ISO 22000/HACCP in Seafood Processing Industry

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Food is the thing for which every human being is working hard. The access to sufficient amount Safe and nutritious food is key to sustaining life and promoting good health. In this changing pattern of life where boundaries are not defined so longer and food trade is taking place. Unsafe food containing harmful bacteria, viruses, parasites or chemical substances, causes more than 200 diseases ranging from diarrhoea to cancers. Almost 1 in 10 people in the world fall ill after eating contaminated food and 4,20,000 die every year, resulting in the loss of 33 million healthy life years. Children under 5 years of age carry 40% of the foodborne disease burden, with 125 000 deaths every year. Diarrhoeal diseases are the most common illnesses resulting from the consumption of contaminated food, causing 550 million people to fall ill and 2,30,000 deaths every year (WHO, 2019).

As unsafe food can have severe health implications, so it's crucial for organizations in the food supply chain to follow steps to ensure their processes and products are safe. Today, many food products are either exported or imported across national borders emphasises the need for a global standard for food safety management. ISO 22000 describes requirements for a food safety management system and sets out what requirements an organization can follow to help identify and control hazards related to food safety.

ISO 22000 (Food Safety Management Systems - Requirements for any organization in the food chain):

ISO 22000 is becoming popular as it is a hybrid of the ISO 9001 Quality Management System and the HACCP Food Safety system which is meant for an international solution to improving food safety. ISO 22000 describes requirements for a food safety management system. This describes requirements an organization which is must to demonstrate that it can control food safety hazards. ISO 22000 industries can get certified to the standard.

ISO 22000 covers organizations across the whole food chain, from the farm to the table. It is designed to ensure fair competition and provide for communication within and between organizations along the food chain. The standard incorporates and complements the main elements of ISO 9001, the standard for quality management systems, as well as hazard analysis and critical control points (HACCP), a preventive approach to food safety.

The standard provides a framework for organizations to develop, implement, monitor and continually improve a food safety management system, or FSMS, within the context of their overall business risks. To comply with the standard, businesses must meet all applicable food safety-related statutory and regulatory requirements.

Organizations that want to create an FSMS that is more focused, coherent and integrated than what the law requires can benefit from ISO 22000. It helps organizations with aspects of their operations such as food safety, hazard controls, their supply chain, HACCP, their business strategy and food traceability.

ISO 22000:2018 is recently got revised over ISO 22000:2005 which is a food safety standard for businesses in the global food chain. The International Organization for Standardization (ISO) developed the standard ISO 22000:2018, Food safety management systems – Requirements for any organization in the food chain.

FSSC 22000 is basically the ISO 22000 standard plus ISO 22002-1:2009 "Prerequisite programmes on food safety – Part 1: Food manufacturing." FSSC 22000 was developed to meet the benchmarking requirements for the Global Food Safety Initiative (GFSI) (see "GFSI-Benchmarked Audit Schemes"). GFSI felt that ISO 22000 did not provide sufficient guidance to companies for the prerequisite programs. Besides those companies seeking certification of an FSMS, there are many that utilize ISO 22000 as a framework to develop an FSMS but have elected not to spend the money on certification. Buyers throughout the world now mandate that their suppliers adopt one of the GFSI-approved audit schemes to ensure the safety of what they are purchasing.

History of ISO 22000

ISO 22000 was initially published in September 2005, it has been widely adopted globally as a response to:

• A number of successive food crises, such as the mad cow disease or adulteration of wines with ethylene glycol and its derivatives, to name a few that occurred in the preceding years.

• The globalisation of food supply chains creating uncertainty with regard to the origin of food products

• The need from the food industry to demonstrate that systems were established and operating in accordance to applicable laws and the requirements specified by the Codex Alimentarius, and

• A need to facilitate the harmonization of international food safety regulations

The revised document of ISO 22000:2005 published in June 2018 as ISO 22000:2018. One of the main motivations for its revision was the alignment of the strategic direction of an organization with its food safety management. Additionally, the adoption of the Annex SL structure allows an easy integration with other international standards such as ISO 9001, ISO 14001 and ISO 45001, making a smooth road for auditors and auditees.

The purpose of ISO 22000

ISO 22000:2018 describes the requirements for a food safety management system and certification is done. It details out needs to do to demonstrate by an organization for its ability to control food safety hazards in order to ensure that safe food and traceability at every step of the supply chain. It can be used by any organization regardless of its size or position in the food chain.

The primary elements of ISO 22000:

The primary elements of an FSMS are:

- Interactive communication across the organization
- System management that includes documentation
- Prerequisite programs, which ensure a clean, sanitary environment
- HACCP principles, which help to identify, prevent and remove food safety hazards

In addition this standard also covers other principles, which are part of all ISO management system standards comprises:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision-making
- Relationship management

Building blocks of the ISO 22000 standard

1. Hazard Analysis and Critical Control Points (HACCP) as defined in the Codex Food Hygiene document

2. Prerequisite programs that define the basic conditions to maintain an hygienic environment

3. The components that are needed to have an effective management system

The final building block is based on ISO 9001:2000 and ISO 9001:2008 "Quality management systems – Requirements."

Benefits of ISO 22000

ISO 22000 helps organizations minimize food risks and improve performance as it relates to food safety. It does so by providing a framework they can use to develop an FSMS, a systematic approach to addressing food safety issues. Compliance with ISO 22000 provides following benefits:

- Improved health and safety
- Improved customer satisfaction
- Helps to meet regulatory requirements
- Help meeting other standards and guidelines
- Enhanced transparency

- Improved response to risks
- Reduced investigation time
- Global recognition
- Increased business opportunities

Details of ISO 22000:2018

1. Scope

2. Normative references

3. Terms and definitions – 45 definitions have been elucidated for proper understanding and implementation.

4. Context of the organization

    4.1 Understand your organization and its unique context
    4.2 Clarify the needs and expectations of interested parties
    4.3 Define the scope of your food safety management system
    4.4 Establish and maintain a food safety management system

5. Leadership

    5.1 Provide leadership by accepting responsibility for safety
    5.2 Provide leadership by establishing a food safety policy
    5.2.1 Provide leadership by developing a food safety policy
    5.2.2 Provide leadership by communicating food safety policy
    5.3 Provide leadership by assigning organizational roles
    5.3.1 Provide leadership by allocating responsibilities
    5.3.2 Provide leadership by supporting food safety teams
    5.3.3 Provide leadership by encouraging feedback

6. Planning

    6.1 Define actions to manage your FSMS risks and opportunities
    6.1.1 Determine risks and opportunities when planning your FSMS
    6.1.2 Plan how you're going to address FSMS risks and opportunities
    6.1.3 Consider requirements and impacts when selecting FSMS actions
    6.2 Formulate FSMS objectives and develop plans to achieve them
    6.2.1 Establish FSMS objectives at relevant functions and areas
    6.2.2 Plan how to achieve your organization's FSMS objectives
    6.3 Control how FSMS changes are planned and implemented

7. *Support*

    7.1 Support your FSMS by providing the necessary resources

    7.1.1 Supply internal and external resources for your FSMS
    7.1.2 Verify the competence of your Organization's FSMS people
    7.1.3 Provide the infrastructure that your FSMS needs to have

7.1.4 Establish a suitable work environment for your FSMS

7.1.5 Consider how external FSMS elements are used

7.1.6 Control the use of external FSMS elements

7.2 Support your FSMS by ensuring that people are competent

7.3 Support your FSMS by making people aware of their duties

7.4 Support your FSMS by controlling relevant communications

7.4.1 Support your FSMS by establishing communication systems

7.4.2 Support your FSMS by facilitating external communication

7.4.3 Support your FSMS by encouraging internal communication

7.5 Support your FSMS by managing documented information

7.5.1 Support your FSMS by including necessary documents and records

7.5.2 Support your FSMS by managing the use of documents and records

7.5.3 Support your FSMS by controlling relevant documents and records

7.5.3.1 Control your organization's FSMS documents and records

7.5.3.2 Control how FSMS documents and records are controlled

8. *Operations*

8.1 Establish processes needed to realize safe products

8.2 Establish suitable prerequisite programmes (PRPs)

8.2.1 Make sure that prerequisite programmes are developed

8.2.2 Make sure that prerequisite programmes are implemented

8.2.3 Make sure that prerequisite programmes are acceptable

8.2.4 Make sure that prerequisite programmes are suitable

8.3 Establish an effective product traceability system

8.4 Establish emergency management arrangements

8.4.1 Formulate emergency response procedures

8.4.2 Respond to emergency situations and incidents

8.5 Establish measures to control food safety hazards

8.5.1 Get ready to do a food safety hazard analysis

8.5.1.1 Consider the context of hazard analysis

8.5.1.2 Consider raw materials and ingredients

8.5.1.3 Consider all end product characteristics

8.5.1.4 Consider intended use of end products

8.5.1.5 Consider your process flow diagrams

8.5.1.5.1 Prepare product and process flow diagrams

8.5.1.5.2 Confirm the accuracy of process flow diagrams

8.5.1.5.3 Describe processes and process environment

8.5.2 Perform your organization's hazard analysis

8.5.2.1 Assign responsibility for hazards and controls
8.5.2.2 Identify hazards and define acceptable levels
8.5.2.2.1 Identify your food safety hazards
8.5.2.2.2 Consider your hazard environment
8.5.2.2.3 Define acceptable levels for hazards
8.5.2.3 Assess your organization's food safety hazards
8.5.2.4 Select measures to control your safety hazards
8.5.2.4.1 Select and categorize each control measure
8.5.2.4.2 Consider how each control can be supported
8.5.3 Validate food safety control measures
8.5.4 Establish your hazard control plan
8.5.4.1 Document your hazard control plan
8.5.4.2 Create critical limits and action criteria
8.5.4.3 Develop a monitoring system for controls
8.5.4.4 Specify corrections and corrective actions
8.5.4.5 Implement your hazard control plan

8.6 Establish up-to-date information if plan changes

8.7 Establish control of your monitoring and measuring

8.8 Establish and maintain food safety verification activities

8.8.1 Plan and perform food safety verification activities
8.8.2 Analyze results of food safety verification activities

8.9 Establish control of product and process nonconformities

8.9.1 Evaluate data derived from OPRP and CCP monitoring
8.9.2 Make corrections whenever products or processes fail
8.9.2.1 Control products when nonconformities occur
8.9.2.2 Handle products as potentially unsafe if CCPs fail
8.9.2.3 Evaluate what happened whenever your OPRPs fail
8.9.2.4 Document corrections made on your nonconformities
8.9.3 Document how corrective actions should be taken
8.9.4 Control all food products that are potentially unsafe
8.9.4.1 Prevent release or regain control of all unsafe products
8.9.4.2 Evaluate lots of products affected by nonconformities
8.9.4.3 Control the disposition of all nonconforming products
8.9.5 Withdraw, recall, and secure all unsafe food products

9. *Evaluation*

9.1 Monitor, measure, analyze and evaluate

9.1.1 Plan how to monitor, measure, analyze and evaluate
9.1.2 Analyze and evaluate the performance of your system

9.2 Use internal audits to examine conformance and performance

9.2.1 Conduct internal audits of your FSMS at planned intervals

9.2.2 Develop an internal audit program for your organization

9.3 Carry out management reviews and document your results

9.3.1 Review suitability, adequacy, and effectiveness, of your system

9.3.2 Plan and perform management reviews at planned intervals

9.3.3 Create management review outputs and document results

10. *Improvement*

10.1 Control nonconformities and take appropriate corrective action

10.1.1 Make corrections and take action when nonconformities occur

10.1.2 Document all nonconformities and the actions that are taken

10.2 Enhance the suitability, adequacy, and effectiveness of your FSMS

10.3 Evaluate and update the FSMS and document your results

HACCP- A global requirement for food safety assurance and its relation to ISO 22000:2017

An effective food safety assurance method is required due to emergence of foodborne pathogens and foodborne diseases which has widespread public health problem. Increased knowledge and awareness of the serious and chronic health effects associated with unsafe food products had made HACCP indispensible in all exporting food processing industries. An effective food safety assurance method such as HACCP is important due to the followings:

- New food technologies and processing methods are introduced now and then
- Increased awareness of the economic consequences of foodborne disease
- Increase in the number of vulnerable people
- Industrialization and mass production
- Urbanization
- Changes in lifestyle
- Increase in tourism and international trade for foodstuffs
- Increase in consumer awareness about food safety

HACCP Concept

It is important to always remember that the establishment of effective HACCP programs involves primarily the application of good common sense and preventive considerations to address situations before they become problems. The emphasis is on prediction rather than reaction, on getting the process right initially rather than correcting it after problems have occurred. It emphasized on identifying potential food safety problems and determining how and where these can be controlled or prevented. Describing what to do and training the personnel, implementation, recording and assurance throughout the food chain are taken care under HACCP system.

The objectives of application of the HACCP system:

- Prevention of foodborne illness

- Reduction of losses due to product recall
- Protection of reputation
- Reduction of costs of food analysis
- More efficient quality assurance system
- Focuses on identifying and preventing hazards from contaminating food, based on sound science.
- Permits more efficient and effective government oversight, primarily because record keeping allows investigators to see how well a firm is complying with food safety laws over a period, rather than how well it is doing on any given day.
- Helps food companies to compete more effectively in the world market.
- Reduces barriers to international trade.

Pre-requisite programs

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Common prerequisite programs may include, but are not limited to Facilities: Supplier Control: Specifications: Production Equipment: Cleaning and Sanitation: Personal Hygiene: Training: Chemical Control: Receiving, Storage and Shipping: Traceability and Recall: Pest Control:

Other examples of prerequisite programs might include quality assurance procedures; standard operating procedures for sanitation, processes, product formulations and recipes; glass control; procedures for receiving, storage and shipping; labeling; and employee food and ingredient handling practices.

*(Clause - 8.1 Operational planning and control ; 8.2 Prerequisite programmes (PRPs) ; 8.4 Emergency preparedness and response; 8.4.1 General; 8.4.2 Handling of emergencies and incidents; Clause 8.3-Traceability system; 8.9.4.1 General; 8.9.4.2 Evaluation for release; 8.9.4.3 Disposition of nonconforming products; 8.9.5 Withdrawal/recall; clause- 8.5.4 Hazard control plan (HACCP/oPRP plan))

Developing a HACCP Plan

In the development of a HACCP plan, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process. The five preliminary tasks are as follows:

Assemble the HACCP team - A multi-disciplinary HACCP team needs to include knowledge of the following aspects: Raw materials, specialist (quality assurance/technical), operation activities, engineering/equipment technical knowledge of HACCP, process, finished product, hazard expertise, environment (premises, property, surroundings)

Describe product - Describe the product giving detail of its composition, physical/chemical structure, and packaging, safety information, processing treatments, storage and method of distribution. Product name, composition, end product characteristics, method of preservation,

primary packaging, shipping, storage conditions, distribution method, shelf life, special labeling, customer preparation.

*(Clause-8.5.1.1 General; clause - 8.5.1.2 Characteristics of raw materials, ingredients and product contact materials; clause - 8.5.1.3 Characteristics of end products)

Identify intended use - Identify the intended use of the product, its target consumer with reference to sensitive population. Five sensitive groups in the population are categorized such as elderly, infants, pregnant, sick and immuno-compromised.

*(Clause - 8.5.1.4 Intended use)

Construct flow diagram -   Details of all process activities including inspections, transportation, storage and delays in the process are to be given. Inputs into the process in terms of raw materials, packaging, water and chemicals and output from the process e.g. waste – packaging, raw materials, product-in-progress, rework and rejected products also need to be mention

*(Clause - 8.5.1.5 Flow diagrams and description of processes; clause - 8.5.1.5.1 Preparation of flow diagrams)

On-site verification of flow diagram - It should be done by all members of the HACCP team during all stages and hours of operation. Validate process flow diagram by HACCP team, observe process flow, sampling activities, interview and outline / non routine operations.

*(Clause - 8.5.1.5.2 On-site confirmation of flow diagrams and clause - 8.5.1.5.3 Description of processes and process environment)

Once these five preliminary tasks are completed, the seven principles of HACCP are applied.

Principles of HACCP

There are seven principles included in HACCP which are as follows

Conduct a hazard analysis:

Identify hazards associated with a specific menu item by prepare a flow diagram that outlines all handling/preparation steps from receiving to service. Listing of likely hazards associated with each step and identification of how to prevent the hazards at each step. Hazards can be biological, chemical, physical or allergens. Also a list of hazards need to be projected that are likely to occur and that will cause severe consequences if not controlled. Hazards that are low risk and are not likely may not need to be considered.

*(Clause 8.5-Hazard control) and (Clause 8.5.1 Preliminary steps to enable hazard analysis) 8.5.2 Hazard analysis 8.5.2.1 General; 8.5.2.2 Hazard identification and determination of acceptable levels; 8.5.2.3 Hazard assessment)

Determine CCPs

A control point is any point, step, or procedure where biological, physical, or chemical factors can be controlled. A critical control point (CCP) is a point, step, or procedure where an identified

hazard can be prevented, eliminated, or reduced to acceptable levels. Critical control points are monitored much more frequently than are control points.

*(Clause - 8.5.2.4 Selection and categorization of control measure(s) ; 8.5.3 Validation of control measure(s) and combination(s) of control measure(s))

Establish critical limits

This step involves establishing criteria that must be met to prevent, eliminate, or reduce the identified hazard at the CCP so that the food is safe to eat. Examples of critical limits are temperature, time, physical dimensions, water activity, pH, and available chlorine. Critical limits can come from regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts. Establish critical limits for each CCP.

*(Clause - 8.5.4.1 General ; 8.5.4.2 Determination of critical limits and action criteria)

Establish monitoring procedures

Monitoring is a planned observation or measurement to determine if a CCP is under control. Examples of monitoring include visual observations, temperature measurements, time assessment, pH measurements, water activity measurements, etc. Establish a monitoring system for each CCP

*(Clause - 8.5.4.3 Monitoring systems at CCPs and for OPRPs)

Establish corrective actions

Corrective actions focus on what to do when a food does not meet the critical limit. Example of a corrective action is temperature of a cooker, throwing out food might be a corrective action. Maintained records of all corrective actions taken. Establish corrective actions (8.5.4.4 Actions when critical limits or action criteria are not met ; 8.5.4.5 Implementation of the hazard control plan ; 8.6 Updating the information specifying the PRPs and the hazard control plan ; 8.7 Control of monitoring and measuring) 8.9.1 General 8.9.2 Corrections ; 8.9.3 Corrective actions

Establish verification procedures

Four phases of verification needed for a HACCP plan:

1. Determine that the critical limits at all CCPS are sound.

2. Make sure that the establishment's HACCP plan is being properly implemented.

3. Have regulatory personnel review the plan to make sure that it is being properly implemented.

4. Check the accuracy of all monitoring equipment.

*(Clause - 8.8 Verification related to PRPs and the hazard control plan ; 8.8.1 Verification; 8.8.2 Analysis of results of verification activities)

Establish record keeping

The following make up the records of a HACCP Plan

- List of HACCP team and their assigned responsibilities
- Description of each menu item
- Flow diagram for each menu item indicating CCPs
- Hazards associated with each CCP and preventive measures
- Critical limits
- Monitoring procedures
- Corrective actions plans
- Record keeping procedures
- Procedures for verification of the HACCP plan

*(8.9 Control of product and process nonconformities ; 8.9.4 Handling of potentially unsafe products)

Advantages of ISO 22000 with reference to HACCP

Most important advantages related to implementation of ISO 22000 in food sector comprises:

- focuses on identifying and preventing hazards that may render food unsafe
- is based on sound science
- permits more efficient and effective government oversight, primarily because the recordkeeping allows investigators to see how well a firm is complying with food safety laws and following practices that reduce the risk of unsafe food over a period rather than how well it is doing on any given day
- places responsibility for ensuring food safety appropriately on the food manufacturer or distributor
- helps food companies compete more effectively in the world market
- reduces barriers to international trade.

Conclusion

HACCP has become a mandated system for processors of all kinds of foods. HACCP forms the foundation of European and international legislation for the food industry and is a key component of international trade in food products. It is relatively easy to combine HACCP and ISO into one overall management system that meets both the requirements for ISO 9000 and the requirements for HACCP. In fact, ISO 22000 is a new standard that specifies the requirements for a food safety management system. ISO 22000 incorporates all the elements of HACCP and of Good Manufacturing Practices (GMP). Today food industry standards play a major role in assisting food businesses to achieve compliance with legislation and in many cases exceed legislative requirements. This is a scientific and cost effective system for controlling product safety and quality. This may enable food business operators to ensure consistency in terms of product safety and quality with fair trade across the boundaries of different countries.

Suggested readings

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

- ISO 22000:2018 FOOD SAFETY MANAGEMENT SYSTEM IMPLEMENTATION GUIDE, NQA Food Safety Certification.

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