IMPLEMENTATION OF ISO 22000:2018 FOOD SAFETY MANAGEMENT SYSTEM

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Introduction

The International Organization for Standardization (ISO) was established in 1947 and ISO is an independent, non - governmental international organization with a membership of 164 national standard bodies. ISO employs a system of technical committees and working groups to develop international standards. ISO 22000 is an international standard that specifies requirements for a food safety management system where an organization in the food chain needs to demonstrate compliance with food safety requirements. The adoption of a food safety management system (FSMS) is a strategic decision for an organization that can help to improve its overall performance in food safety.

ISO 22000 is the food safety management system that can be easily applicable to any organization in the food chain. ISO 22000 was initially developed on September 1st 2005 by the ISO/TC 34/SC 17 as the first truly international FSMS standard. Food safety hazards can occur at any stage in the food chain making adequate control throughout the food chain essential. By combining PDCA and risk-based thinking to manage business risk with HACCP to identify, prevent and control food safety hazards, ISO 22000 helps organizations to reduce exposure to risk and improve safety. ISO 22000 is aligned with the requirements of ISO 9001 in order to enhance the compatibility of the two standards and to ease their joint or integrated implementation.

The potential benefits to an organization of implementing a FSMS are:

- ability to consistently provide safe foods and products and services that meet customer and applicable statutory and regulatory requirements;
- addressing risks associated with its objectives;
- the ability to demonstrate conformity to specified FSMS requirements.

ISO 22000 combines generally recognized key elements to ensure food safety along the food chain:

- Interactive communication

- HACCP principles
- System management
- Prerequisite programmes

Covers the principles that are common to ISO management system standards. The management principles are customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, relationship management.

An ISO 22000 food safety management system (FSMS) can be implemented in small, medium and large-sized food organizations from all aspects of the food chain:

- Food and ingredient manufacturers
- Retailers
- Wholesalers
- Agricultural producers
- Transport, logistics and storage providers
- Packers
- Equipment and packaging manufacturers
- Caterers

Key requirements of ISO 22000

Clause 1: Scope

This clause details the scope of the international standard. This includes requirements about planning, implementation, maintaining and updating an FSMS as well as effective communications.

Clause 2: Normative references

There are no normative references within the standard.

Clause 3: Terms and definitions - 45 definitions have been elucidated for proper understanding and implementation.

Clause 4: Context of the organization

4.1 Understanding the organization and its context - determine external and internal issues that are relevant

4.2 Understanding the needs and expectations of interested parties – as per statutory, regulatory and customer requirements

4.3 Determining the scope of the food safety management system – determine scope based on product, services and processes as per external and internal issues & requirements

4.4 Food safety management system - establish, implement, maintain and continually improve the FSMS in accordance with the requirements of the standard.

Clause 5: Leadership

5.1 Leadership and commitment - Top management shall demonstrate leadership and commitment with respect to the FSMS. Ensure a food safety policy and objectives, integration of FSMS requirements with business

5.2 Policy - establish, implement and maintain a food safety policy appropriate to the purpose and context of organization which satisfy the requirements, communicate the policy

5.3 Organizational roles, responsibilities and authorities –

5.3.1 Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

5.3.2 The food safety team leader shall be responsible for ensuring the FSMS is established, implemented, maintained and updated, ensure relevant training and competencies for food safety team

Clause 6: Planning

Organization plans actions to address both the risks and opportunities identified in Clause 4. It focuses on the development and use of a planning process, rather than a procedure to address both a range of factors and the risk associated with such factors.

6.1 Actions to address risks and opportunities

6.1.1 determine the risks and opportunities of FSMS that need to be addressed

6.1.2 The organization shall plan actions to address these risks and opportunities of FSMS

6.1.3 Consider requirements and impacts when selecting FSMS actions

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

6.2.1 The organization shall establish objectives for the FSMS

The objectives of the FSMS shall:

a) be consistent with the food safety policy;

b) be measurable (if practicable);

c) take into account applicable food safety requirements, including statutory, regulatory and customer requirements;

d) be monitored and verified;

e) be communicated;

f) be maintained and updated as appropriate

6.2.2 Plan how to achieve your organization's FSMS objectives

6.3 Planning of changes

Clause 7: Support

This clause is all about the execution of the plans and processes that will enable your organization to successfully complete their FSMS responsibilities. This is a very powerful requirement covering all management system resource needs.

7.1 Resources

7.1.1 General - The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, update and continual improvement of the FSMS.

7.1.2 People – competence of persons necessary to operate and maintain an effective FSMS

7.1.3 Infrastructure - provide the resources the FSMS need to have

7.1.4 Work environment - provide and maintain the resources for the establishment,

management and maintenance of the work environment necessary

7.1.5 Externally developed elements of the food safety management system - organization establishes, maintains, updates and continually improves its FSMS by using externally

developed elements of a FSMS, including PRPs, the hazard analysis and the hazard control plan ensure conformance with the requirements

7.1.6 Control of externally provided processes, products or services – apply criteria for evaluation, selection and monitoring of performance

7.2 Competence - ensure that these persons, including the food safety team and those responsible for the operation of the hazard control plan, are competent on the basis of appropriate education, training and/or experience

7.3 Awareness - The organization shall ensure that all relevant persons doing work shall be aware of:

a) the food safety policy;

b) the objectives of the FSMS

c) Individual contribution

d) Implications of non conforming the requirements

7.4 Communication - Support your FSMS by controlling relevant communications

7.4.1 General - Support FSMS by establishing communication systems

7.4.2 External communication **-** Support your FSMS by facilitating external communication

7.4.3 Internal communication - Support your FSMS by encouraging internal communication

7.5 Documented information - documented information of the FSMS and food safety requirements required by statutory, regulatory authorities and customers. Creating, updating and control of documents depending upon product, process and services

7.5.1 General

7.5.2 Creating and updating

7.5.3 Control of documented information

Clause 8: Operation

8.1 Operational planning and control - The organization shall plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products, and to implement the actions determined.

8.2 Prerequisite programmes (PRPs) - to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment – appropriate to the size, type and nature of the products handled

8.2.1 Make sure that prerequisite programmes are developed

8.2.2 Make sure that prerequisite programmes are implemented

8.2.3 Make sure that prerequisite programmes are acceptable

8.2.4 Make sure that prerequisite programmes are suitable

8.3 Traceability system - uniquely identify incoming material from the suppliers and the first stage of the distribution route of the end product as per requirements

8.4 Emergency preparedness and response - ensure procedures are in place to respond to potential emergency situations or incidents

8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.1 General - preliminary documented information shall be collected, maintained and updated by the food safety team related to product, process and equipment and also as per requirements

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials – conduct hazard analysis on

a) biological, chemical and physical characteristics;

b) composition of formulated ingredients, including additives and processing aids;

c) source (e.g. animal, mineral or vegetable);

d) place of origin (provenance);

e) method of production;

f) method of packaging and delivery;

g) storage conditions and shelf life;

h) preparation and/or handling before use or processing;

i) acceptance criteria related to food safety or specifications of purchased materials and ingredients appropriate to their intended use.

8.5.1.3 Characteristics of end products

    a) product name or similar identification; b) composition; c) biological, chemical and physical characteristics relevant for food safety; d) intended shelf life and storage conditions; e) packaging; f) labelling relating to food safety and/or instructions for handling, preparation and intended use; g) method(s) of distribution and delivery.

8.5.1.4 Intended use - groups of consumers/users and vulnerable group

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.1 Preparation of the flow diagrams

8.5.1.5.2 On-site confirmation of flow diagrams

8.5.1.5.3 Description of processes and process environment - existing PRPs, process parameters, control measures and follow requirements

8.5.2 Hazard analysis - food safety team shall conduct a hazard analysis, based on the preliminary information, This shall ensure food safety and, where appropriate, a combination of control measures shall be used.

8.5.2.2 Hazard identification and determination of acceptable levels

a) the preliminary information and data collected in accordance with 8.5.1;

b) experience;

c) internal and external information including, to the extent possible, epidemiological, scientific and other historical data;

d) information from the food chain on food safety hazards related to the safety of the end products, intermediate products and the food at the time of consumption;

e) statutory, regulatory and customer requirements.

8.5.2.2.2 The organization shall identify step(s) (eg. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist.

8.5.2.2.3 The organization shall determine the acceptable level in the end product of each food safety Hazard

8.5.2.3 Hazard assessment – likelihood of occurrence prior to control and severity of adverse health effects

8.5.2.4 Selection and categorization of control measure(s)

8.5.2.4.1The organization shall categorize the selected identified control measure(s) to be managed as OPRP(s) or at CCPs

8.5.2.4.2 for each control measure establish measurable critical limits and/or measurable/observable action criteria

8.5.3 Validation of control measure(s) and combinations of control measures - validation shall be done prior to implementation of control measure

8.5.4 Hazard control plan (HACCP/OPRP plan) establish, implement and maintain a hazard control plan

8.5.4.1 General

a) food safety hazard(s) to be controlled at the CCP or by the OPRP;

b) critical limit(s) at CCP or action criteria for OPRP;

c) monitoring procedure(s);

d) correction(s) to be made if critical limits or action criteria are not met;

e) responsibilities and authorities;

f) records of monitoring.

8.5.4.2 Determination of critical limits and action criteria - Critical limits at CCPs shall be measurable. Action criteria for OPRPs shall be measurable or observable

8.5.4.3 Monitoring systems at CCPs and for OPRP – monitoring of failure of control measure relative to critical limit and action criteria

a) measurements or observations that provide results within an adequate time frame;

b) monitoring methods or devices used;

c) applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations

d) monitoring frequency;

e) monitoring results;

f) responsibility and authority related to monitoring

g) responsibility and authority related to evaluation of monitoring results.

At each CCP, the monitoring method and frequency shall be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product. For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.

8.5.4.4 Actions when critical limits or action criteria are not met - specify corrective actions and ensure

a) the potentially unsafe products are not released

b) the cause of nonconformity is identified;

c) the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria;

d) recurrence is prevented.

8.5.4.5 Implementation of the hazard control plan

8.6 Updating the information specifying the PRPs and the hazard control plan update the following information, if necessary:

a) characteristics of raw materials, ingredients and product-contact materials;

b) characteristics of end products;

c) intended use;

d) flow diagrams and descriptions of processes and process environment

8.7 Control of monitoring and measuring

The monitoring and measuring equipment used shall be:

a) calibrated or verified at specified intervals prior to use;

b) adjusted or re-adjusted as necessary;

c) identified to enable the calibration status to be determined;

d) safeguarded from adjustments that would invalidate the measurement results;

e) protected from damage and deterioration.

8.8 Verification related to PRPs and the hazard control plan

8.8.1 Verification

The verification activities shall confirm that:

a) the PRP(s) are implemented and effective;

b) the hazard control plan is implemented and effective;

c) hazard levels are within identified acceptable levels;

d) input to the hazard analysis is updated;

e) other actions determined by the organization are implemented and effective.

8.8.2 Analysis of results of verification activities

8.9 Control of product and process nonconformities

8.9.1 General - The organization shall ensure that data derived from the monitoring of OPRPs and at CCPs are evaluated by designated persons who are competent and have the authority to initiate corrections and corrective actions.

8.9.2 Corrections

8.9.2.1 The organization shall ensure that when critical limits at CCP(s) and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release.

8.9.2.2 When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products

8.9.2.3 Where action criteria for an OPRP are not met, the following shall be carried out:

a) determination of the consequences of that failure with respect to food safety;

b) determination of the cause(s) of failure;

c) identification of the affected products and handling in accordance with 8.9.4

8.9.2.4 Documented information shall be retained to describe corrections made on nonconforming products and processes, including:

a) the nature of the nonconformity;

b) the cause(s) of the failure;

c) the consequences as a result of the nonconformity

8.9.3 Corrective actions – when critical limit or action criteria are not met

a) reviewing nonconformities identified by customer or regulatory

b) reviewing trends in monitoring results that can indicate loss of control;

c) determining the cause(s) of nonconformities;

d) determining and implementing actions to ensure that nonconformities do not recur;

e) documenting the results of corrective actions taken;

f) verifying corrective actions taken to ensure that they are effective. The organization shall retain documented information on all corrective actions.

8.9.4 Handling of potentially unsafe products

8.9.4.1 General - The organization shall take action(s) to prevent potentially unsafe products from entering the food chain

8.9.4.2 Evaluation for release -   Each lot of products affected by the nonconformity shall be evaluated. Products affected by failure to remain within critical limits at CCPs shall not be released, but shall be disposed

8.9.4.3 Disposition of nonconforming products

a) reprocessed or further processed within or outside the organization to ensure that the food safety hazard is reduced to acceptable levels; or

b) redirected for other use as long as food safety in the food chain is not affected; or

c) destroyed and/or disposed as waste.

8.9.5 Withdrawal/recall - The organization shall be able to ensure the timely withdrawal/recall of lots of end products that have been identified as potentially unsafe, by appointing competent person(s)

Clause 9: Performance evaluation

This is all about measuring and evaluating your food safety management system to ensure that it's effective and helps you to continually improve.

9.1 Monitoring, measurement, analysis and evaluation - analyse and evaluate appropriate data and information arising from monitoring, measurement, verification activities

9.2 Internal audit - conduct internal audits at planned intervals, plan, establish, implement and maintain (an) audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting,

9.3 Management review - Top management shall review the organization's FSMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the FSMS, including changes in the organization and its context

c) information on the performance and the effectiveness of the FSMS includes

1)Results of system updating

2) monitoring and measurement results;

3) analysis of the results of verification activities

4) nonconformities and corrective actions;

5) audit results (internal and external);

6) inspections (e.g. regulatory, customer);

7) the performance of external providers;

8) the review of risks and opportunities and of the effectiveness of actions taken to address

9) the extent to which objectives of the FSMS have been met;

d) the adequacy of resources;

e) any emergency situation, incident or withdrawal/recall

f) relevant information obtained through external and internal communication,

g) opportunities for continual improvement.

Clause 10: Improvement

This clause requires organizations to determine and identify opportunities for continual improvement of the management system.

10.1 Nonconformity and corrective action - When a nonconformity occurs, the organization shall react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences

10.2 Continual improvement - The organization shall continually improve the suitability, adequacy and effectiveness of the FSMS.

10.3 Update of the food safety management system - Top management shall ensure that the FSMS is continually updated – based on external and internal inputs, verification, management review etc.

Reference

- ISO, 2018. ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain. Second edition, International Organization for Standardization, Geneva, Switzerland.

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