ISO 22000: 2005 “Food safety management systems — Requirements for any organization in the food chain”

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ISO 22000 is to demonstrate ability of organization to control food safety hazards

- This International Standard specifies requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption
- Standard is intended to address only aspects of food safety concerns
- Developed as an auditable standard

ISO 22000 for the food safety

- Is related to the presence of and levels of food-borne hazards in food at the point of consumption
- As food safety hazards may be introduced at any stage of the food chain, adequate control throughout the food chain is essential
- Is a joint responsibility of all parties participating in the food chain
- Failures in food supply can cause human suffering, death, poor reputation, violations, poor nutrition, poor quality products and decreased profits

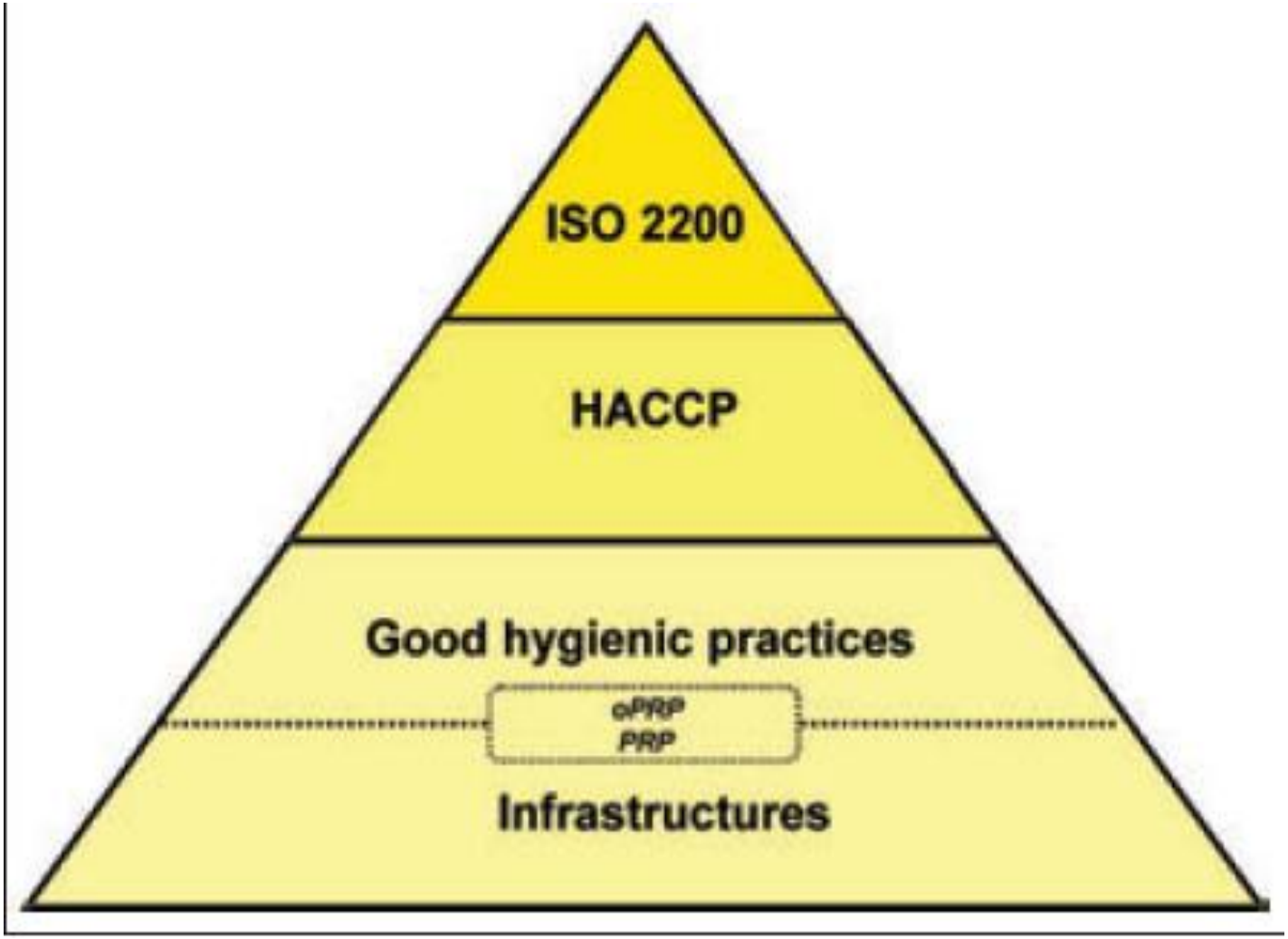
ISO 22000 represents an international consensus

- Technological know-how
- Defines characteristics that products and services will be expected to meet on export markets
- Give a basis for making the right decisions when investing
- The existence of divergent national or regional standards can create technical barriers to trade, International Standards are the technical means by which political trade agreements can be put into practice

Key elements

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
- prerequisite programmes
- HACCP principles


ISO 2200
HACCP
Good hygienic practices
oPRP
PRP
Infrastructures

Communication

Essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain

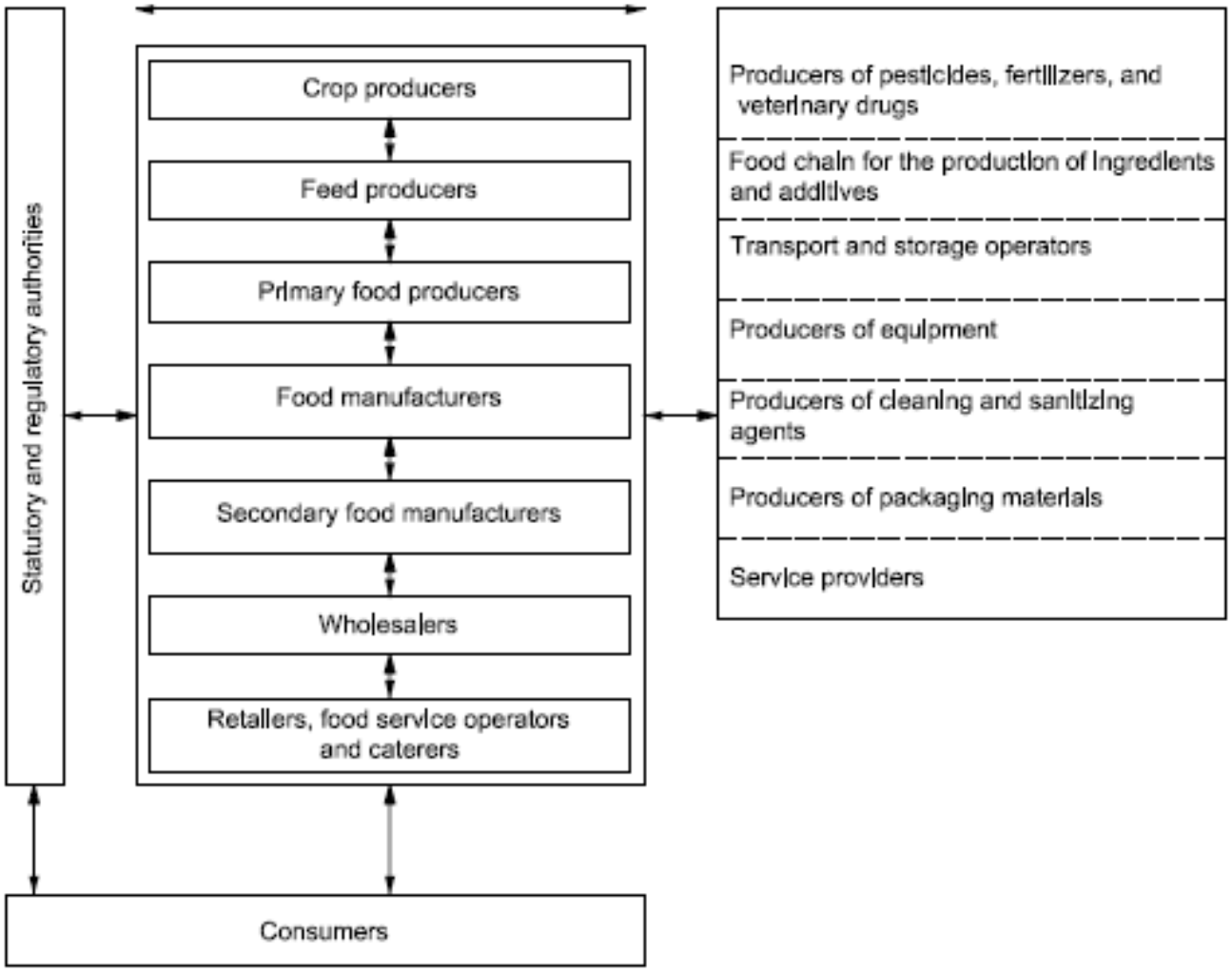
This implies communication:

- between organizations both upstream and downstream in the food chain
- with customers and suppliers about identified hazards and control measures

ISO 22000 is consensus agreements between all the economic stakeholders concerned:

- Suppliers
- Food business operators
- Government regulators
- Consumers
- NGO
- other stakeholders

Communication channels among interested parties of the food chain



Benefits (1)

- Confidence that organizations implementing ISO 22000 have the ability to identify and control food safety hazards
- International in scope
- Provides potential for harmonization of national standards
- Provides a reference for the whole food chain
- Provides a framework for third party certification

Benefits (2)

- Saves resources by reducing overlapping system audits
- Organizes and targets communication among partners
- Resource optimization
- Improves documentation
- Better planning, less post-process verification

Standard applicable to organizations within the food chain

- feed producers
- primary producers
- food manufacturers
- transport and storage operators and subcontractors
- retail
- food service outlets
- inter-related organizations such as producers of equipment, packaging material, cleaning agents, additives and ingredients
- service providers

ISO 22000 and ISO 9001?

- The 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 provides maximum benefit for the organization and interested parties
- ISO 22000 was specifically developed to be easily integrated with ISO 9001 systems (Quality management systems). The management system elements of the standard are largely word-for-word that of the ISO 9001 equivalent, with some small amendments relating specifically to food safety

The Scope of ISO 22000

- The standard is applicable to all organizations, regardless of size, which are involved in any aspect of the food chain

Strategy to be used to ensure hazard control

- During hazard analysis, the organization determines the strategy to be used to ensure hazard control by combining:
- PRP(s)
- operational PRP(s)
- HACCP plan

HACCP is an approach to food safety

It's about identifying and managing risk

- Anticipating potential hazards
- Designing controls to prevent hazards
- Implementing controls
- Monitoring the controls
- Continuously improving the controls

Standard specifies requirements to enable an organization

- to plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer
- to demonstrate compliance with applicable statutory and regulatory food safety requirements
- to evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction

Standard specifies requirements to enable an organization (2)

- to effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain
- to ensure that the organization conforms to its stated food safety policy
- to demonstrate such conformity to relevant interested parties
- to seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to this International Standard

Food safety requirements in the Standard

- Food safety management system
- Management responsibility
- Resource management
- Planning and realization of safe products
- Validation, verification and improvement of the food safety management system

ISO 22000 and Codex Alimentarius

- ISO 22000 integrates the Codex Alimentarius Commission's 7 principles of HACCP and dynamically combine it with PRPs necessary to control and reduce any food safety hazards
- PRPs (PRE-REQUISITE PROGRAM) are also referred to as good hygienic practices(GHP), good agricultural practices, good production practices, good manufacturing practices(GMP), good distribution practices, and good trading practices

Food safety management system

General requirements for a food safety management system

An effective food safety management system shall be:

- developed
- documented
- implemented
- maintained
- evaluated
- updated

Scope of application of FSMS shall be identified

Organization shall:

- Ensure that hazards shall be identified, evaluated and managed as food produced would not harm consumer
- To communicate within food chain on the food safety issues
- To ensure proper internal communication
- Periodically evaluate and update food safety management system
- Any external process chosen shall me managed (incl. documentation)

Documentation requirements

- Food safety management documents shall include:
  - documents on food safety policy and objectives
  - procedures
  - records

- Food safety management documents shall be managed
  - procedure to control your FSMS documents shall be developed

- Food safety records shall be controlled
- Set of records shall be established
- Documented procedure to control FSMS records shall be developed

Management responsibility

Management commitment

- Top managers shall demonstrate commitment to develop and implement food safety management system
- Adequate resources shall be allocated
- Food safety policy shall be defined, documented and communicated

Food safety management system planning

- Top managers plan the development of FSMS
- Integrity of FSMS shall be maintained when changes in FSMS are planned and implemented

Responsibility and authorities

- Top managers shall define and communicate organization's FSMS responsibilities and authorities
- All personnel are responsible for reporting organization's FSMS problems
- Designated personnel are given the responsibility and authority to solve FSMS problems

Food safety team leader

- Appointed by top management
- Irrespective of other responsibilities has responsibility and authority:
  - to manage food safety team and organize its work
  - ensure training and education of team members
  - ensure that FSMS is established, implemented, maintained and updated
  - report to top managers on the effectiveness and suitability of FSMS

External communication

- Effective communication shall be established with:
  - suppliers and service providers
  - consumers
  - authorities
  - other relevant organizations
- Information important for other organizations in the food chain to address food safety issues shall be communicated
- Records on such communication shall be available
- Responsibility and authority to communicate externally about food safety shall be allocated

Internal communication

- Effective internal communication arrangements shall be established, implemented and updated on the food safety issues
- Food safety team shall have appropriate information on any changes related to food safety (e.g. new raw materials, equipment, cleaning programmes, legal requirements, complains etc.)
- Food safety team responsible for updating FSMS according this information

Emergency preparedness and response

- Procedures to manage food safety emergencies and accidents shall be established, implemented and maintained by top managers

Management review

- Top managers shall plan and carry out regular food safety management system reviews
- Records of your food safety management reviews shall be kept

Management review inputs

- Follow-up actions from previous reviews
- Verification results
- Changing circumstances
- Emergencies, accidents, withdrawals
- System-updating results
- Review of communication activities
- External audits or inspections

Management review outputs

Management review outputs shall generate decisions and actions (outputs) that:

- assure the safety of the food products
- improve the effectiveness of organization's FSMS
- address FSMS resource needs
- update and revise food safety policy and objectives

Resource management

Provision of resources

- Organization shall be provided by the resources needed to establish, implement, maintain and update FSMS

Human resources

- Competent food safety personnel
- Records of the contracts and agreements with external food safety management system experts shall be maintained
- Records of agreements or contracts defining the responsibility and authority of external experts shall be available

Competence, awareness and training

- Necessary competencies are identified
- Training to ensure that personnel have the competencies they need is delivered
- Personnel aware of how their individual job performance influences food safety
- Effectiveness of FSMS training and awareness activities is evaluated
- Records

Infrastructure

- Organization shall provide the resources for the establishment and maintenance of the infrastructure needed to comply with ISO 22000

Work environment

- The organization shall provide the resources for the establishment, management and maintenance of the work environment needed to implement the requirements of the ISO 22000

Planning and realization of safe products

Implementation of food safety program

Review

- Prerequisite programmes

Update

- Preliminary steps of HACCP

Document

- HACCP

Planning and realization of safe products

- The organization shall plan and develop the processes needed to realize safe products
- The organization shall implement, operate and ensure effectiveness of planned activities
- This includes:
  - PRPs
  - operational PRPs
  - HACCP plan

PRP and operational PRP

- **Prerequisite programme (PRP) -** (food safety) basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption
- **Operational prerequisite programme (Operational PRP) -** PRP identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment

Prerequisite programs (PRPs)

PRPs shall be established, implemented and maintained to assist in controlling:

- the likelihood of introducing food safety hazards to the product through the work environment
- biological, chemical and physical contamination of the product including cross contamination
- food safety hazard levels in food and environment

PRPs shall be suitable

- Meet organization's unique food safety needs
- Reflect and respect the nature of organization and how it operates
- Meet legal requirements
- Shall be approved by food safety team

When selecting and/or establishing PRPs appropriate information from external sources shall be considered and utilized

- Construction and lay-out of buildings
- Lay-out of premises
- Supplies of air, water, energy, etc.
- Supporting services (incl. waste and sewage disposal)
- Equipment
- Management of purchased materials, disposals and handling of products
- Measures for prevention of cross-contamination
- Cleaning and sanitizing
- Pest control
- Personnel hygiene etc.

Steps for the implementation of the HACCP principles

1. Assemble HACCP team
2. Describe product
3. Identify intended use
4. Construct flow diagram
5. On-site confirmation of flow diagram

+ 7 HACCP principles

7 HACCP Principles

1. Conduct a Hazard Analysis of the production process which identifies on a flow diagram where significant hazards may occur
2. Identify the Critical Control Points (CCPs) in the production process
3. Establish Critical Limits for the preventative measures set up to control the hazards associated with each CCP identified
4. Establish CCP monitoring requirements which will verify the efficacy of the preventative measures
5. Establish Corrective Actions to take when monitoring results show that a critical limit has not been met
6. Establish an effective record-keeping system that documents all aspects of the HACCP system and its operation
7. Establish a program to verify the HACCP system is functioning properly

Step	HACCP principle
1. Assemble HACCP team	
2. Describe product	
3. Identify intended use	
4. Construct flow diagram	
5. On-site confirmation of flow diagram	
6. Identify potential hazards	1 principle
7. Determine critical control points	2 principle
8. Establish critical limits for critical control points	3 principle
9. Establish monitoring procedures	4 principle
10. Establish corrective actions	5 principle
11. Establish verification procedures	6 principle
12. Establish documentation and record keeping	7 principle

Preliminary steps to enable hazard analysis

All relevant information needed to conduct hazard analysis shall be

- collected,
- maintained,
- updated and
- documented

Food safety team

- Shall be appointed
- Multidisciplinary knowledge and experience
- Includes organization's products, processes, equipment and food safety hazards
- Records that show that your food safety team has the necessary knowledge and experience shall be maintained

Product characteristics. Raw materials, ingredients and product-contact materials

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis, including:

- Product characteristics
- Composition of ingredients
- Origin
- Method of production
- Packaging and delivery methods
- Storage conditions and shelf life
- Preparation and handling before use
- Food safety related acceptance criteria, specifications

Product characteristics. Characteristics of end products

Characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis, including:

- Product name
- Composition
- Characteristics relevant to food safety
- Intended shelf life and storage conditions
- Packaging
- Labelling
- Method of distribution

Intended use

- Shall be considered and described:
  - the intended use
  - the reasonably expected handling of the end product
  - any unintended bust reasonably expected mishandling and misuse of the end product
- User groups (groups of consumers) for each end product shall be identified
- Vulnerable to specific food safety hazards shall be considered
- Documents shall be kept up to date

Flow diagrams

- Is schematic and systematic presentation of the sequence and interactions of steps
- Provide basis for evaluating the possible occurrence, increase or introduction of food safety hazards
- Clear, accurate and sufficiently detailed
- Flow diagrams include:
  - Sequence and interaction of all steps in the operation
  - Any outsourced processes and subcontracted work
  - Where raw materials, ingredients and intermediate products enter the flow
  - Where reworking and recycling take place
  - Where end products, intermediate products, by-products and waste are released or removed
- Shall be checked on-site (verification)

Hazard analysis

Hazard analysis shall be conducted by the food safety team to determine:

- which hazards need to be controlled
- degree of control required to ensure food safety
- which combination of control measures is required

- All hazards shall be identified and recorded
- The steps from raw materials, processing and distribution at which each hazard may be introduced shall be indicated
- Acceptable level of food safety hazard in the end product shall be determined

Hazard assessment

- Shall be conducted to determine, for each hazard, whether its elimination or reduction to acceptable levels is essential to produce safe food and whether its control is needed to enable acceptable levels to be met
- Hazard assessment methodology shall be described
- Results of food safety hazard assessment shall be recorded

Selection and assessment of control measures

- Based on hazard assessment, an appropriate combination of control measures shall be selected which are capable of preventing, eliminating or reducing hazards to defined acceptable levels
- Control measures shall be reviewed with respect to its effectiveness
- Control measures selected shall be categorized as to whether they need to be managed through operational PRPs or by the HACCP plan

Selection and categorization of control measures includes:

- Effect on identified hazard
- Feasibility for monitoring
- Its place within the system relative to other control measures
- Likelihood of failure
- Severity of consequences in case of failure
- Whether control measure is specifically established and applied to eliminate or significantly reduce level of hazard
- Synergistic effects (interaction between two or more measures)

Establishing operational prerequisite programs (operational PRPs)

Operational PRPs include following information for each programme:

- Hazard controlled by the programme
- Control measure
- Monitoring procedure
- Corrections and corrective actions
- Responsibilities and authorities
- Records of monitoring

Establishing HACCP plan

- Documented
- Shall include following information for each identified CCP:
  - food safety hazards to be controlled
  - control measures
  - critical limits for each (CCP)
  - monitoring procedures
  - corrections and corrective actions (if critical limits are exceeded)
  - responsibilities and authorities
  - records of monitoring

Determination of critical limits for CCP

- Critical limits – for monitoring of each CCP
- Critical limits shall be established to ensure that the identified acceptable level of the food safety hazard in the end product is not exceeded
- Shall be measurable
- Rationale for the chosen critical limits shall be documented
- Critical limits based on subjective data (e.g. visual inspection) shall be supported by instructions or specifications and/or education and training

System for monitoring of CCP

- Demonstrates that CCP is under control
- Established for each CCP
- Covers:
  - measurements or observations that provide results within an adequate time frame
  - monitoring devices used
  - applicable calibration methods
  - monitoring frequency
  - responsibility and authority
  - record requirements

Actions when critical limits are exceeded

- Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified
- Actions shall ensure that:
  - cause of conformity is identified
  - parameters controlled at the CCP are brought back under control
  - recurrence is prevented
- Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products

Updating

- If necessary, following information shall be updated:
- Product characteristics
- Intended use
- Flow diagrams
- Process steps
- Control measures
- HACCP plan
- Procedures and instructions specifying PRPs

Verification planning

- Verification activities shall confirm that:
  - PRPs are implemented
  - input to hazard analysis is continually updated
  - operational PRPs and HACCP are implemented and effective
  - hazard levels are within acceptable levels
  - …
- Results of verification activities shall be recorded

Traceability system

- Shall be established and applied
- Enables the identification of product lots and their relation to batches of raw materials, processing and delivery records
- Incoming materials from the immediate suppliers and the initial distribution route of the end product should be traceable

Control of nonconformity

- Nonconforming products (when CCPs are exceeded or there is a loss of control of operational PRPs) shall be identified and controlled with regard of their use and release
- Documented procedure shall be established and maintained defining:
  - identification and assessment of effected end products
  - review of the corrections carried out
- All corrections shall be approved by responsible person
- Cause and consequence, information needed for traceability shall be recorded

Corrective actions

- Taken when critical limits are exceeded or there is a lack of conformity with operational PRPs
- Documented procedures shall specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence and bring process or system back into control:
  - reviewing nonconformities
  - reviewing trends and monitoring results
  - determining causes
  - actions that nonconformities do not recur
  - results of taken corrective actions
  - reviewing corrective actions taken to ensure that they are effective

Handling of potentially unsafe products

- It shall be prevented that nonconforming product enter food chain unless it is possible to ensure that:
  - hazards of concern have been reduced to defined acceptable levels
  - hazards of concern will be reduced to defined acceptable levels prior to entering food chain
  - product still meets defined acceptable levels despite of nonconformity
- All lots affected shall be held under control until they have been evaluated
- In case of determined unsafe product – relevant interested parties shall be notified and withdrawal initiated

Evaluation for release

- Each lot affected by nonconformity shall only be released as safe when any of following conditions apply:
- Evidence other than monitoring system demonstrates that control measures have been effective
- Evidence shows that combined effect of control measures complies with intended performance
- Results of sampling, analysis or other verification activities demonstrate that affected product complies with the identified acceptable levels

Disposition of nonconforming products

If following evaluation the lot of product is not acceptable for release it shall be handled as follows:

- reprocessing or further processing
- destruction and/or other disposal as waste

Withdrawals

- Top management shall appoint personnel having an authority to initiate withdrawal and personnel responsible for executing the withdrawal
- Documented procedure shall be established for:
  - notification to relevant interested parties
  - handling of withdrawn products and affected lots still in stock
  - sequence of actions to be taken
- Withdrawn products shall be held under supervision
- The cause, extent an result of withdrawal shall be recorded and reported
- Effectiveness of withdrawal programme shall be verified

Validation, verification and improvement of the food safety management system

Validation, verification and improvement of the FSM system. General

- Processes needed to validate control measures and to verify and improve the FSM system shall be planned and implemented

Validation of control measure combinations

- Control measures shall be validated prior to implementation in operational PRPs and the HACCP plan and after any change that:
  - selected control measures are capable of achieving the intended control of food safety hazard
  - control measures are effective and capable of, in combination, ensuring control of identified hazards 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

Control of monitoring and measuring

- Evidence shall be provided that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures
- Measuring equipment and methods used shall be:
  - calibrated or verified at specified intervals
  - identified to enable the calibration status to be determined
  - safeguarded from adjustments that would invalidate the measurement results
  - be protected from damage or deterioration

Food safety management system verification

- Internal audits at planned intervals
- Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process
- Managers shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes
- Follow up on the actions taken

Evaluation of individual verification results

- Food safety team shall systematically evaluate the individual results of planned verification
- Actions shall be taken if verification does not demonstrate conformity with the planned arrangements, e.g. review of
  - existing procedures and communication channels
  - hazard analysis, operational PRPs, HACCP plan
  - PRPs
  - effectiveness of human resource management and of training activities

Analysis of results of verification activities

- Food safety team shall analyse the results of verification activities, including internal and external audits
- Analysis shall be carried out in order:
  - to confirm that overall performance meets planned arrangements
  - to identify the need for updating
  - to identify trends which indicate a higher incidence of potentially unsafe products
  - to establish information for planning internal audits
  - to provide evidence that proves that actions taken to address nonconformities are effective
- Results of verification analysis and the activities that result from your analysis shall be recorded and reported
- Analytical results and activities shall be used as input to update FSMS

Improvement

Top managers shall ensure that the organization continually improves effectiveness of FSMS 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
- food safety management system updating

Updating the FSMS

- Top management shall ensure that FSMS is continually updated
- Food safety team shall evaluate FSMS at planned intervals
- Evaluation shall be based on:
  - input from communication (internal and external)
  - input concerning suitability, adequacy and effectiveness
  - output from analysis of results of verification activities
  - output from management review
- Updating activities shall recorded and reported

ISO 22000 is under revision

- ISO 22000, Food safety management systems -- Requirements for any organization in the food chain is under revision, with the draft version available for purchase from mid 2016

- The final updated version is expected early 2017

http://www.iso.org/iso/home/standards/management-standards/iso22000.htm

ISO 22000 family - number of standards each focusing on different aspects of food safety management

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

Thank you for attention!