

Chapter 13

Key elements, Terminologies and Scope of FSMS

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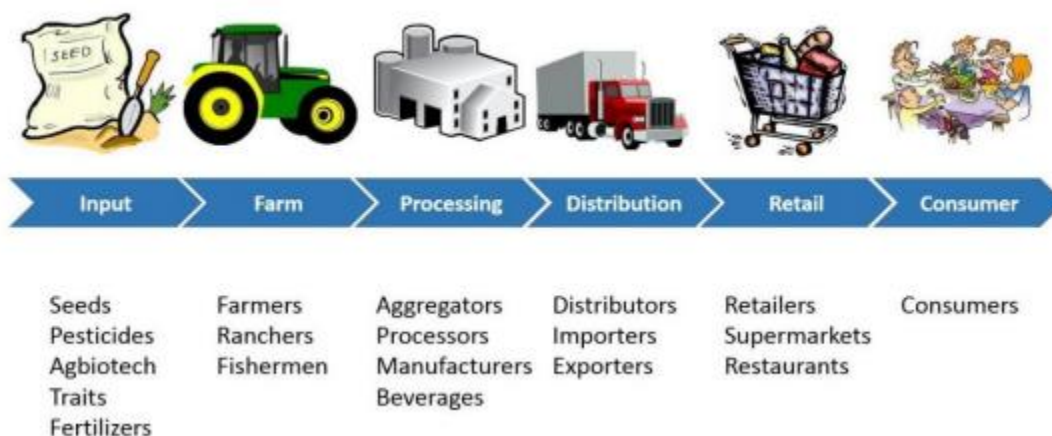
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Introduction

International Standard (ISO:22000) specifies the requirements for a FSMS that combines the following generally recognized key elements to ensure food safety along the food chain, up to the point of final consumption:

- Interactive communication
- System management
- Prerequisite programme
- HACCP principles

ISO 22000 is a Food Safety Management System that can be applied to any organization in the food chain, farm to fork. Becoming certified to ISO 22000 allows a company to show their customers that they have a food safety management system in place. Management: Controlling parameters, material and people System: A regularly interacting or interdependent group of items & people forming a unified whole. Food safety is related: - presence of food-borne hazards in food at the point of consumption. Introduction of food safety hazards can occur at any stage of the food chain - adequate control throughout the food chain is essential. Food safety is ensured through the combined efforts of all the parties participating in the food chain.



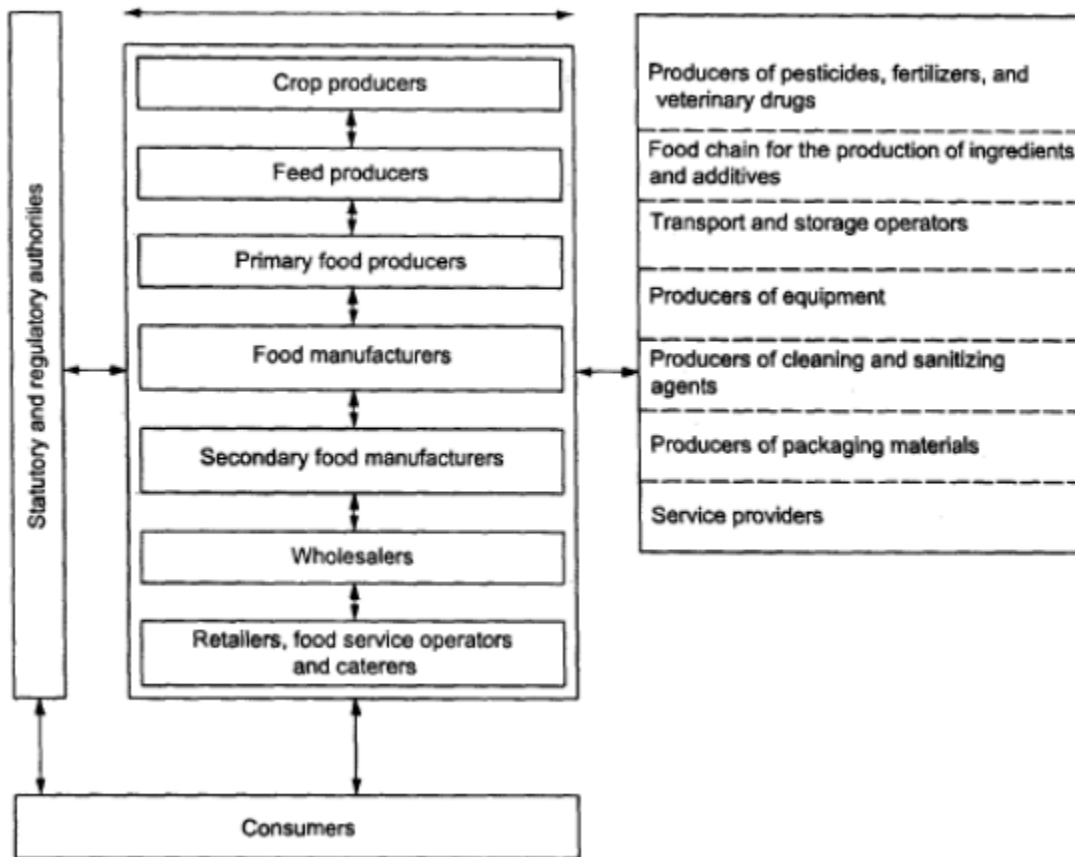
Organizations within the food chain range from:

- feed producers and primary producers through food manufacturers,
- transport and storage operators,

- subcontractors to retail and food service outlets (together with inter-related organizations such as producers of equipment, packaging material, cleaning agents, additives and ingredients).
- service providers.

Interactive communication

- Communication along the food chain is essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain.
- This implies communication between organizations both upstream and downstream in the food chain.
- Communication with customers and suppliers about identified hazards and control measures will assist in clarifying customer and supplier requirements.
- Recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the chain in order to deliver safe food products to the final consumer.
- An example of the communication channels among interested parties of the food chain is shown here.



System management

- Most effective food safety systems are established, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization.

- This International Standard can be applied independently of other management system standards. Its implementation can be aligned or integrated with existing related management system requirements.
- Organizations may also utilize existing management system(s) to establish a food safety management system that complies with the requirements of this International Standard (ISO: 22000-2005/2015).
- It combines the HACCP plan (12 steps) with prerequisite programmed (PRPs).
- Hazard analysis is the key to an effective food safety management system, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures.

Prerequisite programme

- Standard operating procedure (SOP)
- Sanitation standard operating procedure (SSOP)
- Good Agricultural Practice (GAP)
- Good Veterinarian Practice (GVP)
- Good Manufacturing Practice (GMP)
- Good Hygienic Practice (GHP)
- Good Production Practice (GPP)
- Good Distribution Practice (GDP)
- Good Trading Practice (GTP) HACCP principles
- Principle 1: Conduct a hazard analysis
- Principle 2: Determine critical control points (CCPs)
- Principle 3: Establish critical limits
- Principle 4: Establish monitoring procedures
- Principle 5: Establish corrective actions
- Principle 6: Establish verification procedures
- Principle 7: Establish record-keeping and documentation procedures

Scope

- a) To plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance to 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 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.

Terminologies

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

Note 1 to entry: An action criterion is established to determine whether an OPRP remains in control, and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended).

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

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

Note 4 to entry: Relevant disciplines are, for example, food safety management, quality management or environmental management.

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

Note 1 to entry: See also the definition on significant food safety hazards.

Note 2 to entry: Control measure(s) is (are) identified by hazard analysis.

Correction

Action to eliminate a detected nonconformity

Note 1 to entry: A correction includes the handling of potentially unsafe products, and can therefore be made in conjunction with a corrective action.

Note 2 to entry: A correction may be, for example, reprocessing, further processing, and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

Corrective Action

Action to eliminate the cause of a nonconformity and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action includes cause analysis. 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 enables the application of corrections

Critical Limit

Measurable value which separates acceptability from unacceptability

Note 1 to entry: Critical limits are established to determine whether a CCP remains in control. If a critical limit is exceeded or not met the products affected are to be handled as potentially unsafe products.

Documented Information

Information required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to: — the management system, including related processes; — information created in order for the organization to operate (documentation); — evidence of results achieved (records).

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

Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

Feed

single or multiple products, whether processed, semi-processed or raw, which is intended to be fed to food-producing animals

Note 1 to entry: Distinctions are made in this document between the terms food, feed and animal food:

- food is intended for consumption by humans and animals and includes feed and animal food;
- feed is intended to be fed to food-producing animals;
- animal food is intended to be fed to non-food-producing animals, such as pets.

Flow Diagram

Schematic and systematic presentation of the sequence and interactions of steps in the process

Food

Substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances (ingredients) used only as drugs

Note 1 to entry: Distinctions are made in this document between the terms food, feed and animal food:

- food is intended for consumption by humans and animals and includes feed and animal food;
- feed is intended to be fed to food-producing animals;
- animal food is intended to be fed to non-food-producing animals, such as pets.

Animal Food

Single or multiple products, whether processed, semi-processed or raw, which is intended to be fed to non-food-producing animals

Note 1 to entry: Distinctions are made in this document between the terms food, feed and animal food:

- food is intended for consumption by humans and animals and includes feed and animal food;
- feed is intended to be fed to food-producing animals;
- animal food is intended to be fed to non-food-producing animals, such as pets.

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

Note 1 to entry: This includes the production of feed and animal food.

Note 2 to entry: The food chain also includes the production of materials intended to come into contact with food or raw materials.

Note 3 to entry: The food chain also includes service providers.

Food Safety

Assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed according to its intended use

Note 1 to entry: Food safety is related to the occurrence of food safety hazards in end products and does not include other health aspects related to, for example, malnutrition.

Note 2 to entry: It is not to be confused with the availability of, and access to, food (“food security”).

Note 3 to entry: This includes feed and animal food.

Food Safety Hazard

Biological, chemical or physical agent in food with the potential to cause an adverse health effect

Note 1 to entry: The term “hazard” is not to be confused with the term “risk” which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (e.g. death, hospitalization) when exposed to a specified hazard.

Note 2 to entry: Food safety hazards include allergens and radiological substances.

Note 3 to entry: In the context of feed and feed ingredients, relevant food safety hazards are those that can be present in and/or on feed and feed ingredients and that can through animal consumption of feed be transferred to food and can thus have the potential to cause an adverse health effect for the animal or the human consumer. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, disinfectants), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended.

Note 4 to entry: In the context of animal food, relevant food safety hazards are those that are hazardous to the animal species for which the food is intended.

Management System

Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

Note 4 to entry: Relevant disciplines are, for example, a quality management system or an environmental management system.

Policy

Intentions and direction of an organization as formally expressed by its top management

Interested party (preferred term)

Stakeholder (admitted term)

Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

Lot

Defined quantity of a product produced and/or processed and/or packaged essentially under the same conditions

Note 1 to entry: The lot is determined by parameters established beforehand by the organization and may be described by other terms, e.g. batch.

Note 2 to entry: The lot may be reduced to a single unit of product. Measurement Process to determine a value

Monitoring

Determining the status of a system, a process or an activity

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.

Note 2 to entry: In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.

Note 3 to entry: Distinctions are made in this document between the terms validation, monitoring and verification:

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time-frame;

— verification is applied after an activity and provides information for confirmation of conformity.

Nonconformity

Non-fulfilment of a requirement Objective Result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product, and process).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a food safety management system objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of food safety management systems, objectives are set by the organization, consistent with the food safety policy, to achieve specific results.

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

Organization

Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Outsource

Make an arrangement where an external organization performs part of an organization's function or process

Note 1 to entry: An external organization is outside the scope of the management system, although the outsourced function or process is within the scope. Performance Measurable result Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, processes, products (including services), systems or organizations.

Prerequisite programme PRP

Basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety

Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization.

Examples of equivalent terms are: good agricultural practice (GAP), good veterinarian practice (GVP), good manufacturing practice (GMP), good hygiene practice (GHP), good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP).

Process

Set of interrelated or interacting activities which transforms inputs to outputs Product Output that is a result of a process

Note 1 to entry: A product can be a service.

Requirement

Need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in documented information.

Risk

Effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected – positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential “events” and “consequences” or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” of occurrence.

Note 5 to entry: Food safety risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food, as specified in the Codex Procedural Manual.

Significant Food Safety Hazard

Food safety hazard, identified through the hazard assessment, which needs to be controlled by control measures

Top Management

Person or group of people who directs and controls an organization at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the management system covers only part of an organization, then top management refers to those who direct and control that part of the organization.

Traceability

Ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

Note 1 to entry: Movement can relate to the origin of the materials, processing history or distribution of the food.

Note 2 to entry: An object can be a product, a material, a unit, equipment, a service, etc.

Update

Immediate and/or planned activity to ensure application of the most recent information

Note 1 to entry: Update is different from the terms “maintain” and “retain”:

— maintain is to keep something on-going/to keep in good condition;

— retain is to keep something that is retrievable.

Validation

obtaining evidence that a control measure (or combination of control measures) will be capable of effectively controlling the significant food safety hazard

Note 1 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.

Note 2 to entry: Distinctions are made in this document between the terms validation, monitoring and verification:

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time-frame;

— verification is applied after an activity and provides information for confirmation of conformity.

Verification

Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: Distinctions are made in this document between the terms validation (3.44), monitoring and verification:

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time-frame;

— verification is applied after an activity and provides information for confirmation of conformity.

Reference:

Food safety management systems — Requirements for any organization in the food chain. INTERNATIONAL STANDARD ISO/FDIS 22000-2018 (ISO/TC 34/SC 17).

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