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Postgraduate Course MSFP101

SYSTEMS FOR FOOD RISK MANAGEMENT

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Chapter 1

Requirements of Food Safety Management Systems Based on ISO 22000: 2005 for the Organizations in the Food Chain

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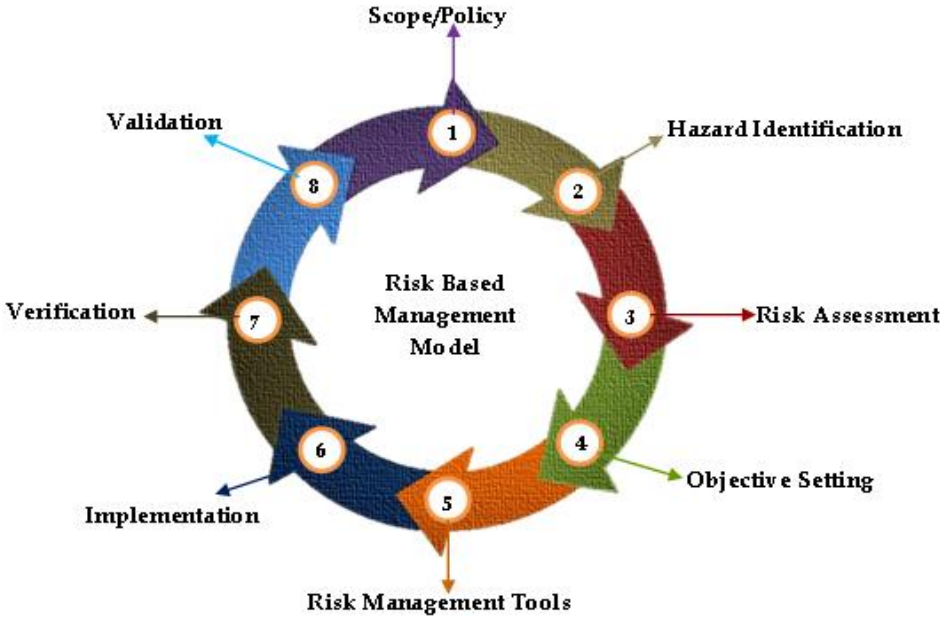
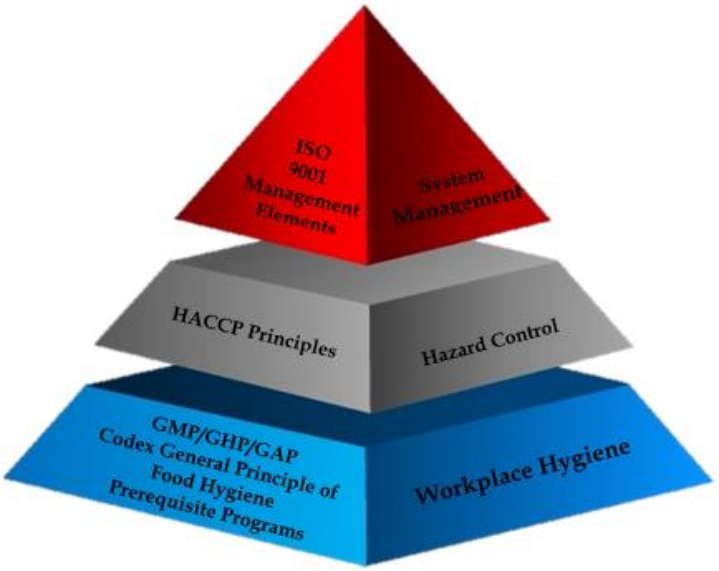
FOREWORD

ISO 22000:2005

- ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.
- International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.
- The main task of technical committees is to prepare International Standards. International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.
- ISO 22000 was prepared by Technical Committee ISO/TC 34, *Food products,* Subcommittee SC.

1.1. Areas of application of ISO 22000:2005. Terms and definitions applicable in the food safety management systems





INTRODUCTION

- The requirements for food safety for all organizations, which produce, manufacture, handle or supply food, is paramount. Furthermore, all these organizations recognize the increasing need to demonstrate and provide adequate evidence of their ability to identify and control food safety hazards and the many conditions impacting food safety. This requirement may apply to all types of organizations within the food chain ranging from feed producers, primary producers through food manufacturers, transport and storage operators and subcontractors to retail and food service outlets - together with inter-related organizations such as producers of equipment, packaging material, cleaning agents, additives and ingredients.
- Food safety is related to the presence of and levels of food borne hazards in food at the point of consumption (intake by the consumer). As food safety hazards may be introduced at any stage of the food chain, adequate control throughout the food chain is essential. Thus, food safety is a joint responsibility that is principally assured through the combined efforts of all the parties participating in the food chain.

- This international standard specifies the requirements for a food safety management system 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;
  - process control;
  - HACCP principles;
  - prerequisite programs.

- 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 of the needs of the organization to both organizations upstream in the food chain and organizations downstream in the food chain. Communication with customers and suppliers, based on the information generated through systematic hazard analysis, will also assist in substantiating customer and supplier requirements with regard to their feasibility, need and impact on the end product.
- 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. The possible scope of the communication channels among typical interested parties of the food chain is schematically exemplified in Figure 1.

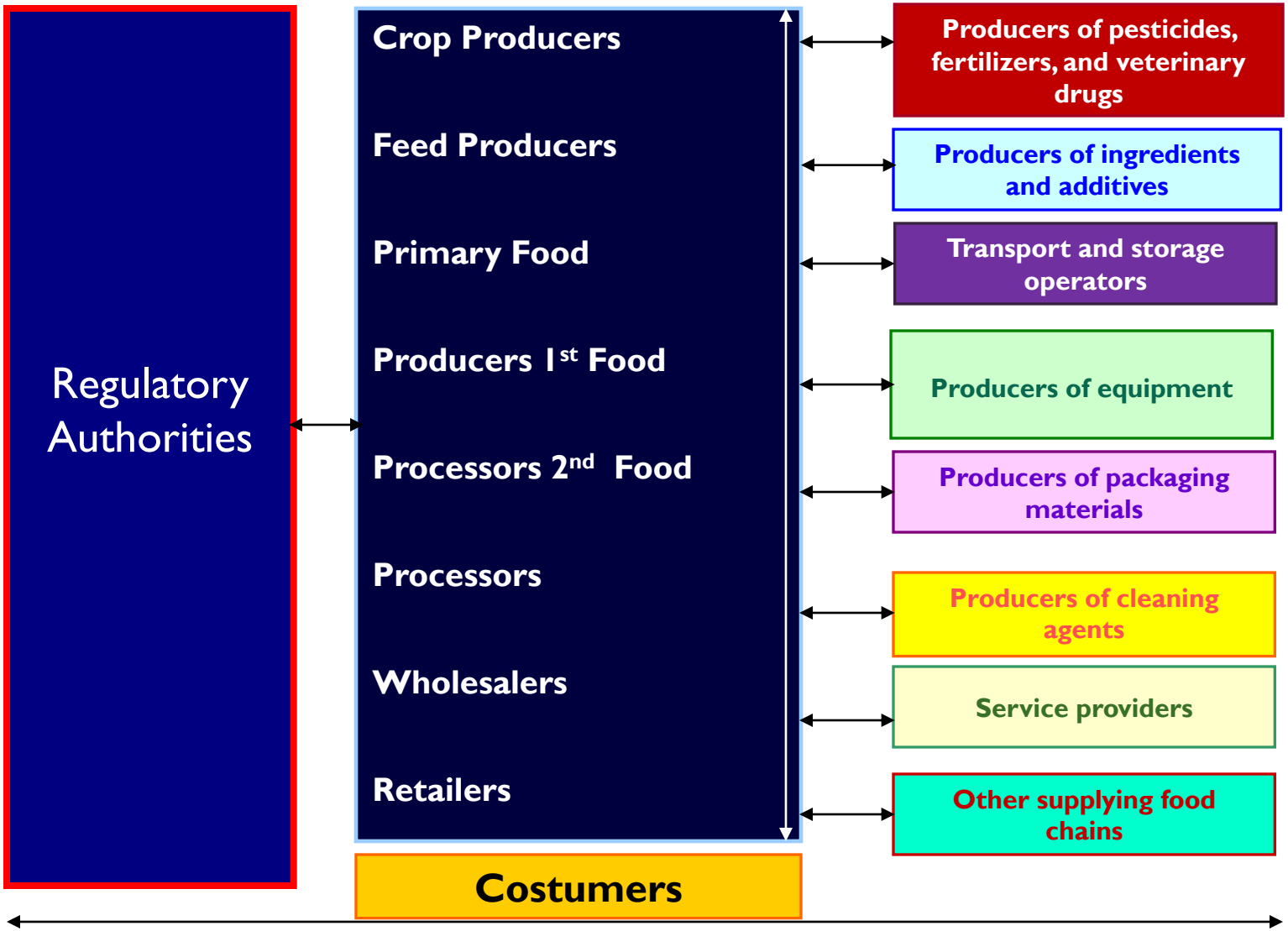


Figure 1. Example for communication along the food chain

- The most effective systems for food safety are installed, running and updated within a structured management system and incorporated into the overall management activities of the organization. ISO 22000: 2005 in accordance with ISO 9001, in order to improve the compatibility of the two standards.
- ISO 22000: 2005 can be used independently of other standards for control. Its introduction may be assimilated or integrated with existing related requirements of other management systems.
- This standard includes the principles of Hazard Analysis and Critical Control Point (HACCP); principles and steps of their applications developed Codex Alimentarius Commission. It combines with HACCP plan "prerequisite" programs (PRP) from GMP-s.
- This standard requires that all hazards that must take place in the food chain, incl. the risks associated with the type of process and production equipment must be identified and assessed.
- Therefore, this standard provides a means for determining and documenting and responding to a question about why some of the need to control whether or not the identified hazards?

- During the risk analysis, organization determines the strategy to be used to ensure hazard control by combining the "prerequisite" programs (PRP) from GMP-s, operative programs (OPR) and HACCP plans.
- To facilitate the application of this international standard, it was designed as a standard that can be audited.
- To help organizations in the implementation of ISO 22000: 2005, instructions for their use are given in ISO / TS 22004.
- This standard enables the organization (e.g., small and / or underdeveloped) to introduce a combination of control measures developed by other external organizations.
- The purpose of ISO 22000: 2005 is to harmonize on a global level the requirements for food safety management of companies in the food chain. It is intended for application by organizations seeking a more focused, coherent and integrated food safety management system (FSMS) than is normally required by law.

1. SCOPE

ISO 22000
EL SISTEMA DE GESTIÓN DE LA INOCUIDAD DE ALIMENTOS
MODULO IV

- **ISO 22000: 2005 specifies requirements for a food chain FSMS.**
- **ISO 22000: 2005 is applicable to all organizations involved in the food chain, regardless of their size. It is applicable to all organizations wishing to use FSMS ensure a stable supply of safe food and drinks.**
- **Means to any requirements of this standard can be achieved with the use of internal and / or external resources.**
- **ISO 22000: 2005 will enable the organization:**

- in the planning, design, implementation, operation, maintenance and renovation FSMS and food products that are safe for the customer;
- demonstrate compliance with legal requirements regarding food safety;
- analysis and evaluation of requirements and demonstrate compliance with the agreed customer requirements related to food safety and customer satisfaction increase;
- effectively communicate issues related to food safety with their suppliers, customers and other stakeholders in the food chain;
- to make sure that it is consistent with the stated policy of the guide to food safety;
- to demonstrate such conformity to relevant stakeholders and
- to seek certification or registration of its FSMS external organization, or to carry out self-assessment or declaration of conformity to this international standard

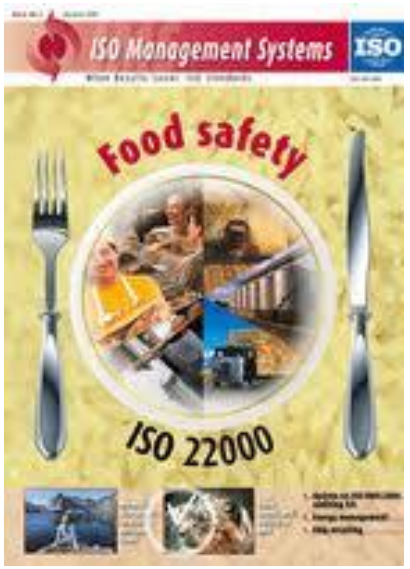
- All requirements of this international standard are generic and are intended for use by all organizations wishing to develop and implement effective FSMS, regardless of their size and complexity.
- It includes organizations that are directly or indirectly included in one or more stages in the food chain.
- Directly involved the organization of animal feed producers, agricultural producers, farmers, manufacturers of dietary protein (soy, eggs, blood, milk and other protein preparations, starch, etc.), food manufacturers, retailers, cafes, restaurants, catering operators, organizations providing services such as cleaning, transportation, storage and distribution, which are indirectly included;
- Organizations indirectly involved in the food chain are producers of technological equipment, detergents, packaging and other materials in contact with food.
- This standard allows small farms, small distributors of packaged foods, small retailers and small snack applied externally developed combination of control measures.

NOTE: ***The use of this standard is resented in ISO / TS 22004.***

- ISO 22000:2005 contains the overall guidelines for food safety management
- ISO 22004:2014 provides generic advice on the application of ISO 22000
- ISO 22005:2007 focuses on traceability in the feed and food chain
- ISO/TS 22002-1:2009 contains specific prerequisites for food manufacturing
- ISO/TS 22002-2:2013 contains specific prerequisites for catering
- ISO/TS 22002-3:2011 contains specific prerequisites for farming
- ISO/TS 22002-4:2013 contains specific prerequisites for food packaging manufacturing
- ISO/TS 22003:2013 provides guidelines for audit and certification bodies

2. LINKS

- ISO 9001:2015 *Quality management systems — Fundamentals and vocabulary* are essential to the realization of this standard.
- For undated references, the latest edition of a document including any amendments ISO 9001:2015 *Quality management systems — Fundamentals and vocabulary*



3. TERMS AND DEFINITIONS

For the purposes of this standard, the terms and definitions given in ISO 9001: 2015, as well as those below:

- **Food safety - the concept that food will not cause harm to the user when they are prepared and / or eaten according to her appointment;**

  NOTE : Food safety is related to the presence of food hazards and does not include other aspects of health such as when people are undernourished.

- **Food chain - the sequence of steps and operations related to the production, processing, distribution, storage and processing of food and its components from harvest to consumption;**

  NOTE 1:This includes the production of feed for livestock.

  NOTE 2:The food chain also includes the production of materials intended for contact with food or raw materials.

Food safety hazard – biological, chemical or physical agent in food (or food property), which may lead to undesirable effects on human health;

NOTE 1: *The term "hazard" is not to be confused with the term "risk" in which food safety is a function of the probability of adverse health effects (e.g., the emergence of the disease) and the severity of that effect (death, hospitalization, absenteeism and more) when exposed to the risk. Risk is defined in ISO / IEC Guide 51 as the combination of the probability of harm and the severity of the injury.*

NOTE 2: *The hazards include allergens.*

NOTE 3: *In the context of the production of animal feed and ingredients, relevant hazard are those in or on animal feed and their ingredients and which can pass the food after consumption of animal fodder and thus have the potential to cause adverse effects on human health. In the context, except the ingredients and production of animal feed (e.g., manufacturers of packaging material, cleaning products, etc.). The hazards are those that could directly or indirectly, to go to the food, in connection with the intended use of the food and / or services, and therefore have the potential to cause adverse effects on human health.*

Food safety policy - The main objectives and principles of the organization with respect to food safety as formally expressed by the leadership of the declaration;

- **Final product - the product, which will not be further processed redone in the organization;**

  NOTE: *The product, which is further processed or converting any organization is the product in the context of the first organization and the raw material or ingredient in the context of the second organization.*

- **Flow diagram - the fundamental and systematic presentation of the sequence and interaction stages of the process;**

- **Control measure - all acts or activities that may be used to prevent or eliminate the risk or to bring them to an acceptable level;**

- **Prerequisite program (PRP) - basic conditions and activities related to food safety, which are necessary to maintain a hygienic environment throughout the food chain suitable for the production, processing and provision of safe end products and safe food for human consumption.**

  NOTE: *The needs from PRP will depends on the sector of the food chain in which the organization operates and from the type of organization.*

  Examples of equivalent terms: Good Agricultural Practices (GAP-s); Good Veterinary Practices (GVP-s); Good Processing Practices (GPP-s); Good Hygiene Practices (GHP-s); Good Manufacturing Practices (GMP-s); Good Distribution Practices (GDP-s); Good Trade Practices (GTP-s).

- **Operational PRP (operational prerequisite program) – program identified by the hazard analysis as essential to control the probability of hazard and / or the contamination or hazard in product development or in the surrounding work environment;**
- **Critical control point (CCP) - a step in which control can be applied, and it is very important to prevent or eliminate the risk or to bring them to an acceptable level;**
- **Critical limit - a criterion that separates acceptability from unacceptability;**

  NOTE: *Critical limits are established to ensure that the CCP-s are under control. If the critical limits are exceeded or disorders are affected the products thay should be treated as potentially hazardous foods or drinks.*
- **Monitoring - implementation of the planned series of observations or measurements to assess whether control measures are working, so that they are available;**

- **Correction - action to eliminate the detected nonconformity**
- **(ISO 9001: 2015);**

Note 1: *For the purposes of ISO 22000: 2005, relates to the correction of the storage and processing of the next potentially hazard product and therefore may be performed in conjunction with a corrective action.*

NOTE 2: *The correction can be, for example, processing, further processing and / or eliminating the adverse effects of nonconformities (e.g. an order for any storage or processing or specific labeling).*

- **Corrective action - every action to eliminate the detected nonconformity or other undesirable situation;**

NOTE 1: *There may be more than one of the reasons for nonconformity (ISO 9001: 2015).*

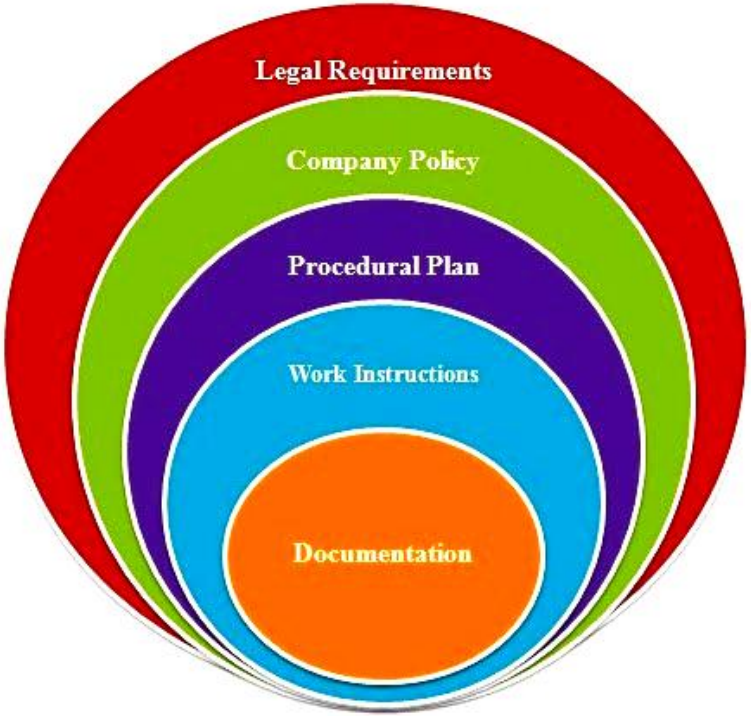
NOTE 2: *Corrective action includes cause analysis and it is taken to prevent recurrence.*

- **Validation - obtain evidence that controls the controlled HACCP plan and operational PRP will be effective;**

NOTE: *This definition is more suited to the food safety of the definition given in ISO 9001: 2015.*

- **Verification - confirmation through the provision of objective evidence that specified requirements have been fulfilled (ISO 9001: 2015);**
- **Updating - immediate and/or planned activity to ensure implementation of the most recent information;**

1.2. Basic requirements of ISO 22000: 2005 management system of food safety and requirements documents and records



4. FOOD SAFETY MANAGEMENT SYSTEM

4.1. GENERAL REQUIREMENTS

- **The organization shall establish, document, implement and maintain effective FSMS and update it in accordance with this standard.**
- **The organization shall define the scope of FSMS specifying products or product categories, processes and production sites that are described in FSMS.**
- **The organization should be:**
  - ensure that the risks to which it is reasonable to expect in the system are identified, assessed and managed in such a way that the products do not cause, directly or indirectly, to the detriment of the consumer;
  - transmit the relevant information throughout the food chain, on the safety of its products;
  - transmit information about the development, implementation and updating of FSMS of the organization to the extent necessary to ensure the food safety by this standard;
- **Periodically evaluate and, if necessary, update FSMS to ensure that the system reflects the organization's activities and includes the latest information on the hazards to be controlled.**
- **The organization shall monitor the outsourcing processes, which affect the compliance of the end product. The control processes carried out by an external contractor, should be defined and documented in FSMS.**

4.2. REQUIREMENTS FOR DOCUMENTATION

4.2.1. Basic information

Food safety documentation shall include:

- documented statements of objectives and policies in the field of food safety;
- documented procedures and records required by this standard;
- documents needed by the organization to ensure the effective development, implementation and updating of FSMS.

4.2.2. Documents' management

- **Documents required for FSMS to control.**
- Records are a special type of document and shall be controlled in accordance with the records management.
- Monitoring should ensure that any proposed changes are considered prior to implementation to determine their effects on food safety and the impact on FSMS.

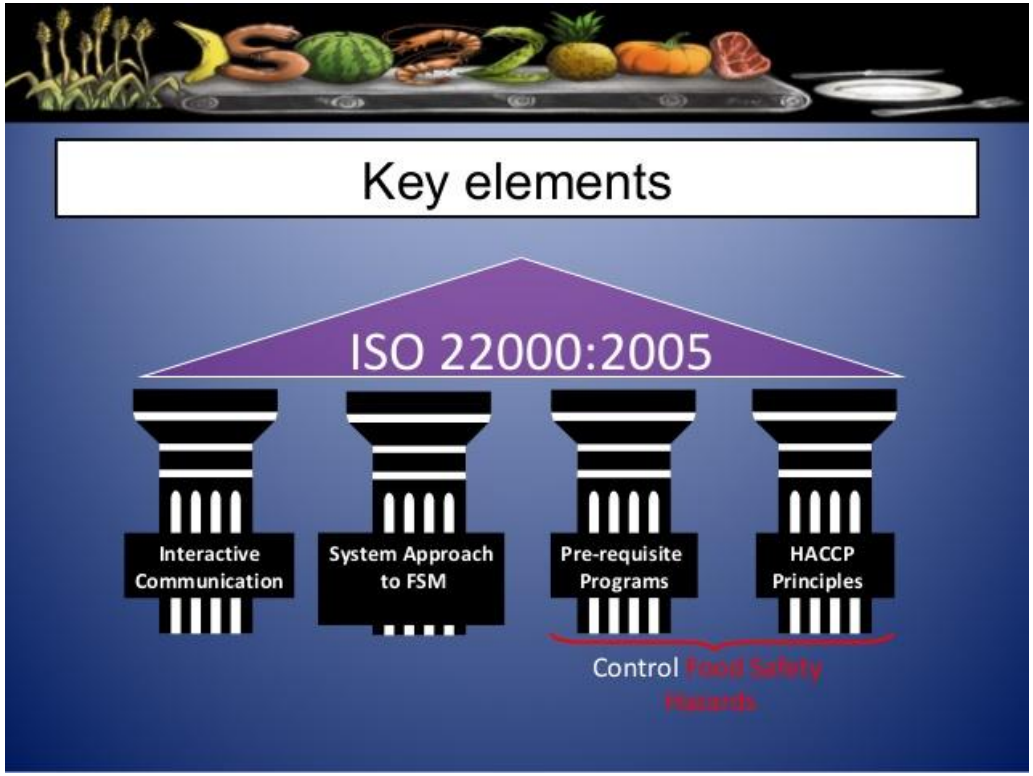
- **Documented procedures should be established to determine the appropriate control over:**

- approve documents for adequacy prior to release;
- review and update, if necessary, and re-approve documents;
- ensure that changes and the current revision status of documents;
- ensure that relevant versions of applicable documents are available at locations where they are used;
- ensure that documents remain legible and readily identifiable;
- ensure that documents of external origin are identified and their distribution controlled;
- preventing inadvertent use of outdated documents, and they should be paid to the correct identification if they are stored for any reason.

4.2.3. Records' management

- **It should be established and maintained records to provide evidence of conformity to requirements and the effective functioning of FSMS. Entries must be clear and easily recognizable and numbered.**
- **There must be a documented procedure established to define the controls needed for the identification, storage, conservation, finding time for the storage and records destruction.**

1.3. Management responsibilities associated with the maintenance and operation of the food safety management system



5. MANAGEMENT'S RESPONSIBILITY

5.1. MANAGEMENT COMMITMENT

- **The top management shall provide evidence of its commitment to the development and implementation of FSMS and continuous improvement of its effectiveness through:**
  - showing that food safety is supported by the business objectives of the organization;
  - extension to the organization the importance of meeting the requirements of the ISO 22000: 2005 standard, all legislative and regulatory requirements and customer requirements related to food safety;
  - creation of food safety policy;
  - conducting management reviews;
  - provisioning.

5.2. FOOD SAFETY POLICY

- **The top management shall define, document and communicates its policy on the area of food safety.**
- **The top management should ensure that this policy on food safety:**
  - is suitable for the role of the organization in the food chain;
  - is a consistent, as statutory and regulatory requirements, as well as jointly agreed customer requirements for food safety;
  - communicated, implemented and maintained at all levels of the organization;
  - is reviewed for continuing suitability and;
  - treat accordingly the information exchange;
  - is supported by measurable objectives.

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FOOD SAFETY POLICY

THE COMPANY SHALL ENSURE THAT ALL PRODUCTS ARE SAFE AND WHOLESOME IN WHICH CUSTOMERS HAVE TOTAL CONFIDENCE.

The Company shall

- Comply with all relevant regulatory requirements
- Meet customer specification
- Comply with Regulation for Hygiene in the Food Retailing and wholesaling
- Comply with Regulation for Food Safety Management incorporating HACCP

The company will document a food safety management system which shall consist a HACCP and supporting good manufacturing management procedures.

An appointed Food Safety Team Leader with the authority and responsibility shall ensure that this policy is adhered to and communicated throughout the entire company.

5.3. PLANNING OF FSMS

- **The top management shall ensure that:**
  - FSMS planning is carried out in accordance with the requirements listed in the ownership and office management, as well as those organizations that support food security;
  - FSMS integrity of the planning and making changes to it.

5.4. RESPONSIBILITY AND AUTHORITY

- **The top management shall ensure that responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of FSMS.**
- **Staff have to be responsible to report any problems in FSMS.**
- **It have to be appointed personnel who should be responsible for initiating and post crisis situations and emergency operations.**

5.5. THE HACCP TEAM LEADER

- **The top management should identify a HACCP team leader in the field of food safety, which, irrespective of other responsibilities, shall organize the work of the HACCP team and have responsibility and authority to:**

- lead the HACCP team and organizes its work;
- provide appropriate training and education of members of HACCP team;
- implemented, maintained and updated the FSMS;
- report to the top management for effectiveness of the organization and suitability for food safety.

NOTE: *The responsibility of the HACCP team leader for food safety can include liaison with external parties on matters relating to food safety management.*

I'm the HACCP team leader

5.6.COMMUNICATIONS

5.6.1. External communications

- **To provide sufficient information about the food safety available in the food chain, the organization shall establish, implement and maintain effective communication measures:**

- retailers and suppliers;
- customers, particularly in respect of product information (including the structures on the intended use, the particular storage conditions and, if necessary, hold) engaged requests contracts or orders, and their changes and customer feedback, including their complaints;
- legislative and executive bodies;
- other organizations that have an impact on, or be affected by the performance or upgrade the food safety management system.

5.6.1. External communications

- This exchange must provide information on the security aspects of the organizations' products that may be relevant to other organizations in the food chain.
- This refers to the known hazards that must be controlled by other organizations in the food chain.
- It must keep a records of communications.
- The food safety requirements of the legislative and executive authorities and customers need have to be available.
- Only specifically designated staff can provide food safety information outside the organization.
- Information received via the external communications should be included as input to update the FSMS and management review.

5.6.2. Internal communications

- **The organization shall establish, implement and maintain effective arrangements for communicating with employees on issues related to food safety.**
- **In order to maintain the effectiveness of FSMS, organizations must ensure that the HACCP team information on changes over time, including the following examples, without limitations:**
  - products or new products;
  - raw materials, ingredients and services;
  - production systems and processing equipment;
  - production capacity, the location of the process equipment and the environment;
  - program for cleaning and disinfection;
  - systems for packaging, storage and distribution;
  - the level of qualification of the personnel and / or allocation of responsibilities and powers;
  - legal and regulatory requirements;
  - knowledge about the food hazards and control measures;
  - customer, industry, and other requirements to which the organization held;
  - requests from interested parties;
  - complaints indicating health hazards associated with the product;
  - other conditions related to food safety.

- **HACCP team must ensure that this information is included in the FSMS updating procedure. The top management shall ensure that relevant information is included as input to the management review.**

5.7. EMERGENCY PREPAREDNESS AND ABILITY TO REACT

- Top management should establish, implement and maintain procedures for the control of possible emergencies and accidents that may affect on the food safety and which are relevant to the organization's role in the food chain.

5.8. MANAGEMENT REVIEW

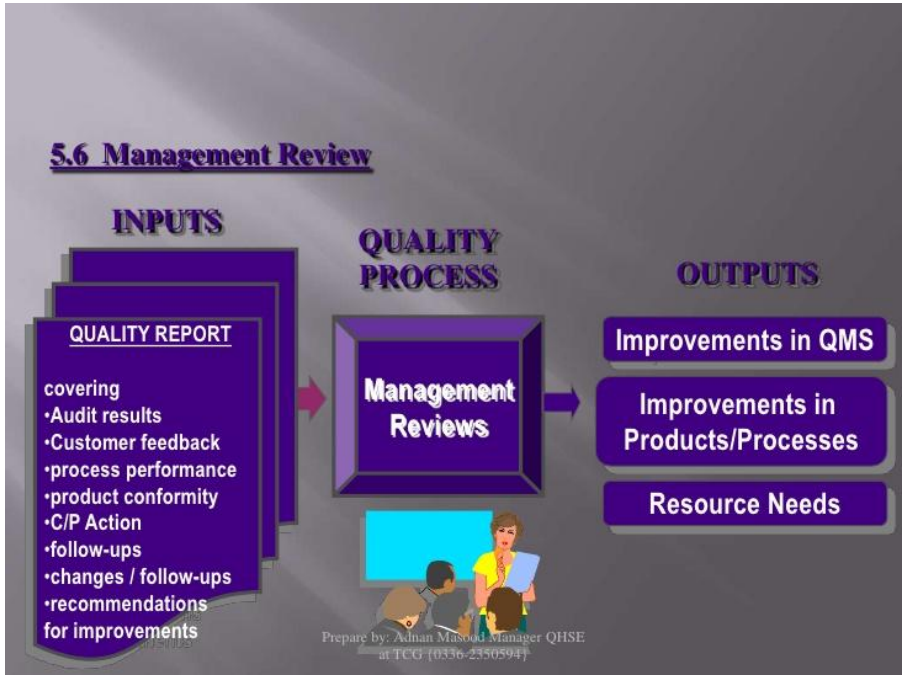
5.8.1. Background information

- The top management shall review the FSMS of organization at planned intervals to ensure its continuing suitability, adequacy and effectiveness.
- This review shall include assessing opportunities for improvement and the need for FSMS amendments including policy and food safety.
- It must keep a records of the management review.

5.8.2. Input data for the management review

- **The input data for the management review shall include, but not limited to such information:**

- follow-up actions from previous management reviews;
- analysis of results of verification activities;
- changing circumstances that can affect on food safety;
- emergencies, accidents and withdrawal from the market;
- review the results of the update operation of the FSMS;
- review of activities related to communication, including customer feedback;
- external audits or inspections.



***NOTE**: The term "withdrawal" including the return journey (recall).*

- **Data should be presented in such way to ensure the top management to associate information with the FSMS stated objectives.**

5.8.3. Output data for the management review

- **Data from the management review shall include decisions and actions related to:**

- food security;
- FSMS efficiency;
- the necessary resources;
- review of security policy the organization of food and related purposes.

1.4. Resource management related to maintenance and operation of the food safety management system

Figure 1: Levels of Food Safety Management Systems

6. RESOURCE MANAGEMENT

6.1. PROVISION OF RESOURCES

- The top management should provide sufficient resources to develop, implement, maintain and update its FSMS.

6.2. HUMAN RESOURCES

6.2.1. Basic information

- HACCP team and other personnel carrying out activities affecting food safety shall be competent and have the appropriate education, training, skills and experience.
- If you want to use the assistance of external experts for the development, implementation or operation of the FSMS of organization should maintain records of agreements (contracts) with definition of the experts responsibility and authority.

6.2.2. Competence, awareness and preparation

- **The organization should:**

- determine what skills and competencies of staff are needed, whose activities would be affect on food safety;
- provide training or take other actions to ensure that staff have the necessary knowledge;
- ensure that personnel responsible for monitoring, corrections and corrective action ensuring FSMS was trained;
- evaluate the efficacy of 1), 2) and 3);
- ensure that personnel is aware of the relationship and the importance for the individual activities of each of them on food safety promoting;
- ensure that the requirements for effective communication are understood by all employees and whose activities affect on food safety;
- maintain appropriate records of education and on the actions described in 2) and 3);

6.3. INFRASTRUCTURE

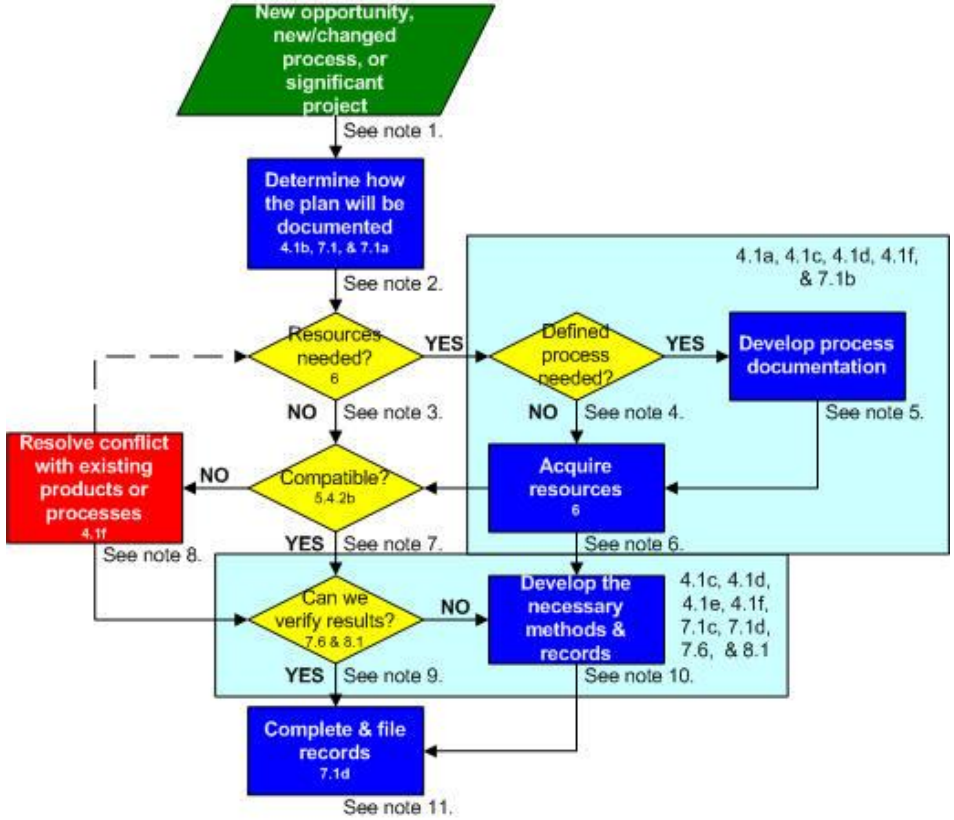
- The organization shall provide the resources to build and maintain the infrastructure needed to implement the requirements of this standard.

6.4. WORKING ENVIRONMENT

- The organization shall provide resources for creating, managing and maintaining the work environment needed to meet the requirements of this standard.

ISO 22000:2005
Certified Food Safety Management System

1.5. The safe food planning and realization



7. PLANNING AND IMPLEMENTATION OF FOOD SAFETY

7.1. BASIC INFORMATION

- The organization shall plan and develop the processes necessary for the realization of safe foods.
- The organization shall manage and ensure the effectiveness of the planned measures and any amendments to these activities. This includes the PRP-s and / or HACCP plans.

7.2. PREREQUISITES PROGRAMS

7.2.1. The essence of the prerequisites program (PRP) of good manufacturing practices (GMP-s)

- The organization shall establish, implement and maintain PRP-s of GMP-s which should help in its work as:

- management likelihood of hazards in the working environment of the products;
- controlling of biological, chemical and physical contamination of products, including cross-contamination between them;
- controlling the risk levels of the environment and product to its processing.

7.2.3. Requirements to Prerequisites Program (PRP) of good manufacturing practices (GMP-s)

- **PRP-s of GMP-s have to:**
  - meet the organization's needs in terms of food safety;
  - match the size and type of production and the nature of production and / or products that are processed;
  - implement in the entire system and production as the commonly used programs or applicable to specific products or product line approved by the food safety team.
- **The organization shall identify statutory and regulatory requirements related to the above.**

7.2.4. Information that is considered to be in the Prerequisites Programs (PRP-s) development of good manufacturing practices (GMP-s)

- **When selecting and / or developing PRP-s of GMP-s, the organization shall consider and utilize appropriate information (e.g. legal and regulatory requirements, customer requirements agreed recommendations, guidelines and codes of practice of the *Codex Alimentarius Commission*, national and international or industry standards).**

- **In developing these programs, the Organization should consider the following:**
  - construction and plan-distribution of buildings and related facilities ;
  - plan-space allocation, including working space and a bathroom for the staff;
  - delivery of air, water, energy and other utilities;
  - supported services, including disposal of waste and garbage return water;
  - the suitability of the process equipment and its accessibility for cleaning, repair and maintenance;
  - management of purchased materials (e.g. raw materials, ingredients, chemicals and packages) and food (e.g. water, air, steam and ice), delete (for example, waste water and reverse) and product processing (e.g. storage and transportation);
  - measures for cross-contamination prevention;
  - cleaning and disinfection;
  - pest control;
  - personal hygiene of the staff;
  - other aspects, as appropriate.

- **PRP-s should be checked and their transformation should be planned in accordance to the FSMS of organization.**
- **I must keep records of inspections and modifications of the PRP-s. Documents must determine how to manage the activities included in the PRP-s.**

7.3. PRELIMINARY STEPS OF RISK ANALYSIS

7.3.1. Basic information

- All the information needed to conduct the hazard analysis shall be collected, maintained and updated in controlled documents. The organization must keep records.

7.3.2. HACCP team

- It should be assigned to the HACCP team.
- HACCP team must have interdisciplinary experience for development and implementation of the FSMS. This includes, but is not limited to the products, processes and food processing equipment to hazard institutions in the food safety management.
- It is necessary to keep records to demonstrate that the HACCP team has appropriate knowledge and experience.

7.3.3. Product features

7.3.3.1. Raw materials and components in contact with the product

- **All raw materials, ingredients and other materials in contact with the product must be described in the documents, to the extent that is sufficient for identification and evaluation of food hazards on, where appropriate:**

  - biological, chemical and physical characteristics;
  - formulation ingredients, including additives and auxiliary materials;
  - their origin;
  - methods of manufacturing;
  - delivery methods and packaging;
  - storage conditions and shelf-life ;
  - preparation and/or handling before use or before further processing;
  - criteria for food safety and technical specifications (technological documentations) of the purchased materials and components that meet their purpose.
- **The organization shall identify statutory and regulatory requirements for food safety in connection again.**
- **Technical specifications (technological documentations) have to be kept up to date, including and, if necessary, update the preliminary information and documents specifying the PRP-s and HACCP plans.**

7.3.3.2. Characteristics of the end product

- **The characteristics of the end product have to be listed in the documents to a degree sufficient to conduct a hazard analysis, including the need to have information on the following issues:**
  - name or similar identification;
  - proximate composition;
  - formulation of the concentration of raw materials ads additives;
  - biological, chemical and physical characteristics related to food safety;
  - intended shelf life and storage conditions;
  - type of packaging;
  - labeling according food safety requirements and/or handling instructions for preparation and use;
  - distribution channels;
- **The organization shall identify statutory and regulatory requirements for food safety in connection again.**

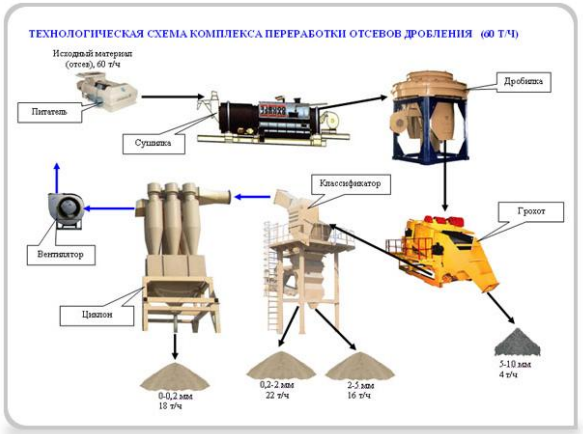
7.3.4. Directions to use

- Intended use, there is reason to believe, the processing of the end product and any junk, but reasonably expected mishandling and misuse of the end product should be considered and should be described in documents to the extent necessary to conduct the hazard analysis.
- For each product and user groups, if necessary, should be taken into account by groups of users who are known to be particularly vulnerable to the hazards of certain foods.
- Descriptions must be updated, including if necessary, update the preliminary information and documents specifying the PRP-s and HACCP plans.

7.3.5. Flow diagrams, process steps management and control measures

7.3.5.1. *Flow diagrams*

- **It must prepare the technological schemes (flow diagrams) for different categories of products or processes involved in food safety management system.**
- **Flow diagrams have to include new measures. They are the basis for assessing the possible presence or increasing the hazards in a result of food consumption.**
- **Flow diagrams should be clear, accurate and sufficiently detailed. They should include, as appropriate:**

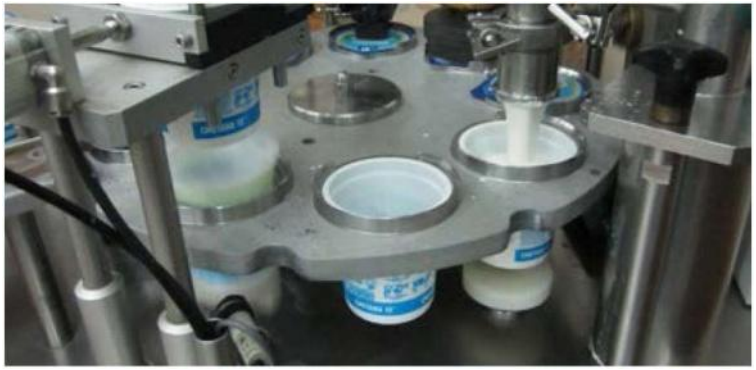


- the sequence and interaction at all stages of production;
- all processes carried out by external organizations, and subcontractors;
- places for raw materials, ingredients, additives, intermediates (semi-finished products) obtaining during their production and packaging;
- handling and processing centers;
- disposal of end products, semi-finished products, by-products and waste.

- In accordance with the requirements of the HACCP plan, the HACCP team shall verify the accuracy of flow diagrams and whether they are updated after inspection. Verified flow diagrams shall be kept as records.

7.3.5.2. Description of the steps and control measures

- The existing control measures, process parameters and / or the rigor with which they are administered or procedures that could affect the safety of food products, should be described to the extent necessary to conduct the hazard analysis.
- external requirements (for example, customers or supervisory bodies), which may influence the choice and severity of controls must be defined.



7.4. Hazard analysis

7.4.1. Basic requirements

- **HACCP team must carry out a hazard analysis to determine how to control the hazards, the degree of control necessary to ensure food safety, and which combination of control measures required.**

7.4.2. Hazard identification and definition of acceptable levels

7.4.2.1. Identifying and documenting of hazards

- **All food hazards can occur in connection with the types of products, processes and production conditions must be identified and documented. The identification should be based on:**
  - previously collected data and information on the preliminary hazards analysis step;
  - professional experience;
  - external information including the extent possible, epidemiological and other historical data;
  - information about the food chain for food hazards which may be safe the end products, intermediates and end products in food chain;
  - phase(s) (from raw materials, processing and commercial distribution), in which hazards can be imported, must be specified.

7.4.2.2. *Algorithm for hazards identifying*

- **In determining the hazards should be considered:**
  - the steps preceding and following the specified operation;
  - technological equipment for processing, utilities, maintenance and the environment;
  - preceding and subsequent steps in the food chain.

7.4.2.3. *Identification and documentation of acceptable levels*

- **If possible, acceptable levels of risk should be identified in the end product for each of the identified hazards.**
- **Nominal level should take into account existing legal and regulatory requirements, customer requirements for food safety, the intended use by the customer and other data relevant to the problem.**
- **It must be written justification of the determination and the result of this.**

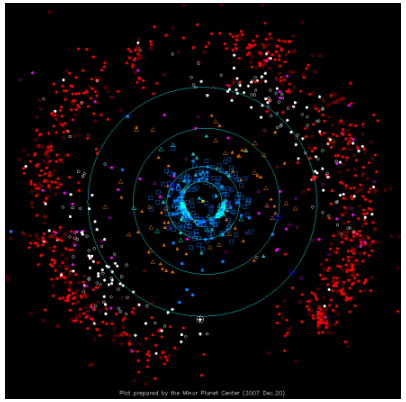
7.4.3. Assessment of the possible hazards

- It should assess the hazards in order to determine each identified risk.
- Is it the elimination or reduction to acceptable levels is needed for the production of safe food?
- Do I need a hazard control in order to reach a certain acceptable level?
- Any nutritional hazards should be assessed, depending on the severity of the adverse effects on human health and the probability of its occurrence.
- The methodology and results of the hazards assessment must be documented.

7.4.4. Selection of control measures

- Based on the hazards assessment, using an appropriate combination of control measures the organization should be selected and defined the control measures for preventing, eliminating or reducing the those hazards to acceptable levels. In these elections, each of which is determined by the degree of control, as described in the stages of production, should be reviewed in terms of its effectiveness against the identified hazards.

7.4.5. Assessment of control measures



Each selected control measure have to be classified in terms of whether it requires controlled through OPR or HACCP plans, using a logical approach, including an assessment of:

- its impact on the identified hazard, depending on the hardness of the execution;
- its ability to control (for example, for the timely monitoring, allowing immediate corrective action);
- its place in the system in comparison with other control measures;
- the probability of failure in the control measure or significant processing variability;
- the severity of the consequences (impact) in case of failure in its functioning;
- do control measure specifically designed and implemented to eliminate or significantly reduce the level of hazards;
- synergistic effects (i.e. the interaction that occurs between two or more measures, as a result of those that their combined effect is greater than the sum of their individual effects);
- control measures (categorized as belonging to the HACCP plan) shall be implemented in accordance with the requirements for the development of HACCP plans.
- other control measures should be implemented in the form of OPR in accordance with the requirements for the OPR development.
- the methodology and parameters used for classification must be defined in the documents and f the results evaluated should be documented, too.

7.5. THE DEVELOPMENT OF OPERATIONAL PREREQUISITES PROGRAMS (OPR)

- **OPR have to be documented and include the following information for each program:**
  - food hazards that should be monitored under the program;
  - measurements for control;
  - monitoring procedures that demonstrate that OPR introduced;
  - corrections and corrective actions to be taken if the monitoring show that the OPR does not control the hazard;
  - duties and powers;
  - record(s) for monitoring.

7.6. DEVELOPMENT OF HACCP PLANS

7.6.1. HACCP plan

- **HACCP plan shall be documented and include the following information for each critical control point (CCP):**
  - hazard (s) that should be manage by CCP;
  - critical limit (s) measure (s) and control (s);
  - monitoring procedure (s);
  - corrections and corrective actions to be taken if critical limits are violated;
  - responsibilities and authorities;
  - record (s) of monitoring.

7.6.2. Identification of CCPs

- For each hazard identified in the CCP should specifically have the control measures that can be controlled through the HACCP plans.

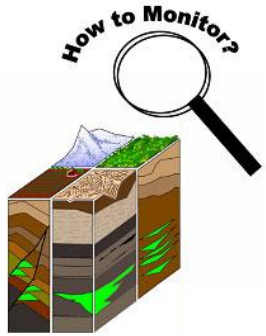
7.6.3. Determination of critical limits for CCPs

- FSMS must to set monitoring the critical levels of each critical control point.
- Should be to establish critical limits to ensure that a certain acceptable level of hazard in the end product will not be exceeded.

- Critical limits shall be measurable.
- The reason for chosen critical limits shall be
- documented.
- Critical limits based on subjective data (such as visual inspection of product, process, handling, etc.) have to be supported by instructions or specifications and/or education and training.

7.6.4. CCP monitoring system

- **A monitoring system which to show that CCP is under control, should be maintained for every one CCP. Such a system should include all scheduled measurements or observations of critical limits.**
- **The monitoring system shall consist of relevant procedures, instructions and records that provide the following:**
  - measurements or observations that provide timely results;
  - measuring;
  - appropriate calibration methods;
  - monitoring frequency;
  - duties and powers related to the monitoring and evaluation of results;
  - requirements for methods and records.



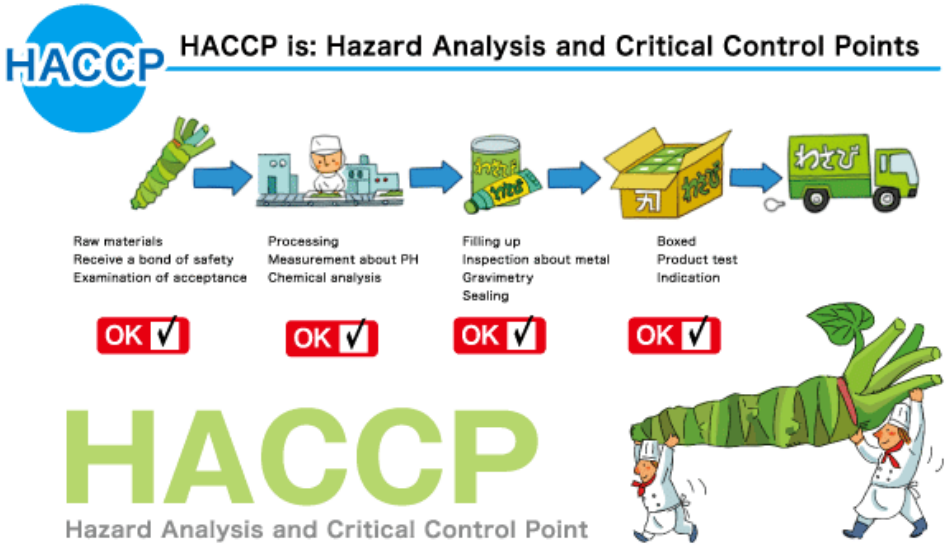
- **The frequency and method of monitoring should allow the Organization to determine when a critical limit is exceeded, so that the product was isolated in a timely manner prior to its use or consumption.**

7.6.5. Actions when the monitoring results exceed critical limits

- Planned corrections and corrective actions to be taken when critical limits are exceeded, have to be listed in the HACCP plan.
- The action have to ensure that the reason for the identified hazard nonconformities were returned under control and prevent their recurrence.
- The Organization should be established and maintained documented procedures consistent treatment of potentially dangerous products to ensure that they will not be released for implementation to evaluation.

7.7. UPDATING OF PRELIMINARY INFORMATION AND DOCUMENTS SPECIFYING THE PRP-s AND THE HACCP PLAN

- **Following the development of PRP-s and/or HACCP plans, if necessary, the organization shall update the following information:**
  - product performance;
  - use of the products at their destination;
  - flow diagrams;
  - stages of the process;
  - control measures.



- **If necessary, HACCP plans, procedures and instructions defining the PRP-s must be fixed.**

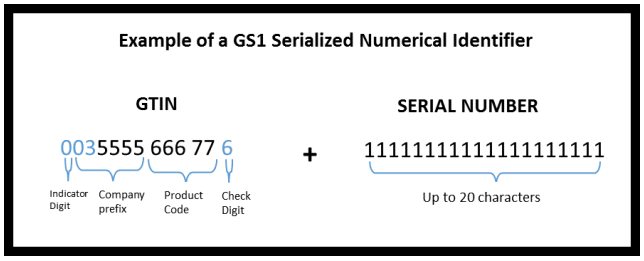
7.8. PLANNING OF THE VERIFICATION

- **A planning of verification shall define the purpose, methods, frequencies and responsibilities for the verification activities.**
- **The verification activities shall confirm that:**
  - the PRP(s) are implemented;
  - input to the hazard analysis is continually updated;
  - the OPR(s) and the elements within the HACCP plan are implemented and effective;
  - hazard levels are within identified acceptable levels, and
  - other procedures required by the organization are implemented and effective.

- **The output of this planning shall be in a form suitable for the organization's method of operations.**
- **Verification results shall be recorded and shall be communicated to the HACCP team. Verification results shall be provided to enable the analysis of the results of the verification activities.**
- **If system verification is based on analyzing the samples of the end product, and where such samples show nonconformity with the acceptable level of the food safety hazard, the affected lots of product shall be handled as potentially unsafe in accordance with the procedure for handling of potentially unsafe products.**

7.9. TRACEABILITY SYSTEM

- The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.
- The traceability system shall be able to identify incoming materials from the immediate suppliers and the initial distribution route of the end product.
- Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal.
- Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, to be based on the end product lot identification.



7.10. CONTROL OF NONCONFORMITY

7.10.1. Corrections

- **The organization shall ensure that when critical limits for CCP(s) are exceeded, or there is a loss of control of OPR (s), the products affected are identified and controlled with regard to their use and release. A documented procedure shall be established and maintained defining:**
  - the identification and assessment of affected end products to determine their proper handling,
  - and a review of the corrections carried out.

- **Products manufactured under conditions where critical limits have been exceeded are potentially unsafe products and shall be handled in accordance with handling of potentially unsafe products. Products manufactured under conditions where OPR(s) have not been conformed with shall be evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety and shall be handled in accordance with handling of potentially unsafe product. The evaluation shall be recorded.**
- **All corrections shall be approved by the responsible person(s), and shall be recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots.**

7.10.2. Corrective actions

- **Data derived from the monitoring of operational PRPs and CCPs shall be evaluated by designated person(s) with sufficient knowledge and authority to initiate corrective actions.**
- **Corrective actions shall be initiated when critical limits are exceeded or when there is a lack of conformity with OPR(s).**

- **The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered. These include:**
  - reviewing of nonconformities (including customer complaints),
  - reviewing of trends in monitoring results that may indicate development towards loss of control,
  - determining the cause(s) of nonconformities,
  - evaluating the need for action to ensure that nonconformities do not recur,
  - determining and implementing the actions needed,
  - recording the results of corrective actions taken, and
  - reviewing of corrective actions taken to ensure that they are effective.
- **Corrective actions shall be recorded.**

7.10.3. Handling of potentially unsafe products

7.10.3.1. General

- **The organization shall handle nonconformity products taking action(s) to prevent them from entering the food chain unless it is possible to ensure that:**
  - the food safety hazard(s) of concern has (ve) been reduced to the defined acceptable levels,
  - the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain, or
  - the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

- **All lots of product that may have been affected by a nonconforming situation shall be held under control of the organization until they have been evaluated.**
- **If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal.**

  NOTE: *The term "withdrawal" includes recall.*
- **The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.**

7.10.3.2. *Evaluation or release*

- **Each lot of product affected by the nonconformity shall only be released as safe when any of the following conditions apply:**
  - evidence other than the monitoring system demonstrates that the control measures have been effective;
  - evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (i.e. identified acceptable levels as identified in accordance with hazard identification and determination of acceptable levels);
  - the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned:

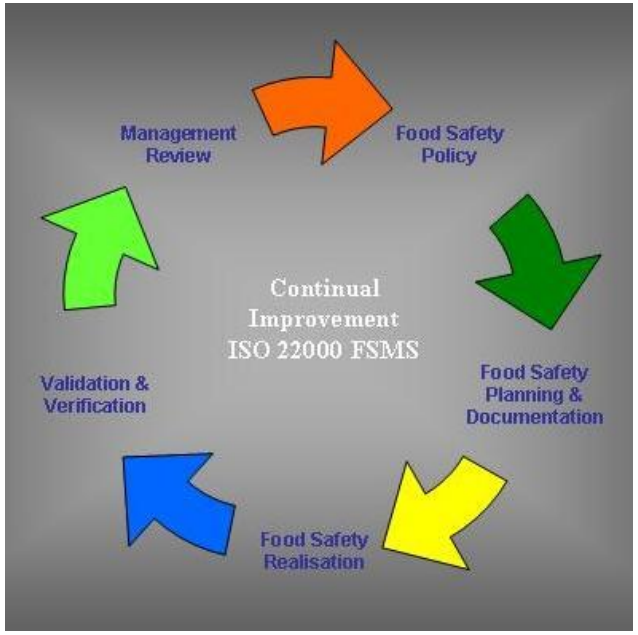
7.10.3.3. *Disposition of nonconforming products*

- **Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:**
  - reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels;
  - destruction and/or disposal as waste.

7.10.4. Withdrawals

- **To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe**
  - top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and
  - the organization shall establish and maintain a documented procedure for
    - notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
    - handling of withdrawn products as well as affected lots of the products still in stock, and
    - the sequence of actions to be taken.
- **Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.**
- **The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review.**
- **The organization shall verify and records the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. mock withdrawal or practice withdrawal).**

1.6. Validation, verification and improvement of food safety management system



8. VALIDATION, VERIFICATION, AND IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM

8.1. GENERAL

- **The food safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations, and to verify and improve the food safety management system.**

8.2. VALIDATION OF CONTROL MEASURE COMBINATIONS

- **Prior to implementation of control measures to be included in OPR(s) and the HACCP plan and after any change therein, the organization shall validate) that:**
  - the selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated, and
  - the control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels.
- **If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed.**
- **Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.**

8.3. CONTROL OF MONITORING AND MEASURING

- **The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures.**
- **Where necessary to ensure valid results, the measuring equipment and methods used**
  - shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded,
  - shall be adjusted or re-adjusted as necessary,
  - shall be identified to enable the calibration status to be determined,
  - shall be safeguarded from adjustments that would invalidate the measurement results, and
  - e) shall be protected from damage and deterioration.
- **Records of the results of calibration and verification shall be maintained.**
- **In addition, the organization shall assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is nonconforming, the organization shall take action appropriate for the equipment and any product affected. Records of such assessment and resulting actions shall be maintained.**
- **When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and shall be reconfirmed as necessary.**

8.4. FOOD SAFETY MANAGEMENT SYSTEM VERIFICATION

8.4.1. Internal audit

- **The organization shall conduct internal audits at planned intervals to determine whether the food safety management system**
  - conforms to the planned arrangements, to the food safety management system requirements established by the organization, and to the requirements of this international standard, and
  - is effectively implemented and updated.
- **An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work.**
- **The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, shall be defined in a documented procedure.**
- **The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.**

8.4.2. Evaluation of individual verification results

- **The food safety team shall systematically evaluate the individual results of planned verification.**
- **If verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity. Such action shall include, but is not limited to, review of**

- existing procedures and communication channels ,
- the conclusions of the hazard analysis, the established OPR(s) and the HACCP plan,
- the PRP(s), and
- the effectiveness of human resource management and of training activities.

8.4.3. Analysis of results of verification activities

- **The food safety team shall analyses the results of verification activities, including the results of the internal audits and external audits. The analysis shall be carried out in order**

  - to confirm that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the organization,
  - to identify the need for updating or improving the food safety management system,
  - to identify trends which indicate a higher incidence of potentially unsafe products,
  - to establish information for planning of the internal audit programme concerning the status and importance of areas to be audited, and
  - to provide evidence that any corrections and corrective actions that have been taken are effective.
- **The results of the analysis and the resulting activities shall be recorded and shall be reported, in an appropriate manner, to top management as input to the management review. It shall also be used as an input for updating the food safety management system.**

8.5. IMPROVEMENT

8.5.1. Continual improvement

The top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of control measure combinations, corrective actions and food safety management system updating.

NOTE : *ISO 9001 addresses continual improvement of the effectiveness of quality management systems. ISO 9004 provides guidance on continual improvement of the effectiveness and efficiency of quality management systems beyond what is addressed in ISO 9001.*

8.5.2. Updating the food safety management system

- **The top management shall ensure that the food safety management system is continually updated.**
- **In order to achieve this, the food safety team shall evaluate the food safety management system at planned intervals. The team shall then consider whether it is necessary to review the hazard analysis, the established OPR(s) and the HACCP plan.**
- **The evaluation and updating activities shall be based on**
  - input from communication, external as well as internal, as stated in paragraph 5.6.
  - input from other information concerning the suitability, adequacy and effectiveness of the food safety management system,
  - output from the analysis of results of verification activities, and
  - output from the management review.

- **System updating activities shall be recorded and reported, in an appropriate manner, as input to the management review.**

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