



Chapter 14

Implementation of ISO 22000:2018 Food Safety Management System

Laly S.J.

Quality Assurance and Management Division
ICAR-Central Institute of Fisheries Technology, Cochin
Email: lalyjawahar@gmail.com

ISO 22000:2018 is the latest global food safety management system (FSMS). This standard replaces the old ISO 22000:2005. ISO 22000:2018 was published in 19 June 2018. The aim of the standard is to harmonize the requirements for food safety management on a global level. The ISO 22000:2018 international standard enables organizations to control food safety hazards along the food chain in order to ensure that food is safe at the time of consumption. ISO 22000:2018 applies to all organizations participating in the food chain, regardless of type, size and complexity. The standard contributes to ensure food safety throughout the whole food chain farm-to-table.

ISO (International Organization for Standardization) is a non-governmental organization (NGO) established in 1947. The head quarter is in Geneva, Switzerland. It has a membership of around 165 national standards institutes from countries in all regions of the world. ISO 22000 was developed by a working group (WG) under ISO Technical Committee 34 (Food Products). This working group evolved into ISO sub-committee (SC 17). This subcommittee is responsible for the management of the ISO 22000 family of standards.

Due to the ever growing global population and raising demand for food to meet the requirements, made food safety a very important aspect. In the manufacturing process it is vital to ensure that the products delivered to consumers do not interfere with the consumers' health adversely. If the production system fails to comply with the food safety regulations, that will lead to the transmission of foodborne illness.

ISO 22000

ISO 22000 is a global standard for Food Safety Management Systems (FSMS). It is designed to enable organizations to control food safety hazards along the food chain. The standard applies to all types and sizes of organizations participating in the food supply chain. ISO 22000 (Food safety management systems -- Requirements for any organization in the food chain) describes the requirements for a food safety management system. The standard is utilized with ISO 22002-1 (Prerequisite programmes on food safety - Part 1: Food manufacturing) to form the technical basis for a Global Food Safety Initiative (GFSI) recognized audit scheme known as FSSC 22000 ISO 22000:2018 is having high level structure

with a different approach to understand risk i.e. It is having a risk based approach. As a result of the high-level structure, the clauses of the standard are largely changed compared to the previous version – ISO 22000:2005.

Food Supply chain:

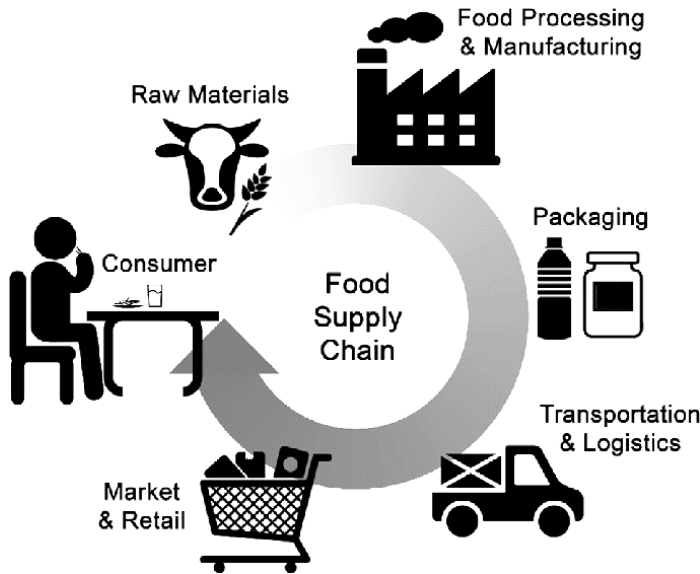


Fig. 1. Food Supply Chain

Food supply chain or food system refers to the processes that describe how food from a farm ends up on our tables. The processes include production, processing, distribution, consumption and disposal. Every step of the supply chain requires human and/or natural resources. In the food supply chain, food moves from producer to consumer via the processes of production, processing, distribution, retailing and consumption; At the same time, money that consumers pay for food moves from consumers to producers in the reverse process.

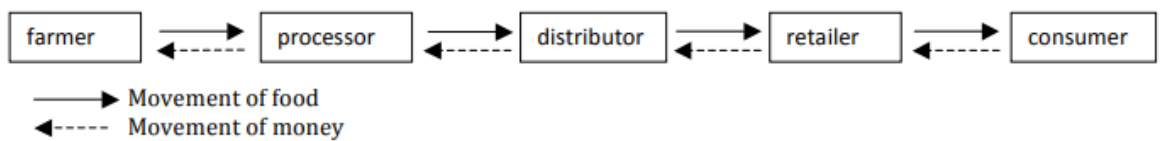


Fig.2.Movements of food and money in a simple food supply chain

According to World Health Organization reports, about 2 million deaths occur every year from contaminated food or drinking water. Around 600 million cases are caused by 22 different enteric diseases (disease caused by intestinal infection) and among that about 52000 deaths are caused by enteric disease caused by *Salmonella typhi*. Over 40% people suffering from enteric diseases caused by consumption of contaminated food were children under the age of 5 years.



ISO 22000:2018 Food Safety Management System (FSMS)

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. The potential benefits to an organization of implementing a FSMS based on this document are:

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

ISO 22000:2018 employs the process approach which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. This process approach enables an organization to plan its processes and their interactions. The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on. Risk-based thinking enables an organization to determine the factors that could cause its processes and its FSMS to deviate from the planned results, and to put in place controls to prevent or minimize adverse effects.

ISO 22000:2018, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

“NOTES” provide guidance in understanding or clarifying the requirements in this document.

FSMS principles

Food safety is related to the presence of food safety hazards at the time of consumption (intake by the consumer). Food safety hazards can occur at any stage of the food chain. Therefore, adequate control throughout the food chain is essential. Food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a FSMS that combines the following generally recognized key elements:

- interactive communication;
- system management;
- prerequisite programmes;
- hazard analysis and critical control point (HACCP) principles.



In addition, ISO 22000:2018 is based on 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.

Process approach

ISO 22000:2018 adopts a process approach when developing and implementing a FSMS and improving its effectiveness to enhance production of safe products and services while meeting applicable requirements. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the food safety policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle, with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results. The recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the food chain.

Plan-Do-Check-Act cycle

The PDCA cycle can be described briefly as follows:

Plan: establish the objectives of the system and its processes, provide the resources needed to deliver the results, and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where relevant) measure processes and the resulting products and services, analyse and evaluate information and data from monitoring, measuring and verification activities, and report the results;

Act: take actions to improve performance, as necessary.

The process approach uses the concept of the PDCA cycle at two levels. The first covers the overall frame of the FSMS (Clause 4 -7 and Clause 9 - 10). The other level (operational planning and control) covers the operational processes within the food safety system as



described in Clause 8. Communication between the two levels is therefore essential. So, the Plan-Do- Check- Act (PDCA) cycle of ISO 22000:2018 is having 2 separate cycles working together to handle management system and principles of Hazard Analysis and Critical Control Point (HACCP) respectively. The operation process, clearly deals with key points -Critical Control Points(CCPs), Operational Pre-requisite Programmes (OPRPs) and Pre-requisite Programmes (PRPs).

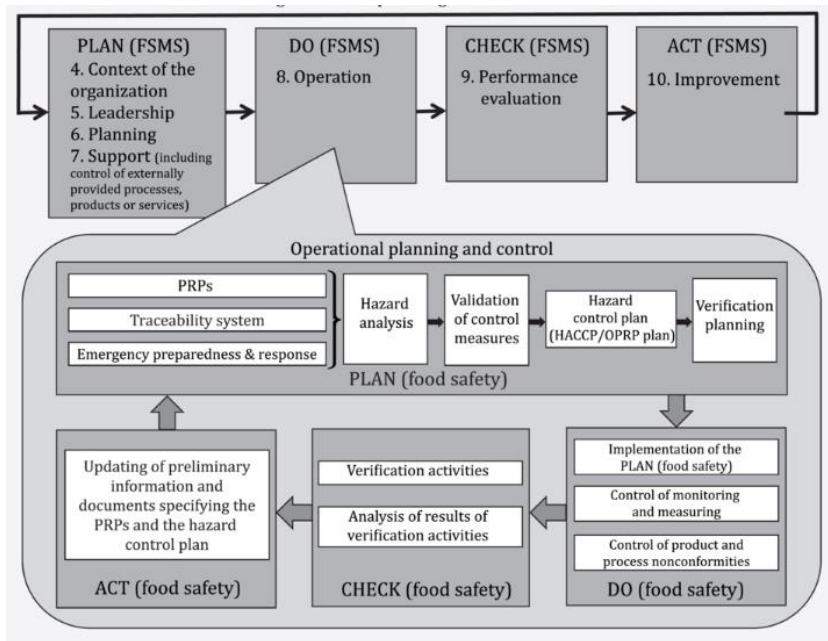


Fig Organizational planning and control of ISO 22000:2018
(Source: ISO 22000:2018- Food safety management systems)

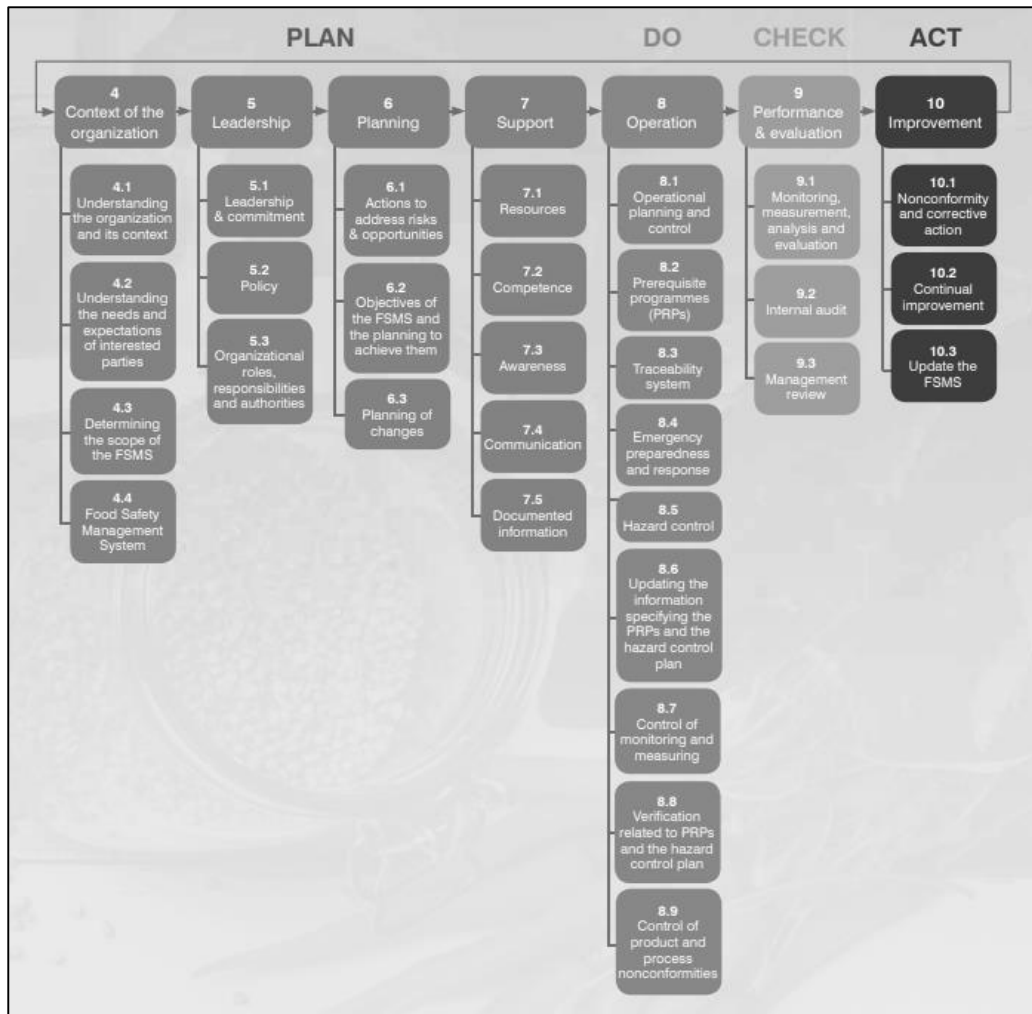


Fig.3. PDCA cycle of ISO22000:2018

(source: NQA-ISO-22000-

Implementation-Guide)

Risk-based thinking

Risk-based thinking is essential for achieving an effective FSMS. In ISO 22000:2018, risk-based thinking is addressed on two levels, organizational and operational, which is consistent with the process approach.

Organizational risk management:

Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. In the context of organizational risk management, a positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities. Addressing risks establishes a basis for increasing the effectiveness of the FSMS, achieving improved results and preventing negative effects.

Hazard analysis — Operational processes:

The concept of risk-based thinking based on the HACCP principles at the operational level is implicit in ISO22000:2018. The subsequent steps in HACCP can be considered as the

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necessary measures to prevent hazards or reduce hazards to acceptable levels to ensure food is safe at the time of consumption. Decisions taken in the application of HACCP should be based on science, free from bias and documented. The documentation should include any key assumptions in the decision-making process.

Relationship with other management system standards:

ISO 22000:2018 has been developed within the ISO high level structure (HLS). The objective of the HLS is to improve alignment between ISO management system standards. It enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its FSMS approach with the requirements of other management systems and supporting standards. ISO 22000:2018 is the core principle and framework for FSMSs and sets out the specific FSMS requirements for organizations throughout the food chain. Other guidance related to food safety, specifications and/or requirements specific to food sectors can be used together with this framework.

In addition, ISO has developed a family of associated documents. These include documents for:

- prerequisite programmes (ISO/TS 22002 series) for specific sectors of the food chain;
- requirements for auditing and certification bodies;
- traceability.

Key changes in ISO 22000:2018

These are some of the key changes to consider:

Changes due to the adoption of HLS

Clause no. 4- Business Context and interested parties.

4.1 - for systematic determination and monitoring of the business context

4.2 - introduces demands to identify and understand factors that can (potentially) affect the ability of Management System to reach the intended results.

Clause no. 5 - Strengthened emphasis on leadership and management commitment:

5.1- new demands to actively engage and take accountability for the effectiveness of the management system.

Clause no. 6 - Risk management



6.1 - companies to determine, consider and, where necessary, take action to address any risks that may impact (either positively or negatively) the ability of the management system to deliver its intended results.

6.2 - Strengthened focus on objectives as drivers for improvements

Clause no. 7 - Extended requirements related to communications

7.4 - “mechanics” of communication, including determination of what, when and how to communicate

7.5 - Documented information shall be controlled to ensure it is adequately protected (ref.

7.5.3). The explicit requirement to have a documented procedure has been removed.

Clause no. 9 - Performance evaluation

Other changes that are specific to ISO 22000 and food safety management

- The PDCA cycle: the standard clarifies the Plan-Do-Check-Act cycle, by having two separate cycles in the standard working together: one covering the management system and the other, covering the principles of HACCP.
- The scope now specifically includes animal food: food for animals not producing food for human consumption. Feed is intended to be fed to food producing animals.
- Some important changes in the definitions: ‘Harm’ is replaced by ‘adverse health effect’ to ensure consistency with definition of food safety hazard. The use of ‘assurance’ highlights the relationship between the consumer and the food product, based on the assurance of food safety.
- Communicating the food safety policy – Clause no. 5.2.2: Explicitly requires the management to facilitate understanding of the food safety policies by employees.
- Food Safety Management System Objectives: Establishing objectives for the food safety management system is further specified in Clause no. 6.2.1 and includes items as *e.g.*, ‘consistent with customer requirements’, ‘monitored’ and ‘verified’.
- Control of externally-provided processes, products or services – Clause no. 7.1.6- introduces the need to control the suppliers of products, processes and services (including outsourced processes) and to ensure adequate communication of relevant requirements, to meet the food safety management system requirements.



ISO 22000:2018 FSMS - Food safety management systems — Requirements for any organization in the food chain

The main clauses of ISO 22000:2018 FSMS with high level structure are as follows:

1. Scope
2. Normative references
3. Terms and Definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Annex A: cross references between the CODEX HACCP and this document

Annex B: cross references between this document and ISO 22000:2005

Scope of the standard:

ISO 22000:2018 FSMS specifies requirements to enable an organization that is directly or indirectly involved in the food chain:

- a) to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use;
- b) to demonstrate compliance with applicable statutory and regulatory food safety requirements;
- c) to evaluate and assess mutually agreed customer food safety requirements and to demonstrate conformity with them;
- d) to effectively communicate food safety issues to interested parties within the food chain
- e) to ensure that the organization conforms to its stated food safety policy
- f) to demonstrate conformity to relevant interested parties
- g) to seek certification or registration of its FSMS by an external organization, or make a self-assessment or self-declaration of conformity to this document

Terms and Definitions:

Some of the important terms and definitions used in the standard are as follows:

- **Acceptable level** - level of a food safety hazard not to be exceeded in the end product provided by the organization



- **Action criterion** - measurable or observable specification for the monitoring of an OPRP
- **Audit**- systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled
- **Competence**- ability to apply knowledge and skills to achieve intended results
- **Conformity** - fulfilment of a requirement
- **Contamination** - introduction or occurrence of a contaminant including a food safety hazard in a product or processing environment
- **Continual improvement** - recurring activity to enhance performance
- **Control measure** - action or activity that is essential to prevent a significant food safety hazard or reduce it to an acceptable level
- **Correction**-action to eliminate a detected nonconformity
- **Corrective action** -action to eliminate the cause of a nonconformity and to prevent recurrence
- **Critical Control Point (CCP)** -step in the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level, and defined critical limit(s) and measurement enable the application of corrections
- **Critical limit** - measurable value which separates acceptability from unacceptability
- **Effectiveness** - extent to which planned activities are realized and planned results achieved
- **End product** -product that will undergo no further processing or transformation by the organization
- **Flow diagram** -schematic and systematic presentation of the sequence and interactions of steps in the process
- **Food chain**- sequence of the stages in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption
- **Food safety**- assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use
- **Management system** - set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives
- **Measurement** -process to determine a value
- **Monitoring** - determining the status of a system, a process or an activity



- **Nonconformity**-non-fulfilment of a requirement
- **Objective**-result to be achieved
- **Operational Prerequisite Programme (OPRP)**-control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level, and where action criterion and measurement or observation enable effective control of the process and/or product
- **Pre-Requisite Programme (PRP)**- basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety
- **Organization**-person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives
- **Policy**-intentions and direction of an organization as formally expressed by its top management
- **Top management**- person or group of people who directs and controls an organization at the highest level
- **Process** -set of interrelated or interacting activities which transforms inputs to outputs
- **Product** -output that is a result of a process
- **Risk** -effect of uncertainty
- **Traceability** -ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution
- **Update** -immediate and/or planned activity to ensure application of the most recent information
- **Validation** - obtaining evidence that a control measure (or combination of control measures) will be capable of effectively controlling the significant food safety hazard
- **Verification** -confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Reference:

1. ISO 22000:2018- Food Safety Management Systems — Requirements for any organization in the food chain