10. HACCP, ISO & IMPORTING COUNTRIES REQUIREMENT IN SEAFOOD EXPORTS

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Introduction

The issue of seafood safety is even more important in view of the growth in international fish trade, which has undergone tremendous expansion in the last three decades, increasing from US$8 billion in 1976 to a record export value of US$ 102.5 billion in 2010 and to a recent record of US$ 164 billion in 2018 (FAO, 2020). In the new millennium, seafood production and distribution are globalized and even more complex. The advent of emerging pathogens and the impacts of climate change on seafood safety are adding to this complexity. The media and consumers have developed a much greater interest in seafood safety issues owing to the continuing incidence of food scares. The advent of the Hazard Analysis and Critical Control Points (HACCP) system in recent decades has provided a single system that has now been adopted by international bodies and trading countries and regions to control seafood safety. HACCP or Hazard Analysis Critical Control Points is a scientific and systematic approach to identify, assess and control hazards in the food production process. With the HACCP system, food safety control is integrated into the design of the process rather than relied on end-product testing. Therefore HACCP system provides a preventive and thus cost-effective approach in food safety.

General Principles of Food Hygiene CXC 1-1969 Revised in 2020

Codex Alimentarius Commission has revised the General Principles of Food Hygiene (CXC-1 1969) and it's HACCP Annex in 2020. Eating habits have undergone major changes in many countries and new food production, preparation, storage, and distribution techniques have developed to reflect this. Effective food hygiene practices, therefore, are vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including primary producers, importers, manufacturers and processors, food warehouse/logistics operators, food handlers, retailers, and consumers, has a responsibility

to ensure that food is safe and suitable for consumption. Food Business Operators (FBOs) should be aware of and understand the hazards associated with the food they produce, transport, store and sell, and the measures required to control those hazards relevant to their business, so that food reaching consumers is safe and suitable for use. WHO 5 keys to Safer Food are keep clean, separate raw and cooked, cook thoroughly, keep food at safe temperatures and use safe water and raw materials.

Good Hygiene Practices (GHPs) are the foundation of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety. The sufficiency of the implemented GHP to address food safety could be determined through conducting a hazard analysis and determining how to control identified hazards.

Objectives

Objectives of Good Hygiene Practices (GHPs) and the Hazard Analysis and Critical Control Point (HACCP) are

- Provide principles and guidance on the application of GHPs applicable throughout the food chain to
- Provide food that is safe and suitable for consumption; provide guidance on the application of HACCP principles;
- Clarify the relationship between GHPs and HACCP; and
- Provide the basis on which sector and product-specific codes of practice can be established.

Scope

Production (including primary production), processing, manufacturing, preparation, packaging, storage, distribution, retail, food service operation and transport of food, and where appropriate, specific food safety control measures at certain steps throughout the food chain.

Use

The document is intended for use by FBOs (including primary producers, importers, manufacturers/processors, food warehouse/logistics operators, food service operators, retailers

and traders) and competent authorities, as appropriate. It provides basic information to meet the needs of food businesses, irrespective of the nature of product and size of food business, in the context of food trade.

Roles of Competent Authorities, Food Business Operators, and Consumers

- Protect consumers from illness, injury, or death caused by consumption of food;
- Ensure FBOs implement an effective control system so that food is safe and suitable for consumption;
- Maintain confidence in domestically and internationally traded food; and
- Provide information that effectively communicates the principles of food hygiene to food business operators and consumers.

General Principles

- GHPs should ensure that food is produced and handled in an environment that minimizes the presence of contaminants.
- Properly applied prerequisite programmes, which include GHPs, should provide the foundation for an effective HACCP system
- Each FBO should be aware of the hazards associated with the raw materials and other ingredients, the production or preparation process, and the environment in which the food is produced and/or handled, as appropriate to the food business.
- Depending on the nature of the food, food process, and the potential for adverse health effects, to control hazards it may be sufficient to apply GHPs, including, as appropriate, some that require more attention than others, as they have a greater impact on food safety. When the application of GHPs alone is not sufficient, a combination of GHPs and additional control measures at CCPs should be applied.
- Control measures that are essential to achieve an acceptable level of food safety, should be scientifically validated
- The application of control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate to the nature of the food product and the size of the food business.

- Food hygiene systems should be reviewed to determine if modifications are needed. This should be done periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment, new scientific knowledge) associated with the food business.
- Appropriate communication about the food and food process should be maintained among all relevant parties to ensure food safety and suitability across the entire food chain.

Good Hygiene Practices

Section 1: Introduction and Control of Food Hazards

The development, implementation and maintenance of GHPs provide the conditions and activities that are necessary to support the production of safe and suitable food at all stages of the food chain from primary production through to handling of the final product. Applied generally, they assist in controlling hazards in food products. Knowledge of the food and its production process is essential for the effective implementation of GHPs. GHPs manage many sources of food hazards which could contaminate food products, e.g. persons who handle food at harvest, during manufacturing, and during preparation; raw materials and other ingredients purchased from suppliers; cleaning and maintaining the work environment; storage and display. FBOs should consider whether the application of GHPs alone is sufficient to manage some or all of the hazards associated with the operation through control of their sources

- Control of water quality – minimizes the presence of many potential hazards (e.g. biological, chemical, physical);
- Control of faecal contamination – minimizes the potential for contamination with many foodborne pathogens such as *Salmonella*, *Campylobacter*, *Yersinia*, pathogenic strains of *E.coli*
- Control of food handler practices and hygiene – prevents many potential communicable diseases that could be foodborne; and
- Control of food contact surfaces by cleaning – removes bacterial contaminants, including foodborne pathogens, and allergens.

Section 2: Primary Production

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. It will include:

- An assessment of the suitability of water used where it may pose a hazard, for example, crop irrigation, rinsing activities, etc.
− Avoiding the use of areas where the environment poses a threat to the safety of food (e.g. contaminated sites);
− Controlling contaminants, pests and diseases of animals and plants, to the extent practicable, to minimize the threat to food safety (e.g. appropriate use of pesticides and veterinary drugs);
− Adopting practices and measures to ensure food is produced under appropriately hygienic conditions (e.g. cleaning and maintaining harvest equipment, rinsing, hygienic milking practices).

All provisions apply for all primary production situations and consideration will need to be given by the FBO on the appropriateness of the measures to be taken.

- Environmental control - Potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of contaminants would lead to an unacceptable level of such contaminants in food, e.g. using polluted areas
- Hygienic Production - Producers should as far as practicable implement measures to control contamination from soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production; protect food sources from faecal and other contamination (e.g. zoonotic foodborne agents); control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product (e.g. observe the withdrawal period of veterinary drugs and pesticides, keeping records where applicable); and manage waste and store harmful substances appropriately.
- Handling, Storage and Transport - Procedures should be in place to sort food to remove material which should not be used for human consumption; dispose of any rejected material in a hygienic manner; and protect food from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (e.g. sorting, grading, washing), storage and transport. Care should be taken to prevent

deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

- Cleaning, Maintenance and Personnel Hygiene - Appropriate facilities and procedures should be in place to ensure that cleaning and maintenance are carried out effectively and do not compromise food safety (e.g. ensuring equipment used in harvest is not a source of contamination); and an appropriate degree of personal hygiene is maintained to ensure personnel are not a source of contamination (e.g. by human faeces).

Section 3: Establishment - Design of Facilities and Equipment

Depending on the nature of the operations and the associated risks, premises, equipment and facilities should be located, designed and constructed. It includes

- Location and structure
  - Location of establishment - establishments should normally be located away from environmentally polluted areas and industrial activities which are reasonably likely to contaminate food; areas subject to flooding; areas prone to infestations of pests; and areas where wastes, either solid or liquid, cannot be removed effectively
  - Design and layout of food establishment - The design and layout of food establishments should permit adequate maintenance and cleaning. The layout of premises and the flow of operations, including the movements of personnel and material within the buildings, should be such that cross-contamination is minimized or prevented
  - Internal structures and fittings - specific conditions should be satisfied where necessary to protect the safety and suitability of food the surfaces of walls, partitions and floors should be made of impervious materials that are easy to clean and, where necessary, disinfect; walls and partitions should have a smooth surface up to a height appropriate to the operation; floors should be constructed to allow adequate drainage and cleaning; ceilings and overhead fixtures (e.g. lighting) should be constructed to be shatterproof where appropriate, and finished to minimize the build-up of dirt and condensation and the shedding of particles; windows should be easy to clean, be constructed to minimize the build-up of dirt and, where necessary, be fitted with removable and cleanable insect-proof screens; and doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect.

- Temporary/mobile food establishments and vending machines - Establishments and structures covered here include market stalls, street vending vehicles, vending machines and temporary premises such as tents and marquees. Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of pests. Adequate facilities for toileting and washing hands should be provided, where appropriate.

➢ Facilities

- Drainage and waste disposal facilities - They should be designed and constructed so that the likelihood of contaminating food or the water supply is avoided. For plumbing, steps should be taken to prevent backflow, cross-connections, and backup of sewer gases. It is important that drainage does not flow from highly contaminated areas (such as toilets or raw production areas) to areas where finished food is exposed to the environment. The waste disposal site should be located away from the food establishment to prevent pest infestation.
- Cleaning facilities - Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas.
- Personnel hygiene facilities and toilets- . They should include: adequate means of washing and drying hands, including soap (preferably liquid soap), wash basins and, where appropriate, a supply of hot and cold (or suitably temperature controlled) water; hand washing basins of an appropriate hygienic design, ideally with taps not operated by hands; where this is not possible, appropriate measures to minimize contamination from the taps should be in place; and suitable changing facilities for personnel
- Temperature - Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, and, when necessary, controlling ambient temperatures to ensure the safety and suitability of food.
- Air quality and ventilation - Adequate means of natural or mechanical ventilation should be provided. Ventilation systems should be designed and constructed so that air

does not flow from contaminated areas to clean areas; the systems should be easy to maintain and clean.

- Lighting - Lighting should be such that it does not adversely impact the ability to detect defects of, or contaminants in, food or the examination of facilities and equipment for cleanliness. Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements.
- Storage - The type of storage facilities required will depend on the nature of the food. Separate, secure, storage facilities for cleaning materials and hazardous substances should be provided.

➢ Equipment

- General - Equipment and containers coming into contact with food should be suitable for food contact; designed, constructed and located to ensure that they can be adequately cleaned (other than containers which are single use only); disinfected (where necessary); and maintained or discarded as necessary to avoid the contamination of food, according to hygienic design principles.
- Food control and monitoring equipment - monitoring equipment should be calibrated to ensure that temperatures of food processes are accurate.

Section 4: Training and Competence

All those engaged in food operations who come directly or indirectly into contact with food should have sufficient understanding of food hygiene to ensure they have competence appropriate to the operations they are to perform.

- Awareness and Responsibilities - Those who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in proper use to prevent contamination of food.
- Training Programmes
- Instruction and Supervision
- Refresher Training

Section 5: Establishment Maintenance, Cleaning and Disinfection, and Pest Control

➢ Maintenance and Cleaning

- General - Establishments and equipment should be maintained in an appropriate condition to: facilitate all cleaning and disinfection procedures; function as intended; and prevent contamination of food, such as from pests, metal shards, flaking plaster, debris, chemicals, wood, plastic, glass, paper.
- Cleaning and disinfection methods and procedures
- Monitoring of Effectiveness

➢ Pest control systems

- General
- Prevention
- Harbourage and infestation
- Monitoring and detection
- Control of pest infestation
- Waste management

Section 6: Personal Hygiene

To ensure that those who come directly or indirectly into contact with food: maintain appropriate personal health; maintain an appropriate degree of personal cleanliness; and behave and operate in an appropriate manner.

- Health Status
- Illness and Injuries
- Personal Cleanliness
- Personal Behaviour
- Visitors and other persons from outside the establishment

Section 7: Control of Operation

Control of operation is achieved by having an appropriate food hygiene system in place. The following section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.

➢ Description of products and processes

- Product description - The description could include, the intended use of the food, e.g. whether it is ready-to-eat or whether it is intended for further processing either by consumers or another business, for example raw seafood to be cooked; products intended for specific vulnerable consumer groups e.g. infant formula or food for special medical purposes; any relevant specifications e.g. ingredient composition, aw, pH, type of preservation method used (if any), or important characteristics associated with the food, such as any allergens present; any relevant limits established for the food by the competent authority or, in the absence thereof, set by the FBO; instructions provided for further use, for example keep frozen until cooking, cook to a specified temperature for a specified length of time, product shelf-life (use-by date); storage of product (e.g. refrigerated/frozen/shelf stable) and transport conditions required; and food packaging material used.
- Process description
- Consideration of the effectiveness of GHPs
- Monitoring and corrective action - Corrective action should consist of the following actions, such as: bringing the process back into control by, for example, altering temperature or timing, or concentration of disinfectant; isolating any affected product and evaluating its safety and/or suitability; determining proper disposition of affected product that is not acceptable to market; identifying the cause that resulted in the deviation; and taking steps to prevent reoccurrence. Records of corrective actions should be retained.
- Verification - verification activities could include review of GHP procedures, monitoring, corrective actions and records; review when any changes occur to the product, process and other operations associated with the business; and assessment of the efficacy of cleaning. Records of GHP verification activities should be kept, where appropriate.

➢ Key aspects of GHPs

- Time and temperature control - Inadequate time and temperature control, e.g. during cooking, cooling, processing and storage, are among the most common failures of operational control. These allow survival or growth of microorganisms that may cause foodborne illness or food spoilage.

- Specific process steps - The composition of a food can be important in preventing microbial growth and toxin production, e.g. in its formulation by adding preservatives, including acids, salts, food additives or other compounds.
- Microbiological, physical, chemical and allergen specifications - Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized.
- Microbiological contamination - Microbiological contamination occurs through direct contact or indirectly by food handlers; contact with surfaces; cleaning equipment; splashing; airborne particles etc. Raw, unprocessed food, where not considered ready-to-eat, which could be a source of contamination, should be separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and, where appropriate, effective disinfection. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a potentially high microbiological load such as meat, poultry, and fish have been handled or processed.
- Physical contamination - Systems should be in place throughout the food chain to prevent contamination of foods by extraneous materials, such as personnel belongings, especially any hard or sharp object(s), e.g. jewellery, glass, metal shards, bone(s), plastic, wood fragments, that could cause injury or present a choking hazard. Detection or screening devices which are appropriately calibrated should be used where necessary (e.g. metal detectors, x-ray detectors). Procedures should be in place for personnel to follow in the case of breakages (e.g. breakage of glass or plastic containers).
- Chemical contamination - Systems should be in place to prevent or minimize contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, chemical residues from pesticides and veterinary drugs such as antibiotics. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, safely stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials.
- Allergen Management - Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives (not an inclusive list; allergens of concern differ among countries and populations),

should be identified in raw materials, other ingredients and products. A system of allergen management should be in place at receipt, during processing and storage to address the known allergens. This management system should include controls put in place to prevent the presence of allergens in foods where they are not labelled.

- Incoming Materials - Incoming materials including food ingredients should be procured according to specifications, and their compliance with food safety and suitability specifications should be verified where necessary. Supplier quality assurance activities, such as audits, may be appropriate for some ingredients. Documentation of key information for incoming materials (e.g. supplier details, date of receipt, quantity etc.) should be maintained.
- Packaging - Packaging design and materials should be safe and suitable for food use, provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling.
- Water - Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g. some water used for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food.
- Documentation and Records
- Recall Procedures - removal from the market of unsafe food

Section 8: Product Information and Consumer Awareness

- Lot Identification and Traceability - Lot identification or other identification strategies are essential in product recall and also help effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) applies. A traceability/product tracing system should be designed and implemented according to the Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CXG 60-2006).
- Product Information

- Product Labelling
- Consumer Education

Section 9: Transportation

During transportation, measures should be taken where necessary to protect food from potential sources of contamination, including allergen cross- contact; protect food from damage likely to render the food unsuitable for consumption; and provide an environment which effectively controls the growth of pathogenic or spoilage microorganisms and the production of toxins in food.

- General
- Requirements
- Use and Maintenance

Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on control measures for significant hazards along the food chain, rather than relying mainly on end-product testing. Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied. Any HACCP system should be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments. HACCP principles can be considered throughout the food chain from primary production to final consumption, and their implementation should be guided by scientific evidence of risks to human health. Although it is not always feasible to apply HACCP at primary production, some of the principles can be applied and may be incorporated into good practices programmes (e.g. Good Agricultural Practices (GAPs), etc.

Principles of the HACCP System

The HACCP system is designed, validated and implemented in accordance with the following seven principles

1. Conduct a hazard analysis and identify control measures.
2. Determine the Critical Control Points (CCPs).
3. Establish validated critical limits.
4. Establish a system to monitor control of CCPs.
5. Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred.
6. Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended.
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

General Guidelines for the Application of the HACCP System

Prerequisite programmes should be well-established, fully operational and verified, where possible, in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of prerequisite programmes including GHPs. Management awareness and commitment to food safety are necessary for implementation of an effective HACCP system. Appropriate HACCP training and competency is essential. The intent of the HACCP system is to focus control at Critical Control Points (CCPs). HACCP provides consistent and verifiable control beyond that achieved by GHPs. A HACCP approach should be customized to each food business. The HACCP system should be reviewed periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures.

Application of HACCP system

1. **Assemble HACCP Team and Identify Scope** - This may be achieved by assembling a multidisciplinary team responsible for different activities within the operation, e.g. production, maintenance, quality control, cleaning and disinfection. The HACCP team is responsible for developing the HACCP plan. Where relevant expertise is not available in house, expert advice should be obtained from other sources.

2. **Describe product -** A full description of the product should be developed, including relevant safety information such as composition (i.e. ingredients), physical/chemical characteristics (e.g. aw, pH, preservatives, allergens), processing methods/technologies (heat-treatment, freezing, drying, brining, smoking, etc.), packaging, durability/shelf life, storage conditions and method of distribution.
3. **Identify intended use and users** - Describe the use intended and the expected uses of the product.
4. **Construct flow diagram** - A flow diagram that covers all steps in the production of a specific product, including any applicable rework, should be constructed. The flow diagram should indicate all inputs, including those of ingredients and food contact materials, water and air if relevant. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis.
5. **On-site confirmation of flow diagram** - Steps should be taken to confirm the processing activities against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.
6. **List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards** - The HACCP team should list all potential hazards. The HACCP team should then identify where these hazards are reasonably likely to occur at each step. The HACCP team should next evaluate the hazards to identify which of these hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food. In conducting the hazard analysis to determine whether there are significant hazards and consider hazards associated with producing or processing the type of food, including its ingredients and process steps, the likelihood of occurrence of hazards, taking into consideration prerequisite programs, in the absence of additional control; the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control, identified acceptable levels of the hazards in the food e.g. based on regulation, intended use, and scientific information, the nature of the facility and the equipment used in making the food product , survival or multiplication of pathogenic microorganisms; production or persistence in

foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, allergens) or physical agents (e.g. glass, metal); the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe; and, conditions leading to the above.

7. **Determine the Critical Control Points**- . Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens).
8. **Establish validated critical limits for each CCP** - Critical limits establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, aw, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting. A deviation from the critical limit indicates that it is likely that unsafe food has been produced.Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented 9 . Validation of critical limits may include conducting studies (e.g. microbiological inactivation studies). FBOs may not always need to conduct or commission studies themselves to validate critical limits. Critical limits could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer

9. **Establish a Monitoring System for Each CCP** - Monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures should be able to detect a deviation at the CCP. Further, the monitoring method and frequency should be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product. Where possible, process adjustments should be made when monitoring results indicate a trend towards a deviation at a CCP. The adjustments should be taken before a deviation occurs.

   Monitoring procedures for CCPs should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. The method and frequency of monitoring should take into account the nature of the deviation. Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.

10. **Establish corrective actions** - Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO should determine what product may have been impacted by the deviation. The corrective actions taken when a deviation occurs should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposition. A root cause analysis should be conducted

where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. A root cause analysis could identify a reason for the deviation that limits or expands the amount of product impacted by a deviation.

11. Validation of the HACCP Plan and Verification Procedures

- **Validation** - Before the HACCP plan can be implemented, its validation is needed; this consists of making sure that the following elements together are capable of ensuring control of the significant hazards relevant to the food business: identifying the hazards, critical control points, critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded. Validation of control measures and their critical limits is performed during the development of the HACCP plan. Validation could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources. Where HACCP guidance developed by external experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration.
- **Verification Procedures -** After the HACCP system has been implemented, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur. Verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing (internal and external), calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include reviewing monitoring records to confirm that CCPs are kept under control; reviewing corrective action records, including specific deviations, product disposition and any analysis to determine the root cause of the deviation; calibrating or checking the accuracy of instruments used for monitoring and/or verification; observing that control measures are being conducted

in accordance with the HACCP plan; sampling and testing, e.g. for microorganisms (pathogens or their indicators), chemical hazards such as mycotoxins, or physical hazards such as metal fragments, to verify product safety; sampling and testing the environment for microbial contaminants and their indicators, such as *Listeria*; and reviewing the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits).

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties. The frequency of verification activities should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly. Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring, and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred.

12. **Establish Documentation and Record Keeping-** Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business. Examples of documentation include HACCP team composition; hazard analysis and the scientific support for the hazards included or excluded from the plan; CCP determination; critical

limit determination and the scientific support for the limits set; validation of control measures; and modifications made to the HACCP plan. Examples of records include CCP monitoring activities; deviations and associated corrective actions; and verification procedures performed.

Overview of ISO 22000:2018 FSMS

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

ISO (International Organization for Standardization) is a non-governmental organization (NGO) established in 1947. The head quarter is in Geneva, Switzerland. ISO 22000 was developed by a working group (WG) under ISO Technical Committee 34 (Food Products). This working group evoled into ISO sub committee (SC 17). This subcommittee is responsible for the management of ISO 22000 family of standards.

ISO 22000 is a global standard for food safety management system (FSMS). It is designed to enable organizations to control food safety hazards along the food chain. The standard applies to all types and sizes of organizations participating in the food supply chain.

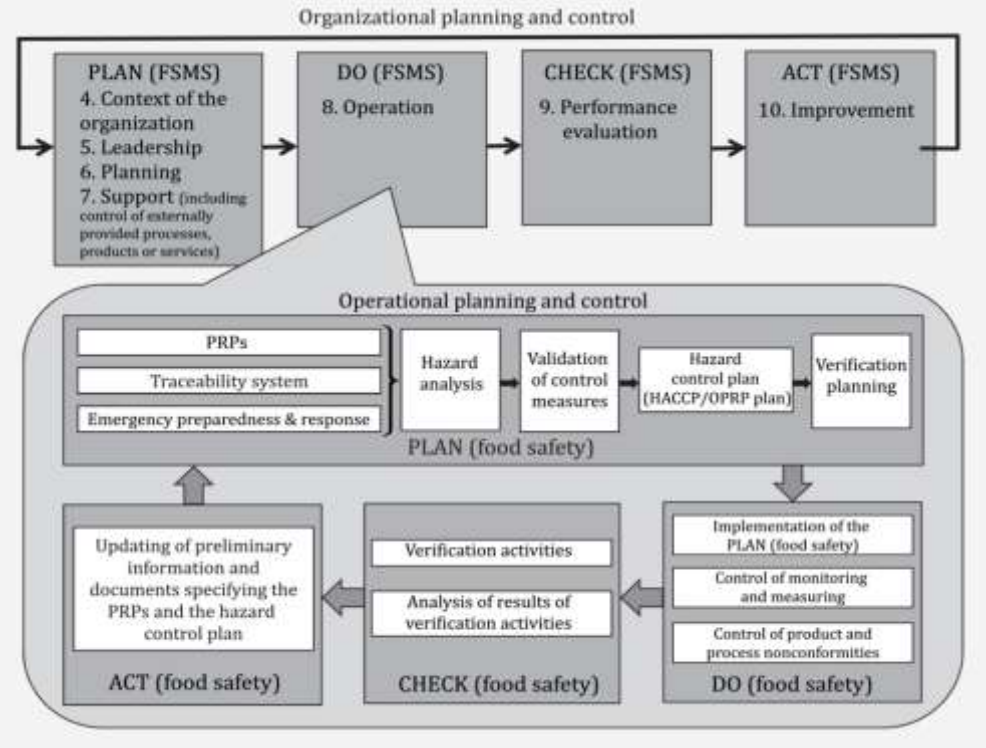

Fig 1. Organizational planning and control of ISO 22000: 2018

(Source: ISO 22000:2018 – Food safety management systems)

Scope

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

Important clauses

4. Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the food safety management system

4.4 Food safety management system

5. Leadership

5.1 Leadership and commitment

5.2 Policy

5.2.1 Establishing the food safety policy

5.2.2 Communicating the food safety policy

5.3 Organizational roles, responsibilities and authorities

6. Planning

6.1 Actions to address risks and opportunities

6.2 Objectives of the food safety management system and planning to achieve them

6.3 Planning of changes

7 Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

8 Operation

8.1 Operational planning and control

8.2 Prerequisite programmes (PRPs)

8.3 Traceability system

8.4 Emergency preparedness and response

8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.2 Hazard analysis

8.5.3 Validation of control measure(s) and combinations of control measures

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.6 Updating the information specifying the PRPs and the hazard control plan

8.7 Control of monitoring and measuring

8.8 Verification related to PRPs and the hazard control plan

8.9 Control of product and process nonconformities

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review

10 Improvement

10.1 Nonconformity and corrective action

10.2 Continual improvement

10.3 Update of the food safety management system

International Regulations for export of fish and fishery products

Fish and fishery products are one of the highly traded commodity across the globe (US$163 billion). Around 37% of global fish production enters international trade, out of which 75% imported by developed nations and 50% are exported by developing nations. Keeping in view the food safety requirements of different countries many international regulations are in place.

Codex Alimentarius Commission

CAC has the mandate to formulate food standards, code of practice, guidelines and recommendations to protect health of consumers, Ensure fair practices in food trade and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations. There are more than 22 codex standards for fish and fishery products, apart from code of practices, and specific guidelines.

European Union

European Union is the biggest importer of fish and fishery products in the world. The food safety regulations set by EU is harmonised, gets periodically updated, transparent and based on principles of risk assessment. The key elements of EU requirements for import of seafood are (a) certification by a competent authority (b) compliance to hygiene and public health requirements

in terms of structure of vessels, landing sites, processing establishments and on operational processes, freezing and storage (c) certified production area for bivalves (d) national control plan on heavy metals, contaminants, residues of pesticides and veterinary drugs (e) approval of establishments. The legal acts of EU are managed through regulations, directives, decision, recommendations and opinions.

USA

In USA both Federal and State Regulatory agencies are involved in ensuring safety and quality of seafood. Multiple federal agencies such as USDA, USFWS, NOAA and USFDA are involved in regulatory oversight of seafood for both importation and export. The U.S. Food and Drug Administration (USFDA) is vested with the primary Federal responsibility for the safety of seafood products in the United States. It operates a mandatory safety program for all fish and fishery products under the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, the Public Health Service Act, and related regulations. The most important regulation enacted by USFDA was ―Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products‖ published as final rule 21 CFR 123 on 18th December 1995 and came into force on 18th December 1997. It required processors to adopt the preventive system of food safety controls known as HACCP (Hazard Analysis and Critical Control Point). Seafood was the first food commodity in the U.S. to adopt HACCP in USA. Food Safety and Modernization Act (FSMA) which came into existence in 2011 strengthens the existing regulatory scenario for imported seafood.

Other countries

Other major importing countries such as China, Japan, Russia, Australia and SE Asian countries have also specific requirements for import of fish and fishery products. Japan uses a positive list system for MRL of agricultural chemicals in foods. The hygienic requirements in Russian regulations are different from other countries as some of the microbiological parameters are expressed as absent in 0.001g or 0.01g. In recent years China has strengthened its SPS measures and has taken a number of precautionary steps to ensure safety to its population.

Reference

General principles of food hygiene CXC 1-1969 Adopted in 1969. Amended in 1999. Revised in 1997, 2003, 2020. Editorial corrections in 2011.

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

Priya E R, Devananda Uchoi, Anuj Kumar and Rejula K (eds.) 2019 ISO 22000/HACCP for fish processing establishments, Central Institute of Fisheries Technology, Cochin, India, pp 201.

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