies the need for improving or updating the system.

The team looks at trends that may show a higher incident of potentially unsafe product or process failures. They use this information for planning the internal audit program and to evaluate the effectiveness of corrections and corrective actions. Maintain this information as documented information. Report this to the top management as an input to management review.

### 9.2 Internal audit

Perform internal audits to verify the effectiveness of the FSMS. Audits determine whether the FSMS conforms to requirements of ISO 22000, **Insert Company Name's** FSMS requirements, and planned arrangements. Verify effective implementation and updating.

An Internal Audit procedure describes the audit process, responsibilities, and authorities. The audit program considers the importance of processes and areas to be audited. The procedure defines the criteria, scope, frequency, and methods used for the audit process. Methods used and selection of auditors ensure impartiality and objectivity.

Management ensures the execution of timely corrective actions and follow-up on any nonconformances identified in their area. Use information from the audits to update the FSMS, as well as maintain and improve the system's effectiveness.

### 9.3 Management review

Conduct a Management Review quarterly to review the effectiveness, adequacy, and continuing suitability of our FSMS. Management evaluates the food safety policy, opportunities for improvement, and the need for changes to the FSMS. The process for management review includes review inputs, review outputs, responsibilities, and authorities. These are documented in our Management Responsibility Procedure.

## **10. Improvement**

### **10.1 Nonconformity and corrective action**

The Corrective Action and Improvement Procedure specifies appropriate actions to identify and eliminate the cause of nonconformities. It aims to prevent reoccurrence by bringing processes back into control. The corrective action process includes: a review of nonconformities and trends in monitoring results, determining causes, evaluating the need for action, implementing actions, recording results, and reviewing corrective action to ensure effectiveness.

### **10.2 Continual improvement**

Use the elements of the FSMS to achieve the continual improvement of the FSMS. This includes management review, internal audits, evaluation of verification results, analysis of results of verification activities, validation of control measure combinations, corrective actions, and FSMS updating.

### **10.3 Update of the food safety management system**

The food safety team evaluates the FSMS every quarter. The team determines if it is necessary to review the hazard analysis, the operational PRPs, and the HACCP plan. The Food Safety Team does the evaluation. Record all system updates and report these as input to management review.