INDIAN TECHNICAL ECONOMIC COOPERATION (ITEC) PROGRAMME

TRAINING MANUAL ON "ISO 22000/HACCP FOR FISH PROCESSING ESTABLISHMENTS "

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(Under ITEC, Ministry of External Affairs, Govt. of India)

ICAR-CENTRAL INSTITUTE OF FISHERIES TECHNOLOGY

(ISO/IEC 17025:2005 NABL Accredited & ISO 9001:2015 certified)

CIFT junction, Matsyapuri, P. O., Willingdon Island, Cochin-682029, Kerala, India

Training Manual

on

ISO 22000/HACCP FOR FISH PROCESSING ESTABLISHMENTS

(Under ITEC, Ministry of External Affairs, Govt. of India)

Venue: ICAR-Central Institute of Fisheries Technology, Cochin, Kerala, India

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FOREWORD

Food safety at any point in the food chain from producer to consumer is a global concern. Food safety hazards may be introduced at any stage, therefore adequate control throughout the production process is very much essential. Outbreaks of contagious diseases in livestock, such as foot and mouth disease, and of micro-organisms like *salmonella* and *listeria* have highlighted the risks of food contamination. Unsafe food is a risk for all consumers it is a health concern while for the industry it may lead to costly corrective actions. Since its inception, ICAR-Central Institute of Fisheries Technology has been working on the safety and quality of water, fish, and fishery products. ICAR-CIFT was the driving force for setting the standards for packaged drinking water in India. The pioneering work done by the Central Institute of Fisheries Technology in the area of seafood quality assurance stands as a milestone in the history of the pre-shipment system in India. A major technological intervention brought about by CIFT was facilitating the implementation of the Hazard Analysis and Critical Control Point (HACCP) based quality assurance system in the fish processing industry throughout the country. ICAR-CIFT is working along with the Food Safety Standards Authority of India to set standards for Fish and Fishery products. In fact, ICAR-CIFT has been recognized as the national referral laboratory as well as the National Reference Laboratory of FSSAI for Fish and fishery products. ICAR-CIFT has provided exclusive support to FSSAI in the development of food safety standards and the development of a code of practices. Technologies developed by the Institute have played a vital role in modernizing the harvest and post-harvest fishery sectors of India and helped to make it a major exporter of processed fish and fish products.

The international training on 'ISO 22000/HACCP FOR FISH PROCESSING ESTABLISHMENTS' sponsored by the Indian Technical & Economic Cooperation Programme (ITEC), Ministry of External Affairs, Government of India, assumes greater importance as the technical expertise developed over many decades by the institute could be shared with researchers and officials from other countries. During the training days, 25 participants from 15 countries were exposed to quality issues in different fish and fishery products, different hazards associated with seafood, HACCP & ISO 22000:2018 implementation, regulatory requirements, traceability, Food Safety Management Systems, export, and trade-related issues, and different extension approaches for technology dissemination in fisheries. The topics for the program were selected to give comprehensive knowledge on quality assurance of fish and fishery products. This training manual comprehensively covers different aspects of quality assurance of fish and fishery products. I am sure that this training manual will be very useful for researchers and entrepreneurs working in the areas of quality assurance of fish and fishery products. The knowledge about ISO 22000/HACCP in food safety management systems will help to ensure food safety along the entire food chain, and safe food for consumers.

Dr. George Ninan.
Director
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PREFACE

Food safety is very much crucial to the society due to its direct effect on human health. Because of that any business working in the food chain should have an effective food safety management system in place to eliminate/reduce the risk of contamination and consequent health risks associated with. The vital tools commonly used to define the requirements for an effective Food Safety Management System are ISO22000 and HACCP (Hazard Analysis and Critical Control Points). These are the basis for Food Safety principles defined by Codex Alimentarius Commission of World Health Organization. HACCP is an internationally recognized risk management tool, which is proactive in nature, while ISO22000 is a complete food safety management system, enabling continual improvement of performance. ISO 22000 incorporates HACCP principle and covers the entire food chain i.e. from farm to fork.Food producers in all parts of the food chain around the world have adopted ISO 22000 as a new global food safety standard.It is important to create a common understanding of the benefits of building a food safety management system based on ISO 22000, especially for developing and under developed countries. The proliferation of diverse food safety management standards and practices has created a situation that is often characterized by a lack of clarity. The training programme on ISO22000/HACCP for fish processing establishments is an attempt to make clear picture about role of ISO 22000/HACCP in food safety management system to ensure safe food to consumers. This book, through its various chapters discusses food safety scenario and regulatory requirements, different hazards associated with seafood processing and control measures, requirements and role of Food Safety Management Systems, export and trade related issues, and different extension approaches for sustainable technology dissemination. Like ISO 22000 covering food safety issues from farm to table, the manual also covers hazards, risk and management system to provide an elaborate picture about Food Safety Management System. We would like to acknowledge the Ministry of External Affairs and ICAR for giving us an opportunity to conduct this training programme. We acknowledge the entire resource persons for immensely contributing for this manual. Infact the entire manual was prepared during the training programme itself and without the support of all faculty it would not have been possible. We would like to acknowledge Dr George Ninan, Director, ICAR-CIFT, Dr.Femeena Hassan and Dr. A. K. Mohanty, Course Directors for all the support, guidance and encouragement given for the successful completion of this training programme as well as training manual. We hope that this publication will serve as guide for academicians, technologists and entrepreneurs engaged in the food safety management system.

Course Co-ordinators

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Chapter 1

Overview of HACCP in Fish Processing Establishments

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Hazard Analysis and Critical Control Point (HACCP) is an internationally recognized system for reducing the risk of safety hazards in food. Hazard Analysis Critical Control Point (HACCP) is a type of food safety management system. HACCP created the foundation for modern food safety standard.HACCP was developed by the Pillsbury Company while working on producing foods for NASA for use in space missions in early 1959. NASA had concerns of food, particularly crumbs, in the space capsule in zero gravity and also food that was free of pathogens and biological toxins that Pillsbury addressed by the use of HACCP. Principles that were mandated as part of NASAs engineering practices were applied to food production for the first time. It was an end-to-end control system that managed risks throughout the entire lifecycle of the space food, from ingredient procurement to transportation, to packaging and storage.The concept of HACCP was first presented to the public in the 1971 National Conference on Food Protection. At that time, it was based on three principles. In 1985, interest in HACCP was renewed when a subcommittee of the Food Protection Committee of NASA issued a report on microbiological criteria. A National Advisory Committee on Microbiological Criteria for Foods was formed and that committee published a report in 1992 that provided the framework for HACCP as we know it today.

Today's fish industry is facing new challenges, with more complex products and processes that require intensive controls during their processing, storage and distribution. The HACCP concept can guarantee the safety of fish products, enhancing consumer confidence in the fish industry, while at the same time can motivate exporting developing countries to build a solid food-safety control system. Here potential biological, chemical or physical hazards are identified and controlled at specific points in the process. Any company involved in the manufacturing, processing or handling of food products can use HACCP to improve food safety

Safe food is one which is free of contaminants and will not cause harm, injury or illness. Food gets contaminated at different stages, may be in the procurement of raw materials or during production but the extent of contamination or abuse determines the hazard potential by the Food-borne diseases, i.e. illnesses due to consumption of contaminated food are one of the most prevalent health problems in India as well as in other parts of the world. (WHO, 1984). In spite of the efforts taken, the incidence of food-borne diseases is increasing in number frequency all over. This problem is likely to continue to grow, unless new methods and strategies are adopted to counter them (WHO, 1991). This feature can be attributed to the insufficiency of the traditional approaches of quality control in controlling and preventing food-borne diseases. Hence, it is imperative that a concerted approach to food safety be developed. This could be achieved by combining two types of information. The information on the socio-cultural and economic situation and (ii) the technical information related to food manufacture and

food habits obtained through the application of the Hazard Analysis and Critical Control Point or HACCP (WHO, 1993).

HACCP is a science-based method, increasingly adopted by food manufacturers throughout the world for the prevention of food-borne diseases (WHO, 1993). It works through a step wise process to identify hazards, put in preventative measures to eliminate or reduce particular hazards in their food products. It is proactive not reactive and is based on risk. It does not rely on product testing as most Quality control programs have done in the past. Final product testing does not identify or remove all hazards as the hazards may not be evenly distributed and can be missed in sampling. A large number of products would need to be tested in order to get statistically accurate results and most testing of food is destructive.

It is a system of controls in a food processing industry, which helps them to identify and prevent problems even before they occur. This system is systematic and scientifically based and is consi9dered as a tool for ensuring food safety throughout the world (Brian, 1992). Even though HACCP was introduced in food system as early as 1960's, it found its way in India little late. Interestingly among the various food processing activities, this system was initially introduced in the fish processing sector. This changeover is rather forced upon the seafood processors because of the emergence of the European Union Market, which contributes to more than 40% of the total export market of marine products from India.

HACCP is a 'Systematic approach to the identification and assessment of the hazards and risks associated with a food operation and defining of the means of their control' (WHO, 1993). Anything which has a potential to cause harm to consumer safety should be considered a hazard. World Health Organization and international Commission of Microbiological specification of Foods recommended HACCP for food safety in developing countries (WHO/ICMSF, 1980). European Commission (European Commission 1991 and 1994) has made HACCP based quality management system mandatory in fisheries to export shrimp/fish products to European Markets. The Codex Alimentarius Commission is currently encouraging practical implementation of HACCP systems in food industries (Codex, 1991). HACCP based quality management systems are also advocated in the USFDA/NOAA Voluntary Seafood Inspection Programme for countries exporting seafood to the USA.

HACCP is a management tool that provides a more structured approach to the control of identified hazards that are identified by traditional inspection and quality control procedure. When applying the HACCP concept in food processing, control is transferred solely form end product testing (i.e., testing for failure). There will, however, always be a need for some end product testing particularly for verification purposes and in product development.

The process variables that are used to control the operation are identified by a HACCP review. Much of the effectiveness of HACCP is achieved through the relevant area, e.g., microbiology, food chemistry, production, quality assurance, that identifies specific hazards and measures for their control to ensure the safety prevention rather than relying mainly on end-product testing and inspection. It is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

The benefits from the use of HACCP are many and can be summarized as follows (Anon, 1996):

- HACCP is a systematic approach covering all aspects of food safety from raw materials, growth, harvesting and purchase to final product use.
- Use of HACCP will move a company from sole retrospective end product testing approach towards a preventive quality assurance approach.
- Provides for a cost-effective control of food borne hazards
- Focuses technical resources into critical parts of seafood processing
- The use of preventive approaches such as HACCP leads to reduced product losses.
- Demonstrating that a HACCP quality management system in place in processing plant will assist in meeting standards in importing countries and contribute to customer satisfaction.

The HACCP system requires food proprietors to identify potential food hazards, decide which of these hazards need to be controlled to ensure food safety, and put into place effective control and monitoring procedures to prevent the hazard causing harm to consumer.

Twelve steps are necessary to develop a solid HACCP plan .It includes seven principles also.

Step1. Assemble the HACCP Team

The first step is assembling a team of individuals who have specific knowledge and expertise about the product and process. The multidisciplinary team should include individuals from departments such as:

- Engineering
- Production
- Sanitation
- Quality assurance

Don't forget to include local personnel who are involved in the operation. The team may benefit from outside experts to weigh in on potential biological, chemical and/or physical hazards, bit these experts should serve as consultants not as a replacement for your HACCP team.

Step 2. Describe the Product

First, the HACCP team provides a general description of the food, ingredients and processing methods. Then the method of distribution should be described along with information on whether the food is to be distributed frozen, refrigerated or at ambient temperature.

Step 3. Identify the Intended Use and Consumers

Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, immunocompromised individuals, the elderly, etc.)

Step 4. Construct Flow Diagram to Describe the Process

The flow diagram should provide a clear, simple outline of all the steps involved in the process that are directly under the control of the establishment. (The flow diagram can also include steps in the food chain which come before and after the processing that occurs in the establishment.)

The diagram can be a block-type design — it should does not need to be as complex as engineering drawings. Also, including a simple schematic of the facility can be useful for understanding product and process flow.

Step 5. On-Site Confirmation of Flow Diagram

The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram, and modifications should be made to the diagram as needed. After these first five preliminary tasks have been completed, the following seven principles of HACCP are applied.

Step 6. - Conduct a Hazard Analysis (Principle 1)

The application of this principle involves listing the steps in the process and identifying where significant hazards are likely to Occur. The HACCP team will focus on hazards that can be prevented, eliminated or controlled by the HACCP plan. A justification for including or excluding the hazard is reported and possible control measures are identified.

Step 7. Identify the Critical Control Points (Principle 2)

A critical control point (CCP) is a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. The HACCP team will use a CCP decision tree to help identify the critical control points in the process. A critical control point may control more than one food safety hazard or in some cases more than one CCP is needed to control a single hazard. The number of CCP's needed depends on the processing steps and the control needed to assure food safety.

Step8. Establish Critical Limits viz., target levels and tolerances which must be net to ensure each CCP is under control.(**Principle 3**)

A critical limit (CL) is the maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The critical limit is usually a measure such as time, temperature, water activity (Aw), pH, weight, or some other measure that is based on scientific literature and/or regulatory standards.

Step 9. Establish a monitoring system to ensure control of the CCP by schedule testing or observations. (Principle 4)

The HACCP team will describe monitoring procedures for the measurement of the critical limit at each critical control point. Monitoring procedures should describe how the measurement will be taken, when the measurement is taken, who is responsible for the measurement and how frequently the measurement is taken during production.

Step 10. - Establish the corrective action or preventive measures to be taken when monitoring indicates that a particular CCP is moving out of control. (Principle 5)

Corrective actions are the procedures that are followed when a deviation in a critical limit occurs. The HACCP team will identify the steps that will be taken to prevent potentially hazardous food from entering the food chain and the steps that are needed to correct the process. This usually includes identification of the problems and the steps taken to assure that the problem will not occur again.

Step 11. - Establish verification procedures which include appropriate supplementary tests, together with a review which confirms that HACCP is working effectively. **(Principle 6)**

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The HACCP team may identify activities such as auditing of CCP's, record review, prior shipment review, instrument calibration and product testing as part of the verification activities.

Step 12- Establish verification procedures which include appropriate supplementary tests, together with a review which confirms that HACCP is working effectively. (Principle 7)

A key component of the HACCP plan is recording information that can be used to prove that a food was produced safely. The records also need to include information about the HACCP plan. Record should include information on the HACCP Team, product description, flow diagrams, the hazard analysis, the CCP's identified, Critical Limits, Monitoring System, Corrective Actions, Recordkeeping Procedures, and Verification Procedures.

The HACCP is implemented in 12 steps which includes five preliminary steps followed by seven principles. The five preliminary steps include Assembly of HACCP team, description of the products, identifying its indented use, construct a flow diagram and on-site verification of process steps.

Before starting any study, senior management of the company must be committed to providing the necessary resources for the exercise to be completed and to implementing the finding of the exercise, including reviews and updates. Without such commitment there is little point in beginning the study. When conducting a HACCP study, the seven principles are applied in the following stages (Anon, 1996).

The success of HACCP depends on educating and training management and employees in importance of producing safe food which includes information of control of foodborne hazards related to all stages of food chain, making sure employees understand what HACCP is and providing specific

training on instructions and procedures that outline employee tasks in monitoring each Critical Control Point.

Definitions of some of the important terms associated with HACCP are given below for better understanding.

HACCP	:	A systematic approach to the identification, evaluation and control of food-safety hazards.
HACCP System	:	The result of the implementation of the HACCP plan
HACCP Plan	:	The written document that is based upon principles of HACCP and that delineates the procedures to be followed
HACCP Team	:	The group of people who are responsible for developing, implementing and maintaining the HACCP system
Flow Diagram	:	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item
Hazard	:	A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control
Severity	:	The seriousness of a hazard (if not properly controlled).
Control	:	(a)(Verb) To manage the conditions of an operation to maintain compliance with established criteria. (b) (Noun) The state in which correct procedures are being followed and criteria are being met.
Control Measure	:	Any action or activity that can be used to prevent, eliminate or reduce a significant hazard
Control Point	:	Any point, step or procedure at which biological, physical or chemical factors can be controlled

Critical Control Point (CCP)	:	A step at which control can be applied and is essential to prevent or eliminate a food-safety hazard or reduce it to an acceptable level.
CCP Decision Tree	:	A sequence of questions asked to determine whether a control point is a CCP.
Critical Limit	:	A criterion which separates acceptability from unacceptability.
	:	-A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.
Operating limits	:	Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation
Monitor	:	To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
Continuous Monitoring	:	Uninterrupted collect ion and recording of data such as temperature on a strip chart.
Corrective Action	:	Any action to be taken when the results of monitoring at the CCP indicate a loss of control
Deviation	:	Failure to meet a critical limit.
Validation	:	Obtaining evidence that the elements of the HACCP plan are effective.
Verification	:	The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

HACCP Does not Stand Alone

The application of HACCP does not stand alone in a food processing facility. The plan must be built on other food safety programs. Good Manufacturing Practices (GMP) that are practiced by the processing facility will support HACCP plan and will address food safety and food quality issues that are not critical for the reduction of food safety hazards. Sanitation Standard Operating Procedures (SSOP's) are required and address procedures for clean facilities, equipment and personnel that are necessary for all products produced in a facility.

Food provides nutrition for human being and quality of food is of at most importance in this health-conscious world. The quality is defined as the Degree to which a set of inherent characteristics fulfils requirements. Therefore, the aim of any food industry is to fulfil the requirements of the customer by adopting strategies in order to improve and stabilize production (and associated processes) to avoid, or at least minimize, issues which led to the defect(S) in the first place.

Chapter 2

Overview of Food Safety Scenario and Regulatory Requirements in Fish and Fishery Products

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Food Safety has been the buzz word in recent days as there are increasing consumer awareness on hazards present in food as well as the ombudsmen role played by independent media. Although regulatory regime across the world has taken proactive steps, in most of the cases it has been a knee-jerk reaction to the impending crisis. Defining the actual goal of food safety has been an arduous task as there are umpteen interrelated factors that influence the intended goals. Some of the definitions on food safety put forward by international agencies are as follows:

- Concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use (ISO 22000:2005)
- A suitable product which when consumed orally either by a human or an animal does not cause health risk to consumer (USDA-FSIS)
- Range of food related activities from prevention and surveillance to detection and control (ASTHO)

Food Safety also encompasses many aspects of handling, preparation and storage that introduces or controls chemical, microphysical and microbiological hazards. Quality of raw material, presence of pathogens, processing methods, climate change and cross-contamination also significantly impacts any food safety measure.

Seafood is always in news as it is proclaimed to be most nutritious and healthy food as well as being linked to increasing number of foodborne outbreaks across the globe. In the nutritional front, fish accounts for 17 percent of the global population intake of animal protein and 6.7% of all protein consumed (FAO, 2016). The world per capita consumption of fish and fishery products has increased from 9.9 Kg in 1960s to 20 Kg in 2014.

Seafood trade apart from being highly volatile accounts for 10 percent of total agricultural exports and 1 percent of world merchandise trade in value terms. In 2010, the quantum of seafood trade has crossed US$109 billion. Ninety percent of global trade in fish and fishery products consists of processed products, where 39% of the total quantity is traded as frozen. This trend indicates high mobility of the fishery products across the globe, which demands stringent traceability system in place to track the movement of the commodity from harvest to consumers. Nearly 75% of the volume of seafood in international trade is imported by developed nations and 50% of that is exported by developing nations. Hence, food safety issues concerned with seafood is no more local or restricted to a particular geographical location, but has acquired global dimension. Some of the major food safety concerns linked to seafood are:

- presence of Ciguatera toxin in reef dwelling finfish
- histamine fish poisoning
- norovirus and *Vibrio parahaemolyticus* in raw shellfish
- *Salmonella* in shrimp products
- *Clostridium botulinum* in processed products
- high level of environmental pollutants
- mercury, cadmium, lead
- polychlorinated biphenyls and pesticides
- antimicrobial residues in aquaculture products

Apart from the above-mentioned concerns which are mostly global, there are regional issues like use of adulterants like formaldehyde to retard decomposition process, ammonia to mask spoilage, use of un-approved additives (preservatives), high level of pesticides in dry fish and presence of emerging pathogens in fisheries environs.

The most challenging task for the policy makers has been to link incidences of foodborne illnesses with a particular food commodity. It needs a strong surveillance and monitoring mechanism to unequivocally attribute a particular food commodity. In USA, Centre for Disease Control (CDC) does the massive work of source tracking for major foodborne pathogens through pulse net programmes. The recent report by CDC (Scallan et al., 2011) indicates that 31 major pathogens reported in the United States caused 9.4 million episodes of foodborne illness, 55,961 hospitalizations and 1,351 deaths during 2. Most (58%) illnesses were caused by norovirus, followed bynon-typhoidal *Salmonella* spp. (11%), *Clostridium perfringens* (10%), and *Campylobacter* spp. (9%). Leading causes of hospitalization were nontyphoidal *Salmonella* spp. (35%), norovirus (26%), *Campylobacter* spp. (15%), and *Toxoplasma gondii* (8%). Leading causes of death were non-typhoidal *Salmonella* spp. (28%), *T. gondii* (24%), *Listeria monocytogenes* (19%), and norovirus (11%). In India, the recently established National Centre for Disease Control (formerly, National Institute of Communicable Diseases), Ministry of Health and Family Welfare, Government of India has a similar mandate to undertake activities on outbreak investigation and provide referral diagnostic services.

In absence of etiological data linked to seafood, the export rejection figures provide an indirect account of food safety hazards associated with seafood. Import refusals and rejections from countries like USA, Japan, Russia and EU are on the rise because of presence of biological and chemical hazards in seafood, leading to heavy economic loss by seafood industries. The most common import refusal of seafood by USA is due to presence of *Salmonella*, *Listeria*, filth or illegal veterinary drugs. The RASFF portal of EU indicates alert notifications due to presence of veterinary drug residues, heavy metals, histamine, foreign bodies, biotoxin, defective packaging, incorrect labelling, improper health certificate, unapproved colour and additives and organoleptic aspects. In recent months most of the rejections from Japan had been due to presence of furazolidone (AOZ) and Ethoxyquin in shrimp. Seafood rejections from Russia are mostly due to presence of high load of mesophilic bacteria, coliforms, pathogens and presence of crystal violet.

Genesis of Food Safety Standards and Regulations

Food safety standards can be classified as regulatory, voluntary, Government/Statutory, private, domestic, international or benchmarked depending upon its scope and range of application. Most of these standards have evolved based upon sanitary and phyto-sanitary (SPS) requirements, economic interest, risk analysis or as precautionary approach. The precautionary approach mostly relies on perception *i.e.* equivalent level of protection, appropriate level of protection (ALOP) or as low as reasonably achievable (ALARA).

In international trade, sanitary and phytosanitary measures are envisioned to be based on sound scientific principles that ensure food safety and do not anyway compromise the production potential and resources of a particular country. These measures should not be linked to prevent market access based on non-scientific reasons, and are requirements but not sufficient condition of trade. As per the Annex A of WTO Agreement, Sanitary and phytosanitary measures are applied to (i) protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms (ii) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs (iii) from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests and (iv) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests. WTO encourages members to use accepted International standards by Codex Alimentarius Commission, OIE (World Organization for Animal Health) and IPPC (International Plant Protection Convention). Countries may introduce or maintain SPS measures that provide higher level of protection than the current international or Codex standards.

Salient features of some Export regulations related to Seafood 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.

Regulation: A binding legislative act applied in entirety across EU

Directives: A "directive" is a legislative act that sets out a goal that all EU countries must achieve.

Decision: A "decision" is binding on those to whom it is addressed (e.g. an EU country or an individual company) and is directly applicable.

Recommendations: A "recommendation" is not binding act that allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

Opinions: An "opinion" is an instrument that allows the institutions to make a statement in a non-binding fashion, in other words without imposing any legal obligation on those to whom it is addressed.

Some of the important EU legislations related to food safety issues of fish and fishery products are as follows:

Regulation (EC) No 178/2002: General principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EC) No 852/2004: Hygiene of foodstuffs.

Regulation (EC) No 853/2004: Specific hygiene rules for food of animal origin

Regulation (EC) No 854/2004: Specific rules for the organisation of official controls on products of animal origin intended for human consumption

Regulation (EC) No 2073/2005: Microbiological criteria for foodstuffs

Regulation (EC) No 882/2004: Official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Regulation (EC) No 1881/2006: Maximum levels for certain contaminants in foodstuffs

Regulation (EC) No 333/2007: Methods of sampling and analysis for the official controls for the levels of lead, cadmium, mercury, inorganic tin, 3- MCPD and benzo(a)pyrene in foodstuffs

Regulation (EC) No 1883/2006: Methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs

Regulation (EC) No 396/2005: Maximum residue levels of pesticides in or on food and feed of plant and animal origin

Council Directive 96/23/EC: Measures to monitor certain substances and residues thereof in live animals and animal products

Commission Decision (2005/34/EC): Harmonised standards for the testing for certain residues in products of animal origin imported from third countries

Commission Decision (2002/657/EC): Implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results

Commission Decision (98/179/EC): Official sampling for the monitoring of certain substances and residues thereof in live animals and animal products

Commission Decision (2004/432/EC): Approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC

Council Directive 96/22/EC: Prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of betaagonists

Regulation (EC) No 470/2009: Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin

Commission Regulation (EU) No 37/2010: Pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

Commission Regulation (EC) No 2023/2006: Good manufacturing practice for materials and articles intended to come into contact with food

Commission Regulation (EC) No 1935/2004: Materials and articles intended to come into contact with food

Commission Regulation (EU) No 1129/2011: Amendment to Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the

Council by establishing a Union list of food additives Commission Regulation (EC) No 1333/2008 : Food Additives

Commission Regulation (EC) No 1334/2008: Flavourings and certain food ingredients with flavouring properties for use in and on foods

Commission Regulation (EC) No 1331/2008: Establishing a common authorisation procedure for food additives, food enzymes and food flavourings

Directive 2000/13/EC: Labelling, presentation and advertising of foodstuffs (until 12 December 2014)

Commission Regulation (EU) No 1169/2011: Provision of food information to consumers, amending Regulations

Commission Regulation (EU) No 1379/2013: Common organisation of the markets in fishery and aquaculture products

USA

In USA both Federal and State Regulatory agencies are involved in ensuring safety and quality of seafood. Multiple federal agencies are involved in regulatory oversight of seafood for both importation and export.

United States Department of Agriculture (USDA) oversees the implementation of country-of-origin labelling (COOL) regulation enacted under the Farm Security and Rural Investment Act of 2002. This law requires that all retailers, such as full-line grocery stores or supermarkets must notify their customers with information regarding the source of certain foods. The COOL regulation for fish and shellfish (7 CFR Part 60) came into force in 2005. Apart from the country of origin, all fish and shellfish covered commodities must be labelled to indicate whether they are wild caught or farm-raised.

United States Fisheries and Wildlife Service (USFWS) is also involved in regulation of import and export of shellfish and fishery products through Convention on International Trade in Endangered Species (CITES) act (50 CFR Part 23), Endangered Species Act (50 CFR Part 17), General Permit

Procedures (50 CFR Part 13), Lacey Act (injurious wildlife) (50 CFR Part 16), Marine Mammal Protection Act (50 CFR Part 18) and Wildlife (import/export/transport) act (50 CFR Part 14). Live farm-raised fish and farm-raised fish eggs are exempted from export declaration and licensing requirements. Imports or exports of any sturgeon or paddlefish product, including meat, caviar, and cosmetics made from sturgeon eggs, dead uneviscerated salmon, trout and char and live fertilized eggs from these salmonid fish require a permit. Aquatic invertebrates and other animals that are imported or exported for human or animal consumption but that do not meet the definition of shellfish such as squid, octopus, cuttlefish, land snails, sea urchins, sea cucumbers and frogs are also covered under these provisions.

National Oceanic and Atmospheric Administration (NOAA) functioning under the United States Department of Commerce (USDC) provides voluntary seafood inspection program for fish, shellfish, and fishery products to the industry as per the 1946 Agricultural Marketing Act. The NOAA Seafood Inspection Programme often referred to as the U.S. Department of Commerce (USDC) Seafood Inspection Programme provides services such as establishment sanitation inspection, system and process audits, product inspection and grading, product lot inspection, laboratory analyses, training, consultation and export certification. NOAA Fisheries is the Competent Authority for export health certification and IUU catch documentation for US seafood products meant for export to EU and non-EU countries.

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. For screening imports, USFDA uses a tool “Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)”, that targets higher risk products for examination and sampling and minimizes the delay in shipments of lower risk products.

Food Safety and Modernization Act (FSMA) is the most important milestone event in the food safety scenario in USA. It was signed in to law on 4th January 2011 which sifted the focus from responding to a contamination to prevention of the actual cause. The salient features of FSMA act are as follows:

Sec. 103.Hazard analysis and risk-based preventive controls

(HARPC): Requires human and animal food facilities to

- evaluate hazards that could affect food safety;
- Identify and implement preventive controls to prevent hazards;
- Monitor controls and maintain monitoring records; and
- Conduct verification activities

Sec. 106.Protection against intentional adulteration

Sec. 111. Sanitary Transportation of Food

Sec. 301. Foreign supplier verification program

• Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements.

Sec. 302. Voluntary qualified importer program

Allows for expedited review and entry; facility certification required

Sec. 303. Certification for high-risk food imports

• FDA has discretionary authority to require assurances of compliance for high-risk foods

Sec. 304. Prior notice of imported food shipments

• Requires information on prior refusals to be added to prior notice submission

• Effective July 3, 2011

Sec. 307. Accreditation of third-party auditors

• FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements

Sec. 308. Foreign Offices of the Food and Drug Administration.

• Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.

Sec. 309. Smuggled Food

• In coordination with DHS, better identify and prevent entry of smuggled food

• Rules on anti-smuggling strategy is already framed

China

In recent years China has strengthened its SPS measures and has taken a number of precautionary steps to ensure safety to its population. Some of the important regulations enacted by Peoples Republic of China are as follows:

- GB 2763—2012: National food safety standard on Maximum residue limits for pesticides in food
- GB 2762—2012: National food safety standard on Contaminants in Food
- GB-2010: National Food Safety Standard for Pathogen Limits in Food (GAIN Report No. 12063)
- GB 2733-2005: Hygienic Standard for Fresh and Frozen Marine Products of Animal Origin
- GB 2760-2011 additives
- GB 10136-1988 Hygienic standard for salt & liquor-saturated aquatic products of animal origin

Russia

Russia has a comprehensive regulatory framework for fish and fishery products. The hygienic requirements are different from other countries as some of the microbiological parameters are expressed as absent in 0.001g or 0.01g. Also some different nomenclature like QMAFAnM is followed instead of APC. The Russian regulation currently in force pertaining to fish and

fishery products are as follows:

- Hygienic requirements for safety and nutrition value of food products. Sanitary and epidemiological rules and regulations, sanpin 2.3.2.1078-01

Japan

Compared to other countries, SPS measures followed by Japan is very stringent. Many additives which are in the approved list of Codex are banned or prohibited in Japan. Japan uses a positive list system for MRL of agricultural chemicals in foods. A uniform limit of 0.01 ppm is followed for the compounds for which no risk assessment is done but which are included in the positive list (MHLW Notification No. 497, 2005). MHLW uses a toxicological threshold of 1.5 µg/day as the basis to determine the uniform limit. Substances having no potential to cause damage to human health are specified by MHLW Notification No.498. 2005. The MRL list is mentioned as compositional specification of foods (MHW Notification, No. 370, 1959, amendment No.499 2005, updated as on March 15, 2013). The relevant food safety acts of Japan as enacted by Ministry of Health, Labour and Welfare and other agencies are as follows:

- Food Sanitation Act (Act No.233, 1947): Latest Revision on June 5, 2009, Act No. 49)
- Specifications and Standards for Food and Food Additives, Latest Revision on September 6, 2010, MHLW Notification No. 336
- Japan's Specifications and Standards for Food Additives" (Eighth Edition). Published by the Ministry of Health, Labour and Welfare in 2007
- Food Safety Basic Act (Act No. 48, 2003)
- Agricultural Chemicals Regulation Law (Law No. 82, 1948)

Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC) was established in 1961- 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to implement their Joint FAO/WHO Food Standards Programme. 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. Codex operates through thee standing expert scientific bodies convened under the auspices of FAO and WHO to generate food data and provide risk-assessment type advice:

- Joint Expert Committee on Food Additives (JECFA)
- Joint Meeting on Pesticide Residues (JMPR)
- Joint Meeting on Microbiological Risk Assessment (JEMRA)

Different subject committees and commodity committees, adhoc intergovernmental task forces and regional coordinating committees function and under codex. Codex Committee on Fish and Fisheries Products (CCFFP) is entrusted with the task of formulating standards for different product categories. Although Codex standards on Fish and Fishery Products specifically do not address food safety requirements, but provide a strong framework for production, hygienic requirements and sampling.

Available Codex Standard for Fish and Fishery Products

1.	Standard for Canned Salmon	CODEX STAN 3-1981
2.	Standard for Quick Frozen Finfish, Eviscerated or Uneviscerated	CODEX STAN 36-1981
3.	Standard for Canned Shrimps or Prawns	CODEX STAN 37-1981
4.	Standard for Canned Tuna and Bonito	CODEX STAN 70-1981
5.	Standard for Canned Crab Meat	CODEX STAN 90-1981
6.	Standard for Quick Frozen Shrimps or Prawns	CODEX STAN 92-1981
7.	Standard for Sardines and Sardine-Type Products	CODEX STAN 94-1981
8.	Standard for Quick Frozen Lobsters	CODEX STAN 95-1981
9.	Standard for Canned Finfish	CODEX STAN 119-1981
10	Standard for Quick Frozen Blocks of Fish Fillets, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh	CODEX STAN 165-1989
11	Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets - Breaded or in Batter	CODEX STAN 166-1989
12	Standard for Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes	CODEX STAN 167-1989
13	Standard for Dried Shark Fins	CODEX STAN 189-1993
14	General Standard for Quick Frozen Fish Fillets	CODEX STAN 190-1995
15	Standard for Quick Frozen Raw Squid	CODEX STAN 191-1995
16	Standard for Crackers from Marine and Freshwater Fish, Crustaceans and Molluscan Shellfish	CODEX STAN 222-2001
17	Standard for Boiled Dried Salted Anchovies	CODEX STAN 236-2003
18	Standard for Salted Atlantic Herring and Salted Sprat	CODEX STAN 244-2004
19	Standard for Sturgeon Caviar	CODEX STAN 291-2010
20	Standard for Live and Raw Bivalve Molluscs	CODEX STAN 292-2008
21	Standard for Fish Sauce	CODEX STAN 302-2011

Code of Practice

Code of Practice for Fish and Fishery Products	CAC/RCP 52-2003

Guidelines

Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories	CAC/GL 31-1999
Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood	CAC/GL 73-2010
Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food	CAC/GL 79-2012
Model Certificate for Fish and Fishery Products	CAC/GL 48-2004
Guideline Procedures for the Visual Inspection of Lots of Canned Foods for Unacceptable Defects	CAC/GL 17-1993
Guidelines on Good Laboratory Practice in Pesticide Residue Analysis	CAC/GL 40-1993
General guidelines on sampling	CAC/GL 50-2004
Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Quantitative Determination of Residues	CAC/GL 56-2005

Codex standard applicable to Fish and Fishery Products

General Standard for Contaminants and Toxins in Food and Feed	CODEX STAN 193-1995
General Standard for the Labelling of Prepackaged Foods	CODEX STAN 1-1985
Standard for Food Grade Salt	CODEX STAN 150-1985
General Standard for Food Additives	CODEX STAN 192-1995
General Methods of Analysis for Contaminants	CODEX STAN 228-2001
Recommended Methods of Analysis and Sampling	CODEX STAN 234-1999
General Methods of Analysis for Food Additives	CODEX STAN 239-2003

Bureau of Indian Standards (BIS)

Bureau of Indian Standards (BIS) functioning under the Ministry of Consumer Affairs, Food and Public Distribution, Government of India. It came into existence on 01 April 1987 through an Act of Parliament on 26 November 1986. It was functioning previously as Indian Standards Institution which was established on 06 January 1947. BIS has so far formulated 64 standards related to fish and fishery products, out of which 33 are active. All these standards are voluntary, which addresses method of production, quality and safety requirements. It also stipulates the method of testing and sampling. There is an attempt by FSSAI to re-draft all BIS standards related to fish and fishery products as most of the food safety requirements are not in sync with the current national standards.

BIS Standards on Fish and Fishery Products

IS 2168	1971	Pomfret Canned in Oil
IS 2236	1968	Prawns/Shrimp Caned in Brine
IS 2237	1997	Prawns (Shrimps) - Frozen
IS 3336	1965	Shark Liver Oil for Veterinary Use
IS 3892	1975	Frozen Lobster Tails
IS 4304	1976	Tuna Canned in Oil
IS 4780	1978	Pomfret, Fresh
IS 4793	1997	Whole Pomfret - Frozen
IS 5734	1970	Sardine Oil
IS 6121	1985	*Lactarius* sp Canned in Oil
IS 6122	1997	Seer Fish (*Scomberomorus* Sp.) - Frozen
IS 6123	1971	Seer Fish (*Scomberomorus* spp.), Fresh
IS 7143	1973	Crab Meat Canned in Brine
IS 7313	1974	Glossary of Important Fish Species of India
IS 7582	1975	Crab Meat, Solid Packed
IS 8076	2000	Frozen Cuttlefish and Squid
IS 9808	1981	Fish Protein Concentrate
IS 10059	1981	Edible Fish Powder
IS 10760	1983	Mussels Canned in Oil
IS 10762	1983	Tuna Canned in Curry
IS 10763	1983	Frozen Minced Fish Meat
IS 11427	2001	Fish and Fisheries Products - Sampling
IS 14513	1998	Beche-de-mer
IS 14514	1998	Clam Meat - Frozen
IS 14515	1998	Fish Pickles
IS 14516	1998	Cured fish and fisheries products - Processing and storage - Code of Practice
IS 14517	1998	Fish Processing Industry - Water and Ice - Technical Requirements
IS 14520	1998	Fish Industry - Operational Cleanliness and layout of market - Guidelines (Amalgamated Revision of IS 5735, 7581 and 8082)
IS 14890	2001	Sardines - Fresh, Frozen and Canned (Amalgamated revision of IS 2421, 6677,8652,8653, 9750 and 10761
4891	2001	Mackerel - Fresh, Frozen and Canned (Amalgamated Revision of IS 2420, 3849,6032, 6033 and 9312)
IS 14892	2000	Threadfin - Fresh and Frozen
IS 14949	2001	Accelerated Freeze Dried Prawns (Shrimps) (Amalgamated revision of IS 4781 and 4796
IS 14950	2001	Fish - Dried and Dry-Salted

Food Safety and Standards Authority of India (FSSAI)

The Food Safety and Standards Authority of India was established under the Food Safety and Standards Act, 2006 as a statutory body for laying down science based standards for articles of food and regulating manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption. Various central acts including the erstwhile Prevention

of Food Adulteration Act (1954) were merged under this act The Food Safety and Standards Regulations (FSSR) came into force in 2011, which is divided to following sections:

FSS (Licensing and Registration of Food businesses) regulation, 2011

- FSS (Packaging and Labelling) regulation, 2011
- FSS (Food product standards and Food Additives) regulation, 2011 (part I)
  FSS (Food product standards and food additives) regulation, 2011
  (part II)
- FSS (Prohibition and Restriction on sales) regulation, 2011
- FSS (contaminants, toxins and residues) regulation, 2011
- FSS (Laboratory and sampling analysis) regulation, 2011

Recently, standards related to microbiological specifications of fish and fishery products, limit of heavy metals, PAH, PCBs and biotoxins have been incorporated in the FSSR.

HACCP concept in seafood quality assurance

Concept of HACCP was developed in the late 1950s and initiated in the early 1960s by the Pillsbury Company, in collaboration with NASA and the Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group. The concepts designed were based on the principles of Failure Mode and Effect analysis (FEMA). It was first presented to regulatory community during National Conference on Food Protection in 1971 by Howard Bauman of the Pillsbury Company and first applied to low acid canned foods in 1974. In 1980s, other food processing companies embraced it voluntarily and at the same time FDA and USDA continued regulatory interest. HACCP gained regulatory approval from USFDA and USDA after it was endorsed by National Academy of Sciences and further by 9National Advisory Committee on Microbiological Specifications of Foods (NACMSF). On December 18, 1995, The Food and Drug Administration (FDA) published as a final rule 21 CFR 123, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" that requires processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations. The regulation became effective December 18, 1997. HACCP was recommended by Codex Alimentarius Commission (CAC) in 1997 which is recognized as “Recommended International Code of Practice-General Principles of Food Hygiene” (CAC/RCP 1-1969, Rev 3, 1997). In European countries, the EU Directive 93/43/EEC mandated the implementation of HACCP in all local legislation by December 1995. Subsequently the EC hygiene regulations 852/2004 and 853/2004 mandated that all food business operators should establish and operate food safety programmes and procedure based on HACCP principles. Since then HACCP has gained acceptance by many countries in Europe, Canada, New Zealand, Australia, Central and South America and many Asian countries. In India voluntary HACCP standards are given by Bureau of Indian Standards (IS 15000:1998).

Hazard Analysis Critical Control Point (HACCP)

The HACCP system is an internationally recognized system used to manage food safety. It has been endorsed by the Codex Alimentarius Commission as a tool that can be used to systematically identify hazards specific to individual products and processes and describe measures for their control to ensure the safety of fish and fish products. It is a dynamic system, capable of accommodating change in the system viz., changes in equipment design, processing procedures and technological advancements.

HACCP is defined as a system which identifies, evaluates, and controls hazards which are significant for food safety

HACCP is a structured, systematic approach for the control of food safety throughout the food system, from the farm to fork. It requires a good understanding of the relationship between cause and effect in order to be more pro-active. HACCP is supported by pre-requisite programmes like Good Manufacturing Practice (GMP), Good Hygienic Practices (GHP), SSOP (Sanitation standard operating procedures), Good Agricultural Practices (GAP), and Good Storage Practices (GSP), *etc*.

Pre-requisite programmes

Prerequisite programs provide a foundation for an effective HACCP system. They are often facility-wide programs rather than process or product specific. They reduce the likelihood of certain hazards. Prerequisite programs set the stage for a HACCP system and provide on-going support for the establishment's food safety system. They keep potential hazards from becoming serious enough to adversely impact the safety of foods produced. Without clean working conditions free from microbiological, chemical, and physical contamination from many sources, a HACCP plan cannot be effective.

Prerequisite programmes are practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety -WHO

Some of the prerequisite programmes include GAP, GMP and GHP which must be working effectively within a commodity system before HACCP is applied. Establishments should revise their prerequisite programs, as necessary, to ensure their effectiveness, and should take appropriate corrective actions when they determine that their prerequisite programs may have failed to prevent contamination and/or adulteration of product. Good Agricultural Practices are "practices that address environmental, economic and social sustainability for on-farm processes, and result in safe and quality food and non-food agricultural products" (FAO).

The Good Manufacturing Practices commonly referred as current good manufacturing practices (cGMPs, 21 CFR 110) give details as to what specific procedures must be followed to comply with the regulation. Standard operating procedures (SOPs) are the steps your company takes to assure that the GMPs are met. They include stepwise procedures, employee training, monitoring methods, and records used by your company. Similarly, SSOP covers eight key sanitation conditions as required by USFDA. Good hygiene practices include all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Basic principles of HACCP

There are seven discrete activities that are necessary to establish, implement and maintain a HACCP plan, and these are referred to as the 'seven principles' in the Codex Guideline (1997). The seven Principles of HACCP are

Principle 1: Conduct a hazard analysis.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Principle 2: Determine the Critical Control Points (CCPs)

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Principle 3: Establish critical limits.

A criterion which separates acceptability from unacceptability, when monitoring a critical control point.

Principle 4: Establish a monitoring system

The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Principle 5: Establish a procedure for corrective action,

Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Principle 6: Establish procedures for verification

The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Principle 7: Establish documentation concerning all procedures and records appropriate to these principles and their application

Developing a HACCP plan (FAO guidelines)

The all-important principles form the essential requirements of a food safety system and are designed to ensure that enough precaution is taken so that any hazard which can interfere with consumer health is addressed. The first principle of HACCP is hazard analysis. But understanding the product thoroughly is extremely important to get an idea on the possible hazards which could be associated with the product so that appropriate action can be taken to control or minimize the hazard. The seven principles of HACCP are usually carried out in twelve steps, as given below.

Step 1 - Establish a HACCP team

Hazard profile is related to the commodity. Therefore in order to understand fully the commodity, to identify the hazards associated, the CCP and to work out a control measures it is pertinent to have a team which has the knowledge about the product or commodity, its production process and shelf-life. This would facilitate the proper implementation of HACCP for the production of the product. Therefore, it is important that the HACCP team is made up of people from a wide range of disciplines. The team should include:

- A team leader to lead the group and direct the team to carry out the work as per the system requirements. He should be well versed with the techniques and manage the team members to contribute to the cause.
- A person conversant with the production system who knows full details of the flow of production.
- Persons from varied field viz., biochemist, microbiologist, toxicologist, quality control manager or an engineer with an understanding of particular hazards and associated risks.
- Others who are involved in the varied activates of the system viz., packaging specialists, raw material buyers, distribution staff or production staff, farmers, brokers, who are involved with the process, and have working knowledge of it in order to provide expert opinion.
- Possibly one person to help the team with secretarial requirements.

Task 2 - Describe the product

Understanding the product is the important step as the hazard associated with depends on the product. To start a hazard analysis, a full description of the product, including customer specification, should be prepared. This should include information relevant to safety regulation/target level, and composition, physical/chemical properties of the raw materials and the final product, the water activity of the product (aw), the pH etc. There should information on the packaging, storage and distribution as well as information on the temperature of storage, distribution, labelling information and shelf-life of the product. This information helps the audit team to understand the possible hazards and their control measures.

Task 3 - Identify the product's intended use

Information on the intended use of the commodity or product as well as the information on the mode of consumption viz., direct consumption, cooked before hazard analysis will have bearing on the hazard analysis. The nature of the target group for the product may also be relevant, particularly if it includes susceptible groups such as infants, the elderly, and the malnourished. The likelihood of misuse of a product should also be considered, such as the use of pet food as a human food, either by accident or design.

Task 4 - Draw up the commodity flow diagram

The first function of the team is inspecting the detailed commodity flow diagram (CFD) of the commodity system and the expertise of the production manager or product expert is important at this stage as far as hazard analysis is concerned.

Task 5 - On site confirmation of flow diagram

After studying the commodity flow diagram the team should visit the system where HACCP is implemented or proposed to be implemented which may include any step in the production viz., procurement of raw material, store, production area, packaging area, storage section where the product is kept before distribution, nature of distribution, conditions of distribution etc. The is known as 'walking the line ', a step by step checking to get information on whether relevant requirements of the system are considered while making the production line. The site for which the HACCP plan is being designed should be visited as many times as possible to ensure that all relevant information has been collected.

Task 6 - Identify and analyse hazard(s) - (Principle 1)

Effective hazard identification and hazard analysis are the keys to a successful HACCP Plan. All real or potential hazards that may occur in each ingredient and at each stage of the commodity system should be considered. Food safety hazards for HACCP programmes have been classified into three types of hazards:

- Biological: typically foodborne bacterial pathogens such as Salmonella, Listeria and E. coli, also viruses, algae, parasites and fungi.
- Chemical: There are three principle types of chemical toxins found in foods: naturally occurring chemicals, e.g. cyanides in some root crops, and allergenic compounds in peanuts; toxins produced by microorganisms, e.g. mycotoxins, and algal toxins; and chemicals added to the commodity by man to control an identified problem, e.gfungicidesor insecticides.
- Physical: contaminants such as broken glass, metal fragments, insects or stones.

The probability that a hazard will occur is called a risk. The risk may take a value from zero to one depending on the degree of certainty that the hazard will be absent or that it will be present. After hazard identification, a hazard analysis must be conducted to understand the relative health risk to man or animal posed by the hazard. It is a way of organizing and analysing the available scientific information on the nature and size of the health risk associated with the hazard. The risk may have to be assessed subjectively and simply classified as low, medium, or high. Once a food safety hazard has been identified, then appropriate control measures should be considered. These are any action or activity that can be used to control the identified hazard, such that it is prevented, eliminated, or reduced to an acceptable level. The control measure may also include training of personnel for a particular operation, covered by GAP, GMP, and GHP.

Task 7 - Determine the critical control points (CCPs) - (Principle 2).

Each step in the commodity flow diagram, within the scope of the HACCP study, should be taken in turn and the relevance of each identified hazard should be considered. The team must determine whether the hazard can occur at this step, and if so whether control measures exist. If the hazard can be controlled adequately, and is not best controlled at another step, and is essential for food safety, then this step is a CCP for the specified hazard. If a step is identified where a food safety hazard exists, but no adequate control measures can be put in place either at this step or subsequently, then the

product is unsafe for human consumption. Production should cease until control measures are available and a CCP can be introduced.

Task 8 - Establish critical limits for each CCP - (Principle 3)

Critical limits must be specified and validated for each CCP. Criteria often used include measurements of temperature, time, moisture level, pH, water activity, and sensory parameters such as visual appearance. All critical limits, and the associated permissible tolerances, must be documented in the HACCP Plan Worksheet, and included as specifications in operating procedures and work instructions.

Task 9 - Establish a monitoring procedure - (Principle 4)

Monitoring is the mechanism for confirming that critical limits at each CCP are being met. The method chosen for monitoring must be sensitive and produce a rapid result so that trained operatives are able to detect any loss of control of the step. This is imperative so that corrective action can be taken as quickly as possible so that loss of product will be avoided or minimized. Monitoring can be carried out by observation or by measurement, on samples taken in accordance with a statistically based sampling plan. Monitoring by visual observation is basic but gives rapid results, and can therefore be acted upon quickly. The most common measurements taken are time, temperature and moisture content.

Task 10 - Establish corrective action - (Principle 5)

If monitoring indicates that critical limits are not being met, thus demonstrating that the process is out of control, corrective action must be taken immediately. The corrective action should take into account the worst case scenario, but must also be based on the assessment of hazards, risk and severity, and on the final use of the product. Operatives responsible for monitoring CCPs should be familiar with and have received comprehensive training in how to effect a corrective action. Corrective actions must ensure that the CCP has been brought back under control. Corrective action can then be applied to pre-empt a deviation and prevent the need for any product disposition.

Task 11 - Verify the HACCP plan - (Principle 6)

Once the HACCP plan has been drawn up, and all of the CCPs have been validated, then the complete plan must be verified. Once the HACCP plan is in routine operation, it must be verified and reviewed at regular intervals. This should be a task of the person charged with the responsibility for that particular component of the commodity system. The appropriateness of CCPs and control measures can thus be determined, and the extent and effectiveness of monitoring can be verified. Microbiological and/or alternative chemical tests can be used to confirm that the plan is in control and the product is meeting customer specifications. A formal internal auditing plan of the system will also demonstrate an ongoing commitment to keep the HACCP plan up to date, as well as representing an essential verification activity.

Task 12 - Keep record - (Principle 7)

Record keeping is an essential part of the HACCP process. It demonstrates that the correct procedures have been followed from the start to the end of the process, offering product traceability. It provides a record of compliance with the critical limits set, and can be used to identify problem areas. Records

that should be kept include: all processes and procedures linked to CCP monitoring, deviations, and corrective actions.

Steps involved in developing HACCP system

(Based on Codex 1997)

Step 1.	Assemble HACCP team	Preliminary Steps
Step 2.	Describe product	
Step 3.	Identify intended use	
Step 4.	Construct flow diagram	
Step 5.	On-site confirmation of flow diagram	
Step 6.	Conduct hazard analysis	HACCP Principle I
Step 7.	Determine Critical Control Points	HACCP Principle II
Step 8.	Establish critical limits for each CCP	HACCP Principle III
Step 9.	Establish a monitoring system for each CCP	HACCP Principle IV
Step 10.	Establish corrective actions	HACCP Principle V
Step 11.	Establish verification procedures	HACCP Principle VI
Step 12.	Establish Documentation and Record Keeping	HACCP Principle VII

HACCP is a core component in all national and international food safety standards such as IS 15000, ISO 22000:2005, USFDA Seafood HACCP regulation (CFR 123, Title 21), Dutch HACCP, BRC Global Standard for Food, SQF 2000, IFS, etc. Hence understanding concepts of HACCP would help in easy implementation of any food safety standard(s) deemed necessary to ensure safety of fish and fishery products.

Definitions in HACCP

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability, when monitoring a critical control point.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Chapter 3

Fish Processing Methods: Orientation

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Introduction

Research on food processing have attracted more due to huge demand in supply of healthy and safe food products. Health, nutrition and convenience are the major factors driving the global food industry in this era. Fish products have attracted considerable attention as a source of high amounts of important nutritional Components like high-quality protein, essential vitamins, minerals and healthful polyunsaturated fatty acids to the human diet. As a result of this the fresh fish and seafood's rank third among the food categories with the fastest overall growth worldwide, next to drinkable yogurt (18 %) and fresh soup (18 %). Consumption of both freshwater and seawater fish is expected to increase in the future. As fish is highly nutritious, it is also highly susceptible to spoilage, due to intrinsic and extrinsic factors. Proper processing and packaging help in maintaining the eating quality of fish for extended period. Worldwide, an array of processing and packaging methods are followed. This ranges from a simple chilled or ice storage, salted and drying to most recent and advanced high pressure and electromagnetic field applications, which attracts opportunities from both small scale and industrial level entrepreneurs. Fish products in live, fresh chilled, whole cleaned, fillets steaks, battered and breaded products, variety of dried products, smoked fish, fish sausage and traditional products are the range of low-cost processing methods which can be readily adopted by small-scale fishers. The processing methods like canning or heat processing, freezing, vacuum and modified atmosphere packaging, analogue products, high pressure processing, pulsed light processing, irradiation, electromagnetic field etc are the processing methods which requires higher investments can be adopted by large scale entrepreneurs, apart from the above-mentioned processing methods.

Benefits of Processing

- Converts raw food into edible, usable and palatable form
- Helps in preservation and storage of perishable and semi-perishable agricultural commodities
- Helps in avoiding glut in the market and reduces post-harvest losses and make the produce available during off-season
- Generates employment
- Development of ready-to-consume convenient products which saves time for cooking
- Helps in improving palatability and organoleptic quality of the produce by value addition and helps in inhibiting anti-nutritional factors
- Helps in easing marketing and distribution tasks
- Enables transportation of delicate perishable foods across long distances
- Makes foods safe for consumption by controlling pathogenic microorganisms
- Modern food processing also improves the quality of living by way of healthy foods developed for special people who are allergic to certain ingredients, diabetic etc., who cannot consume some common food elements
- Food processing can also bring nutritional and food security
- Provides potential for export to fetch foreign exchange

Aim of Preservation/ Processing

Based on the perishability and the extent of preservation required, foods may be classified as:

1. ***Perishable foods*:** Those that deteriorate readily (Seafood, meat, fruits and vegetables) unless special methods of preservation are employed.
2. ***Semi-perishable foods***: Those that contain natural inhibitors of spoilage (root vegetables) or those that have received some type of mild treatment which creates greater tolerance to the environmental conditions and abuses during distribution and handling (such as pickled meat and vegetables).
3. ***Non-perishable foods*** *(shelf-stable)*: Those that are non-perishable at room temperature (cereal grains, sugar, nuts). Some have been made shelf stable by suitable means (canning) or processed to reduce their moisture content (dried fish and shellfishes, raisins). Food preservation in the broad sense, refers to all the measures taken against any kind of spoilage in food.

Live Fishery Products

There is a great demand for live fish and shellfishes, the world over. These products fetch maximum price compared to all the other forms of value-added products as it maintains the freshness. The candidate species for live transportation include high value species, cultured grouper, red snapper, seabreams, seabass, red tilapia, reef fish, air breathing fishes, shrimp, crabs, lobster, clams, oyster and mussels. These are normally transported in air cargo maintained at low temperature in order to lessen the metabolic activities of the animals.

Chilled Fishery Products

Chilling is an effective method of maintaining the freshness of fish products. This normally involves keeping fishes in melting ice or slurry ice to maintain the fish temperature around 1- 4 ºC, which delays the enzymatic action and microbial activity, thereby extending the shelf life of the products. Traditionally, chilling is carried out using melting ice, either flake ice or crushed block ice. Of late, slurry ice has been introduced for chilling. A wide range of fish and shellfish products varying from whole, headless, peeled gutted, headless gutted fish, fillets, steaks, loins, cubes can be preserved by chilling. Shelf life of fishes from different environment has been studied by the Division extensively. Shelf life of 12-15 days has been achieved for seerfish and black pomfret. Indian Mackerel and Indian oil sardine had very short shelf life in ice (3-7 days), due torancidity and belly bursting. Tilapia from freshwater and brackishwater showed significant difference in shelf life when stored in ice. The former kept longer (14-15 days) than latter (8-10 days).

Frozen Fishery Products

Freezing is an age old practice to retain the quality and freshness of fishery products for a long time. This involves the conversion of water present in fishery products to ice i.e., a phase change from liquid to solid phase takes place in freezing. This retards the microbial and enzymatic action by reducing the water available for their action. This involves exposing fish products to very low temperature (<-35^{0}C) to enable freezing of free water and maintained at -18^{0}C till it is consumed. Plate freezing, air blast freezing, cryogenic freezing and individual quick freezing are the methods adopted by the industry to preserve food products.

Canning

Canning is a method of food preservation in which preservation is achieved by the destruction of micro-organisms by the application of heat of food packed in a sealed container. Since the canned foods are sufficiently cooked products and free from micro-organisms, they offer consumer safety besides being ready to consume. Canning has the unique distinction of being an invention in the field of food processing/ preservation whereas all other methods can be considered as adaptation of natural processes or their modifications. Because of their very long shelf life and ready to consume feature canned products have become very popular and a variety of food stuffs, both plant and animal origin and their combinations are produced and distributed.

However, the fish canning industry in India is declining due to the high cost of cans. Recent innovations like polymer coated Tin Free Steel (TFS) cans provide a cheaper alternative. Studies conducted at CIFT showed that polyester-coated TFS cans are used for processing ready to serve fish products, which can be stored at room temperature for long periods. The industry can utilize these cans for processing ready to eat fish and shell fish products for both domestic and export markets. This will help in reviving the canning industry in India.

Unit Operations in a canning process are:

1. Selection and preparation of raw material.
2. Pre-cooking / blanching
3. Filling in to containers.
4. Addition of liquid medium
5. Exhausting
6. Seaming
7. Heat Processing / Retorting
8. Cooling
9. Drying, warehousing, labelling and casing

Dried and Salted Fishery Products

Drying is probably one of the oldest methods of food preservation. It consists of removal of water to a final desired concentration, which in turn reduces the water activity of the product, thereby assuring microbial stability and extended shelf-life of the product. In some cases, common table salt (Sodium chloride) is also used to prolong the shelf life of fish. Salt absorbs much of the water in the food and makes it difficult for micro-organisms to survive.

Smoked Fishery Products

Smoking is one of the most widely used traditional fish processing methods employed in many countries to preserve fish. The preservation effect of the smoke is a result of drying of the product during the smoking as well as due to smoke particle absorption into the flesh. The smoke particles, mainly phenolic compounds, carbonyl and organic acids, being absorbed by the product, inhibit bacterial growth on the surface of the product. The smoke particles also have a positive effect on the taste and colour of the product and in many instances, smoking is normally practiced to improve these sensory characteristics.

Hot and liquid smoked fish chunks and masmin chunks

Battered and Breaded Products

The most prominent among the group of value-added products is the battered and breaded products processed out of a variety of fish and shellfish. Battered and breaded products offer a 'convenience' food widely valued by the consumer. These are products, which receive a coat or two each of a batter followed by coating with breadcrumbs, thus increasing the bulk and reducing the cost element. The pick-up of coating can be increased by adjusting the consistency of the batter or by repeating the coating process. By convention, such products should have a minimum fish component of 50%. Coated products viz., fish fingers, squid rings, cuttlefish balls, fish balls and prawn burgers form one of the major fish and shellfish-based items of trade by the ASEAN countries (Chang et al., 1996).

The production of battered and breaded fish products involves several stages. The method varies with the type of products and pickup desired. In most cases it involves seven steps. They are portioning/forming, pre-dusting, battering, breading, pre-frying, freezing and, packaging and cold storage. The first commercially successful coated product is 'fish finger; or 'fish stick'. Later several other products particularly the coated fish fillet, fish portions, fish cakes, fish medallions, fish nuggets, breaded oysters and scallops, crab balls, fish balls, coated shrimp products, coated squid rings etc. became prominent in most of the developed countries with the advent of the fast-food trade. The present-day production of coated seafood items involves fully automated batter and breading lines which start from portioning and end with appropriate packaging of the product. A variety of battered and breaded products can be prepared from shrimp, squid, clams, fish fillets, minced meat from low-cost fish etc. A brief profile of some important battered and breaded products is given below.

Fish finger or Fish portion

Fish fingers, or portions or sticks are regular sized portions cut from rectangular frozen blocks of fish flesh. They are normally coated with batter, and then crumbed before being flash fried and frozen. They may be packed in retail or catering - size packs. The typical British fish finger normally weighs about 1 oz. (28 g) of which up to about 50% of the total weight may be batter and crumbs. Food Advisory Committee of the UK government has recommended a minimum fish content of 55% for battered and 60% for the fingers coated with breadcrumbs.

Shrimp products

Battered and breaded shrimp can be prepared from wild as well as from farmed shrimp in different styles and forms. The most important among them are butterfly, round tail-on, peeled and deveined (PD), nobashi (stretched shrimp) etc. The products from farmed shrimp have indicated longer shelf life, 16-18 months compared to those from wild variety 12-14 months at –20 ºC

Fish fillets

The brined fillets are battered and breaded. Fillets from freshwater fish are also used for the production of coated products. The only problem noticed in this case is the presence of fin bones; its complete removal is still a major hurdle.

Squid products

Squid rings and stuffed squid are the popular coated products processed out of squid. Cleaned squid tubes are cut in the form of rings of uniform size, cooked in boiling brine (3%) for 1-2 minutes followed by cooling, breading and battering. The coated rings are flash-fried, cooled, frozen and packed. Stuffed squid is generally processed out of small size animals. The cleaned tubes are filled with a stuffing mixture prepared using cooked squid tentacles, potato, fried onion, spices etc. It is then battered, breaded and flash-fried.

Clam and other related products

Meat shucked out from depurated live clams after boiling is blanched in boiling brine, cooled, battered, breaded, flash-fried and packed. Other bivalves such as oyster, mussels etc. can also be converted into coated products by the same method.

Fish cutlet

Cooked fish mince is mixed with cooked potato, fried onion, spices and other optional ingredients. This mass is then formed into the desired shape, each weighing approximately 30g. The formed cutlets are battered and breaded.

Fish balls

Fish balls are generally prepared from mince of low-cost fish. Balls can be prepared by different ways. The simplest method is by mixing the fish mince with starch, salt and spices. This mix is then made into balls, cooked in boiling 1 % brine. The cooked balls are then battered and breaded.

Crab claw balls

Swimming legs of crab may be used for this purpose. Crab claws are severed from the body, washed in chilled portable water and the shell removed using a cracker. The leg meat is then removed and mixed with 2 % starch-based binder. This is then stuffed on the exposed end of the claw. Alternatively, the body meat mixed with the binder also can be used for stuffing. The stuffed claw is then frozen, battered and breaded and flash fried. The coated products are packed in thermoformed containers with built in cavities.

Fish Mince and Mince Based Products

Mechanically deboned fish meat is termed as fish mince. Fish mince is more susceptible to quality deterioration than the intact muscle tissue since mincing operation cause disruption of tissue and exposure of flesh to air, which accelerates lipid oxidation and autolysis. The quality of the mince is dependent on the species, season, handling and processing methods. Also, low bone content in the mince (01-0.4%) is desirable for better functional and sensory properties. Depending on the type of raw material, fish mince can have a frozen storage life up to 6 months without any appreciable quality deterioration. Generally minced fish is frozen as 1-2 kg blocks at -40 ^{0}C in plate freezers and stored in cold store at -18 ^{0} C.

Surimi

Surimi is stabilized myofibrillar protein obtained from mechanically deboned flesh that is washed with water and blended with cryoprotectants. Washing not only removes fat and undesirable matters

such as blood, pigments and odoriferous substances but also increases the concentration of myofibrillar protein, the content of which improves the gel strength and elasticity of the product. This property can be made use of in developing a variety of fabricated products like shellfish analogues. India produces about 40.000 MT of surimi per annum ,70% of which comes from thread fin bream.

Kneaded products

Several kneaded products like kamaboko, chikuwa, hampen, fish ham and sausage are processed using surimi incorporating other ingredients. The ingredients used in most of these preparations are identical; however, the classification is principally based on the manufacturing process involved. The ingredients employed other than surimi include salt, monosodium glutamate, sugar, starch, egg white, polyphosphate and water. The method of processing all these products involves grinding together of the various ingredients to a fine paste and some sort of heat treatment at some stage.

Fiberized products

Fiberized products are in great demand among the surimi based imitation shellfish products. The ingredients used in the formulation of fibreized products includes, besides surimi, salt, starch, egg white, shellfish flavour, flavour enhancers and water. All the ingredients are thoroughly mixed and ground to a paste. The paste is extruded in sheet on the conveyor belt and is heat treated using gas and steam for partial setting. A strip cutter subdivides the cooled sheet into strings and is passed through a rope corner. The rope is coloured and shaped. The final product is formed by steam cooking the coloured and shaped material.

Fish sausage

Fish sausages are surimi or fish mince mixed with additives, stuffed in suitable casings and heat processed. The surimi or fish mince is mixed with salt (3-4%), sugar (2-3%), sodium glutamate (0.3%) starch and soy protein in a silent cutter and stuffed in casings by an automatic screw stuffer. The stuffed sausage is heated in hot water at 85-90°C for 40-60 min. After heating, it is cooled slowly to avoid shrinking of the tube and then stored at refrigerated temperature. The production of fish sausage in India is rather insignificant, although market potential for this product is good. Sausages prepared from rohu mince treated with potassium sorbate had a shelf life of 16 days at refrigerated temperatures.

Emerging technologies for value addition of fish

Retort pouch processing:

As in canning, retort pouch food is sterilized after packing, but the sterilizing procedure differs. The pouches are processed in an over pressure retort. The time and temperature will be standardized depending on the product. With the availability of retort pouches, it can function as an excellent import substitute for metallic cans**.** Besides, cost reduction retort pouch packages have unique advantages like boil in bag facility, ease of opening, reduced weight and do not require refrigeration for storage. Processed food products can be kept for long periods at ambient temperature. The energy saving is more in processing in flexible pouches compared to cans. On a comparison of total costs, including energy, warehousing and shipping, the pouch looks even more favourable. There is 30 to 40%

reduction in processing time compared to cans, solids fill is greater per unit, empty warehousing is 85% smaller and weight of the empty package is substantially smaller.

Extrusion:

In order to improve the utilization of underutilized fisheries resources, there is a need to minimize the post-harvest losses, develop innovative processing technologies and utilize processing waste for industrial and human use. One such technology, which will be suitable for utilization of low value fish or by catch, is extrusion technology. Use of fish mince with cereals for extrusion process will enable production of shelf-stable products at ambient temperature. Extrusion cooking is used in the manufacture of food products such as ready-to-eat breakfast cereals, expanded snacks, pasta, fat-bread, soup and drink bases. The raw material in the form of powder at ambient temperature is fed into extruder at a known feeding rate. The material first gets compacted and then softens and gelatinizes and/or melts to form a plasticized material, which flows downstream into extruder channel. Basically, an extruder is a pump, heat exchanger and bio-reactor that simultaneously transfer, mixes, heats, shears, stretches, shapes and transforms chemically and physically at elevated pressure and temperature in a short time. At times, the extrusion cooking process is also referred as High Temperature Short Time process. In extrusion process gelatinization of starch and denaturation of protein ingredient is achieved by combined effect of temperature and mechanical shear. The conversion of raw starch to cook and digestible materials by the application of heat and moisture is called gelatinization. During extrusion the conditions that prevail are high temperature, high shear rate and low moisture available for starch may lead to breakdown of starch molecules to dextrins.

Irradiation

Irradiation is a physical treatment that consists of exposing foods to the direct action of electronic, electromagnetic rays to assure the innocuity of foods and to prolong the shelf life. Irradiation of food can control insect infestation, reduce the numbers of pathogenic or spoilage microorganisms, and delay or eliminate natural biological processes such as ripening, germination, or sprouting in fresh food. Like all preservation methods, irradiation should supplement rather than replace good food hygiene, handling, and preparation practices.

Three types of ionizing radiation are used in commercial radiation to process products such as foods and medical and pharmaceutical devices (International Atomic Energy Agency (IAEA), radiation from high-energy gamma rays, X-rays, and accelerated electrons.

- Gamma rays, which are produced by radioactive substances (called radioisotopes). The approved sources of gamma rays for food irradiation are the radionuclides cobalt-60 (^{60}Co; the most common) and cesium-137 (^{137}Cs). They contain energy levels of 1.17 and 1.33 MeV (^{60}Co) and 0.662 MeV (^{137}Cs).
- Electron beams, which are produced in accelerators, such as in a linear accelerator (linac) or a Van de Graaff generator at nearly the speed of light. Maximum quantum energy is not to exceed 10 MeV.
- X-rays or decelerating rays, which can be likewise produced in accelerators. Maximum quantum energy of the electrons is not to exceed 5 MeV

Different forms of irradiation treatment are raduarization (for shelf-life extension), radicidation (for elimination of target pathogens) and radappertization (for sterilization). Radiation processing is widely used for medical product sterilization and food irradiation. Moreover, the use of irradiation has become a standard treatment to sterilize packages in aseptic processing of foods and pharmaceuticals.

Irradiation produces some chemical changes, which, although lethal to foodborne bacteria, do not affect the nutritional quality of the food but lead to the production of small amounts of radiolytic products. Gamma irradiation has been considered as an interesting method of preservation to extend the shelf life of fish and also to reduce qualitatively and quantitatively the microbial population in fish and fish products. Irradiation doses of 2–7 kGy can reduce important food pathogens such as Salmonella, Listeria, and Vibrio spp., as well as many fish-specific spoilers such as *Pseudomonaceae*and *Enterobacteriaceae* that can be significantly decreased in number.

Microwave processing:

The applications of microwave heating on fish processing include drying, pasteurization, sterilization, thawing, tempering, baking etc. Microwaves are electromagnetic waves whose frequency varies within 300 MHz to 300 GHz. Microwave heating is caused by the ability of the materials to absorb microwave energy and convert it into heat. Microwave heating of food materials mainly occurs due to dipolar and ionic mechanisms. Water content in the food material causes dielectric heating due to the dipolar nature of water. When an oscillating electric field is incident on the water molecules, the permanently polarized dipolar molecules try to realign in the direction of the electric field. At high frequency electric field, this realignment occurs at a million times per second and causes internal friction of molecules resulting in the volumetric heating of the material. Microwave heating also occur due to the oscillatory migration of ions in the food which generates heat in the presence of a high frequency oscillating electric field. Studies showed that chemical changes involved during different microwave cooking practices of skipjack tuna and will retain omega-3 fatty acids compared to frying/canning. Microwave blanching can be carried out for color retention and enzyme inactivation which is carried out by immersing food materials in hot water, steam or boiling solutions containing acids or salts. Microwave drying is used to remove moisture from fish and fishery products. Microwave drying has advantage of fast drying rates and improving the quality of product. In microwave drying, due to volumetric heating, the vapors are generated inside and an internal pressure gradient is developed which forces the water outside. Thus, shrinkage of food materials is prevented in microwave drying. One of the disadvantages of microwave drying is that excessive temperature along the corner or edges of food products results in scorching and production of off-flavors especially during final stages of drying. Microwave combined with other drying methods such as air drying or infrared or vacuum drying or freeze drying gave better drying characteristics compared to their respective drying methods or microwave drying alone.

Ohmic heating:

Ohmic heating is an emerging technology with large number of actual and future applications. Ohmic heating technology is considered a major advance in the continuous processing of particulate food products. Ohmic heating is direct resistance heating by the flow of an electrical current through foods, so that heating is by internal heat generation. Ohmic heating is defined as a process wherein electric current is passed through materials with the primary purpose of heating the object. During ohmic heating, heating occurs in the form of internal energy transformation (from electric to thermal) within the material. Therefore, it can be explained as an internal thermal energy generation technology and it enables the material to heat at extremely rapid rates from a few seconds to a few minutes. Ohmic heating have a large number of actual and potential future applications, including its use in blanching, evaporation, dehydration, fermentation, extraction, sterilization, pasteurization and heating of foods. The microbial inactivation due to ohmic heating can be explained by the presence of electric field. The additional effect of ohmic treatment may be its low frequency (usually 50e60 Hz), which allows cell

walls to build up charges and form pores. As a main consequence of this effect, the D value observed for the microbial inactivation under ohmic heating is reduced when compared to traditional heating methods. More research is needed to completely understand all effects produced by ohmic heating to food products, effects of applied electric field, the applied electric frequency during ohmic heating over different microorganisms and foods, cold spot determination etc.

Accelerated Freeze Drying

Accelerated freeze-drying is now being increasingly used for the preservation of high value food products. The product has the advantages like absence of shrinkage, quick re-hydration upto 95%, minimum heat induced damage etc. In India this technique is now applied for processing shrimp, squid rings etc. The possibilities for various ready-to-eat products based on fish and shellfish employing this technique are immense. In this, there is a speeding of the freeze-drying process, as a result of modification in the heating mechanism. Food is arranged in single layers between metal sheets or grids held in a tray. This is kept between the heating plates. When the required pressure and temperature is attained in the chamber, fluid contained within the hollow plates is heated to temperature of 60 to 100° C. The heat is conducted through the metal mesh, and trays to the product while allowing the water vapour to escape through the mesh channels to the side of the heating plates from where it is removed. Otherwise, the pressure at the food surface would increase and the ice will melt. When the ice is melted from the surface the pressure is applied to the plates using a hydraulic mechanism so that the mesh will be pressed against the surface of the fish giving more direct heat contact to the product. At the same time the temperature of the heating material is reduced since, after sublimation the surface temperature of the fish will be the same as that of heating plates (Balachandran, 2001). This method appeared to reduce the freeze-drying time appreciably from 10-12 hours to 6-7 hours, depending on the thickness of the food, temperature and pressure, and hence it is termed as accelerated freeze drying.

Infrared and Radiofrequency Processing Technologies:

Electromagnetic radiation is a form of energy that is transmitted through the space at an enormous velocity (speed of light). The heat generation in material exposed to EMR could be due to vibrational movement (as in case IR) or rotational movement (as in case of RF and MW) of molecules. Application of EMR heating is gaining popularity in food processing because of its definite advantages over the conventional processes. Faster and efficient heat transfer, low processing cost, uniform product heating and better organoleptic and nutritional value in the processed material are some of the important features of EMR processing. In conventional heating system like hot air heating, the heat is applied at the surface which is carried inwards through conduction mode of heating. In case of EMR/dielectric heating, the waves can penetrate the material to be absorbed by inner layers. The quick energy absorption causes rapid heat and mass transfer leading to reduced processing time and better product quality.

The main advantage of electromagnetic heating over conventional electric and gas oven-based heating is its high thermal efficiency in converting the electrical energy to heat in the food. In ordinary ovens, a major portion of the energy is lost in heating the air that surrounds the food, fairly a good amount escapes through the vent, besides being lost through the conduction to the outside air. In contrast, almost all the heat generated by electromagnetic radiations, which reaches the interior of the oven, is produced inside the food material itself. According to the reports the energy efficiency of EMR

based systems is 40-70%, as compared to approximately 7-14% in case of conventional electric and gas ovens.

High pressure processing:

High pressure processing (HPP) is an emerging and innovative technology that has a great potential for extending the shelf-life with minimal or no heat treatment. It is also effective in preserving the organoleptic attributes of many foods. High pressure Processing is a non-thermal technology in which the food product to be treated is placed in a pressure vessel capable of sustaining the required pressure and the product is submerged in a liquid, which acts as the pressure transmitting medium. Water, castor oil, silicone oil, sodium benzoate, ethanol or glycol may be used as the pressure transmitting medium. The ability of the pressure transmitting fluid to protect the inner vessel surface from corrosion, the specific HP system being used, the process temperature range and the viscosity of the fluid under pressure are some of the factors involved in selecting the medium.

Ultrasound Processing:

Ultrasound refers to sound that is just above the range of human hearing, i.e., above frequency of 20 kHz. Ultrasound when propagated through a biological structure induces compressions and depressions of the medium particles imparting a high amount of energy to the material. The sound ranges for food applications employed can be divided into two, namely, low energy, high frequency diagnostic ultrasound and high energy low frequency power ultrasound. Low energy applications involve the use of ultrasound in the frequency range of 5-10 MHz at intensities below 1 W/cm^2. Ultrasonic waves at this range are capable of causing physical, mechanical, or chemical changes in the material leading to disrupting the physical integrity, acceleration of certain chemical reactions through generation of immense pressure, shear, and temperature gradient in the medium. Ultrasonics has been successfully used to inactivate *Salmonella* spp., *Escherichia coli*, *Listeria monocytogenes*, *Staphylcoccus aureus* and other pathogens.

Bio preservation:

Bacteriocins are a heterogeneous group of antibacterial proteins that vary in spectrum of activity, mode of action, molecular weight, genetic origin and biochemical properties. Various spices and essential oils have preservative properties and have been used to extend the storage life of fish and fishery products. Natural compounds such as essential oils, chitosan, nisin and lysozyme, bacteriocins have been investigated to replace chemical preservatives and to obtain green label products.

Application of enzymes:

Enzymes have been used for the production of various cured and fermented fish products from centuries. Because of their appreciable activity at moderate temperature, products and process have emerged that utilizes enzymes in a deliberate and controlled fashion in the field of food processing. Cold active enzymes including elastase, collagenase, chymotrypsin extracted from Atlantic cod were used in various food processing applications. The other applications of cold active enzymes include caviar production, extraction of carotenoprotein etc. Treatment with protease under mild treatment conditions extending for a few hours can result in the recovery of the proteins from fish frame or shrimp shell waste. The role of transglutaminase in surimi production is well established. The gel strength of surimi can be improved by the application of extracellular microbial transglutaminase. Lipase extracted

from Pseudomonas spp can be used to produce PUFA enriched cod liver oil. Enzymatic de-skinning of fish fillets was done by partial denaturation of skin collagen using a gentle heat treatment followed by immersion in enzyme solution for several hours at low temperature (0-10 ^{o}C). De-skinning of tuna, Herrin, Squid were also carried out by using different enzyme technology.

Conclusion

Value can be added to fish and fishery products according to the requirements of different markets. These products range from live fish and shellfish to ready to serve convenience products. In general, value-added food products are raw or pre-processed commodities whose value has been increased through the addition of ingredients or processes that make them more attractive to the buyer and/or more readily usable by the consumer. It is a production/marketing strategy driven by customer needs and perceptions. Technology developments in fish processing offer scope for innovation, increase in productivity, increase in shelf life, improve food safety and reduce waste during processing operations. A large number of value added and diversified products both for export and internal market based on fish, shrimp, lobster, squid, cuttlefish, bivalves etc. have been identified.

Chapter 4

PRPs and Physical hazards in seafood

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PREREQUISITE PROGRAMS (PRPs)

Prerequisite programs (PRPs) are those procedures that address environmental and operational conditions which provide the foundation for the HACCP system. Prerequisite programs provide the basic conditions that are necessary for the production of safe and wholesome food. Some of these programs are required by regulations such as Good Manufacturing Practices (GMPs) and Sanitation Control Procedures (SCP) and others are recommended viz., Environmental Monitoring, Shipping Controls, Recall and Traceability Programs, Supplier controls, Preventive maintenance. Based on the existing Seafood HACCP Regulation and FSMS, the following prerequisite programs are required to have in place in order to support the Seafood HACCP program

1. Employee training and training records
2. Good Manufacturing Practices
3. Sanitation Control Procedures

Employee training and training records

Employees who supervise or manufacture, process, pack or hold food must be qualified, trained and/or experienced enough to perform their assigned duties to produce safe food. To meet the training requirements employees must receive training in the principles of food hygiene and food safety, as well as the importance of employee health and personal hygiene. The training may be provided by facility personnel, a third-party source, or a combination of both. Although there is no frequency interval specified in the HACCP regulation for training; it is expected that appropriate training should be conducted prior to employees independently performing their duties. It is also anticipated that refresher training will be provided when needed.

The processors must provide adequate facilities, required to keep records that document the training on the principles of food hygiene and food safety for those who supervise or perform manufacturing, processing, packing, or holding activities for food. Processors must maintain records of this training for at least 2 years.

Good Manufacturing Practices (GMP)

Good Manufacturing Practices (GMPs) provides the basis for determining whether the facility, processing methods, practices and controls used to process food products are suitable to allow for the production of safe and wholesome food and whether the products have been processed under sanitary conditions.

GMPs outline the minimum standards that a food processing facility needs to meet including, but not limited to, personnel, buildings and facilities, equipment, production and process controls, raw materials, and manufacturing operations. GMPs were first released in 1969 as 21 CFR Part 110, and revised in 1986 and again in 2015 (21 CFR Part 117). The 2015 updated version of GMPs explicitly address the allergen cross contact. "Cross-contact" differs from "cross-contamination". Allergen cross-contact is the unintentional incorporation of undeclared food allergens into food while cross-contamination is the contamination of food with bacterial, chemical or physical hazards.

21 CFR Part 117 - Subpart B - Current Good Manufacturing Practices

The 21 CFR part 117 – Good Manufacturing Practices covers various aspects such as

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and controls
- Equipment and utensils
- General processes and controls
- Raw materials and other ingredients
- Manufacturing operations
- Warehousing and distribution
- Holding and distribution of human food byproducts for use as animal food
- Defect action levels

Sanitation Control Procedures (SCPs)

Sanitation Control Procedures are the necessary procedures to meet specified GMPs requirements which, in the absence of control, could impact food safety. When SCPs are in place, HACCP plans can more effectively focus on the hazards associated with the product or process and rather than the processing plant environment or employee practices.

The Seafood HACCP Regulation SCPs (21 CFR part 123.11) include one recommendation and three requirements. It is recommended that processors create a written sanitation standard operating procedure (SSOP) that describes how sanitation procedures will be performed. Written SSOPs would outline the goals, methods and activities that are needed to be performed in order to meet the SCP requirements. Well-designed, written SSOPs that are properly implemented are an effective means to prevent insanitary conditions associated with the processing environment and employee practices that may contribute to food safety hazards.

It is required that processors should monitor the facility sanitation conditions and provisions related to eight key sanitation areas, correct deficiencies noted during monitoring and maintain sanitation control records which document sanitation monitoring and corrections. This monitoring must occur with sufficient frequency to show compliance with current GMP requirements. The regulation also requires that processors correct problems that are identified during monitoring, and keep records of their monitoring results and the corrections that were made.

Eight Key Sanitation Areas

1) *Safety of water*: Water (and ice) that contacts food or food-contact surfaces shall be of safe and of sanitary quality

2) *Condition and cleanliness of food contact surfaces:* Food contact surfaces shall be of a proper design and maintained in a clean and sanitary manner to prevent food contamination

3)*Prevention of cross contamination*: Employee hygiene, personnel practices and the design of the facility must prevent cross-contamination and allergen cross-contact

4) *Maintenance of hand washing, hand sanitizing and toilet facilities:* Sanitary facilities must be accessible, properly maintained, and adequately supplied. An adequate sewage disposal system must be in place

5) *Protection from adulterants*: Food, food contact surfaces, and food packaging material must be protected from microbiological, chemical and physical contaminants and allergen cross-contact

6) *Labeling, storage and use of toxic compounds:* Toxic cleaning compounds, sanitizing agents and pesticides must be properly labeled, used and stored in a manner that protects food, food contact surfaces and packaging material from contamination. Toxic compounds must be stored in a secured area with limited access separated from food processing and areas where food and packaging materials are stored

7) *Employee health*: Controls are necessary to ensure that employee health conditions do not cause food contamination.

8) *Exclusion of pests*: Processors must ensure that pests, such as rodents, birds, domestic animals and insects are not allowed in any area of a food processing and/or storage facility

These eight key areas of sanitation should be monitored at a frequency sufficient to ensure conformance. In addition to that the monitoring results and corrections made for any deficiencies must be recorded. The frequency or time for monitoring will vary according to various types of products and the schedule of operations. The SCP monitoring forms or records must include the name and location of the processor, the date and time the monitoring was performed, corrections made and the signature or initials of person conducting the monitoring. The sanitation monitoring, corrections and sanitation controls recordkeeping may be performed as part of a firm's HACCP Plan controls, or separately.

Sanitation controls are not typically included in the HACCP plan. Sanitation controls address the overall processing plant environment and employee practices. If sanitation controls are established as a prerequisite program, HACCP controls can then focus on the control of species related and process-related hazards for a given finished product.

PHYSICAL HAZARD

A physical hazard is any potential material not commonly found in food which causes illness/injury to consumer on consumption. Hazard Analysis and Critical Control Point (HACCP) is a system which identifies, evaluates, and controls hazards which are significant for food safety. In

HACCP, hazard is defined as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. Accordingly mere contamination or undesirable conditions such as insects, hair, filth, spoilage, economic fraud, and violations of regulations/standards of food, cannot be considered as a hazard.

Physical hazards are potentially harmful extraneous matter, that are not normally found in food; but mistakenly consumed foreign material or object, which is likely to cause choking, injury or other adverse health effects to the consumer. These hazards can enter into food product at any stage of production.

Category of physical hazards:

In general, the physical hazards can be categorized into three

1. *Objects naturally present in the foods*: Naturally, different kinds of extraneous matter can be found in food, like bone fragments, broken pieces of shells in molluscs and broken pieces of chelate & carapace in shrimp and crab etc.,
2. *Objects added during production*: Some extraneous materials may get introduced into the food system during the production process. For example, stone particles, rocks, and mud in the case of vegetables and fruits. These kinds of things can be categorized as 'physical hazards added during production'.
3. *Objects added during processing*: During processing/preparation step, due to poor handling practices, anything that comes into direct contact with food can introduce, some physical hazards into the food. Some examples are jewelry, glass pieces, plastics, small concrete pieces, metal fragments, *etc.*

Glass is a very common physical hazard, that can be introduced into the food system from the lightening facilities and glass containers used in the processing plant. Metal is another physical hazard that can be introduced from metallic equipment's, from worn utensils, broken needles, stapler etc., Packaging materials, gloves, cleaning equipment's and all can introduce plastic into the food system. Stones from concrete structures and floors in food processing facilities; broken pieces of wood from wooden structures and wooden pallets used to store or transport ingredients or food products, fields, boxes, buildings, etc. are also contribute towards the physical hazards.

These extraneous materials can be again categorized into 2- avoidable and unavoidable. Unavoidable extraneous materials can be a by-product of the processing or something inherent to the raw material such as minute insect fragments in fig, microscopic airborne debris, dirt on potatoes etc., But avoidable extraneous materials are preventable and are having zero tolerance in the food system. These may be introduced as a result of poor hygienic/handling practices.

Health issues associated with the physical hazards:

Generally, physical hazards do not cause a disease, but it can result in an injury like laceration (a deep cut or tear in skin or flesh), perforation (piercing) of tissue in the mouth, throat, stomach or intestines, broken teeth, damage to gums, and choking. The severity will vary with infants, elderly,

medically compromised and healthy people. Hence control of this physical hazard is important in food processing.

Control measures of physical hazards:

Preventative approach is the best way to control physical hazards in food system and this approach includes

- ✓ Good Manufacturing Practices (GMP)
- ✓ Standard operating procedures (SOP)
- ✓ Pest control measures
- ✓ Ingredient specifications
- ✓ Supplier certification
- ✓ Use of equipment to screen for physical hazards
- ✓ Using appropriate design of equipment
- ✓ Employee training
- ✓ Personnel precautions (hair cover, gloves, mask, etc.)
- ✓ End product screening

Reference:

FDA source Dec. 2016: (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117)

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Chapter 5

Orientation to hazards - Chemical -I (Antibiotic residues, Additives & Heavy metals)

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Introduction:

Global population is depending upon seafood as a healthy diet choice because of its richness in high value proteins, health beneficial vitamins, minerals and poly unsaturated fatty acids. Fish is also a primary protein source in most parts of the world. Even though fish supplies many health benefits, seafood can be compromised by different chemical contaminants which are harmful to consumers. Fishes are harvested from waters that are contaminated by varying amounts of industrial chemicals, heavy metals, pesticides and antibiotics. These contaminants may accumulate in fish at levels that can cause human health problems (e.g. carcinogenic and mutagenic effects). Food can become contaminated at any point during production, distribution and preparation. Everyone along the production chain, from producer to consumer, has a role to ensure the safety of seafood.

The number of chemical contaminants is increasing day by day, hence threats associated with chemical contamination of seafood is also increasing. Environmental contaminants mainly include ubiquitous pollutants such as heavy metals and dioxins. Even though they are naturally present in the environment their level can be increased due to anthropogenic influences. Contaminants can also come as toxins produced by fungi (Eg. aflatoxins) and algae (Eg. ciguatoxin). The different chemical contaminants in seafood can also include food additives that are intentionally added like preservatives, colour retention agents etc. The contaminants can also generate during processing or cooking which include acrylamide and heterocyclic amines. Residue of agricultural chemicals resulting from previous application of pesticides, and veterinary drugs during production and storage of food crops and animals, have been considered as human health hazards. But these types of contaminants have a great potential in control by proper conditions of usage and their presence. Also some natural components of food can also act as contaminant like allergic substances and phyto haemagglutinin.

Basically the chemical contaminants are classified into three main groups such as:

(i) Naturally occurring – allergens, Mycotoxins, Scomberotoxin (Histamine), Ciguatera poison, Puffer fish poison, Shellfish toxins (PSP, DSP, NSP, ASP)

(ii) Unintentionally or incidentally added chemicals – Pesticides, Fungicides, Fertilizers, Toxic compounds, Toxic metals

(iii) Intentionally added chemicals and food additives - Food preservatives, Food additives, Vitamins, Minerals, Antibiotics used in aquaculture, Sulfites used in shrimp to prevent melanosis, Nitrites as preservatives, Colouring agents, Detergents

Biotoxins

Marine biotoxins are responsible for many seafood borne diseases. It includes both shellfish toxins and ichthyotoxins (fish toxins). Shellfish toxins include Paralytic shellfish toxins, Diarrhetic

shellfish toxins, Azaspriacid shellfish toxins, Neurotoxic shellfish toxin and Amnesic shellfish toxins. Ichthyotoxins include Ciguatera toxin and Tetradotoxin. Fish poisoning is caused by consuming fish containing poisonous tissues and shellfish poisoning results from ingestion of shellfish that have accumulated toxins from the plankton they have consumed.

(i)Tetradotoxin (Puffer fish poison): It is the most lethal of all fish poisons. Toxin production is due to the activity of symbiotic bacteria. Toxin will be accumulated in liver, ovaries and intestine as a defence mechanism. But the muscle is free of toxin. It is also called as Tetradon poisoning or Fugu poisoning. It is 275 times more toxic than cyanide. On an average a dose of 1-2mg of purified tetrodotoxin can be lethal to humans.

(ii) Ciguatera - Ciguatera is a clinical syndrome caused by eating the flesh of toxic fish caught in tropical reef and island waters. Most common fish poisoning and the fish becomes toxic due to feeding of toxic algae – dinoflagellates, Gambeirdiscustoxicus. Red snapper (Lutjanus bohar), Grouper (Variola louti) and Moray eel are recorded as ciguateric. More than 400 species have been implicated in ciguatera poisoning.

(iii)Paralytic shell fish poisoning (PSP) –This is associated with dinoflagellate blooms (Alexandriumcatenella, Gonyaulaxtamerensis). Heat stable saxitoxin will be accumulated inmussels, clams, oysters, scallops etc. grown in algal bloom areas. Greater number of human deaths is reported due to consumption of contaminated shellfish. The current regulatory level for fresh bivalve molluscs in most countries is 80 μg/100 g.

(iv)Diarrhetic shellfish poisoning (DSP) - Dinoflagellate Dinophysisforti is the algae which producesokadoic acid, the causative of DSP. Primary symptom is acute diarrhoea. Regulatory level in fresh bivalve molluscs in most countries is 0-60 μg /100 g.

Mouse bioassay and analysis by HPLC are the important methods for monitoring biotoxins. Reliable sampling plans are required for effective monitoring.

Heavy metals

Heavy metals are toxic metals and above a normal level can affect the quality, safety and marketability of seafood. They are “Cumulative poisons” which can irreversibly accumulate in the body. They have atomic weight higher than 40.04 and specific density > 5g/ cm. The main threats are Arsenic, Cadmium, Mercury and Lead. These metals have no beneficial effects in human and they have no homeostasis mechanism. These contaminants are highly depend upon geographic location, species and fish size, feeding pattern, solubility of chemical and their persistence in the environment.

Lead is mostly deposited in bones and not in soft tissues. But, from food safety point of view lead accumulation in edible parts is important. Compared to fish lead content is higher in shellfishes as it is getting accumulated in hepatopancreas. The organic form of lead, tetra alkyl lead is mostly found in fish. In fishes Cd is mostly deposited in kidney and liver and in muscles the level is quite low. In invertebrates like Cephalopods it can go as high as 30 ppm in digestive glands. Hence the digestive gland must be removed immediately after catch. Both Cd and Pb are carcinogenic in nature. Mercury is one of the most toxic heavy metal in the environment. Among metal contaminants methyl mercury ha s elicited the most concern among consumers. It is toxic to the nervous system especially the

developing brain. Arsenic is a widely distributed metalloid and major contaminant in case of ground water. IARC has classified inorganic arsenic as a human carcinogen.

The most widely used techniques for detection and quantification of heavy metals are Atomic Absorption Spectrometry, Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) and Inductively Coupled Plasma-Mass Spectrometry (ICP-MS).

Determination of heavy metals in seafood

Principle

Plasma is a stream of highly ionized gas containing an equal number of electrons and positive ions. Plasma is electrically conductive. It is affected by a magnetic field. When plasma energy is given to an analysis sample from outside, the component elements (atoms) is excited. When the excited atoms return to low energy position, emission rays (spectrum rays) are released and the emission rays that correspond to the photon wavelength are measured. The element type is determined based on the position of the photon rays and the content of each element is determined based on the rays intensity.

To generate plasma, first argon gas is supplied to torch coil, and high frequency electric current is supplied to the work coil at the tip of the torch tube. Using the electromagnetic field created in the torch tube by the high frequency current, argon gas is ionized and plasma is generated. This plasma has high electron density and temperature (10000K) and this energy is used in the excitation-emission of the sample. Solution samples are introduced into the plasma in an atomized state through the narrow tube in the centre of torch tube. The steps leading to the emission are desolvation, vaporization, atomization and ionization.

Sample digestion

Sample should be homogenous, representative of bulk, free of suspended particles and free flowing. Samples are digested in a microwave digestion unit. Take 0.25 to 0.5 g of sample to pre cleaned digestion vessel. Add 8 ml nitric acid and slowly add 2 ml H2O2 to it. Keep it for 10 mintes. Close the vessel and keep in microwave digestion chamberfor digestion. After digestion the samples are made upto 100 ml. digested sample is introduced to ICP-OES for analysis.

Hydride generation kit is used for analysing elements like Hg, As, Bi and Se.

Sample analysis – Inductively Coupled Plasma (ICP) Spectrometer ICAP 6300 Duo view

The detector is solid state CID detector, which can simultaneously analyse a sample for multiple elements. ICAP 6300 has a high performance optical system. The design has been optimized to offer resolution over the entire spectrum from 166 nm to 847 nm enabling access to all wavelengths and minimizing spectral interference.

Histamine in fish

Though all types of biogenic amines can be formed in fish, the most toxic amine detected in fish is histamine. Histamine poisoning is the most common form of toxicity caused by ingestion of fish and is generally due to the ingestion of foods containing unusually high levels of histamine. The commonly implicated incidents of histamine poisoning are associated with the fish families Scombridae and

Scomberesocidae. It is also known as Scombroid poisoning. Histamine is a powerful biologically active chemical present in the mast cells and basophils in larger amounts. Histamine poisoning is often manifested by a wide variety of symptoms. Major symptoms affecting the cutaneous system include rashes, urticaria, edema and localized inflammation etc. gastrointestinal effects include nausea, vomiting, diarrhoea and abdominal cramps. Also include symptoms like hypotension, headache, palpitation, tingling and flushing. Severe suffocation and respiratory distress have been reported in severe cases of histamine poisoning. The onset of histamine poisoning can extend from 10 minutes to 1 hour following consumption of contaminated fish and can last from 12 hour to a few days. Histamine concentration required to produce poisoning varies with respect to the susceptibility of each individual. In case of susceptible individuals concentration between 5 and 10 mg/100g can cause symptoms. Many foods contain small amounts of histamine which can be tolerated easily.

As per USFDA guideline the toxicity and defect action level established are 50 mg/100g and 5 mg/100g respectively. According to EU regulation No 2073/2005 mean value all samples (nine) must not exceed 10 mg/100g, two samples may be > 10 mg/100g but < 20 mg/100g and no sample may exceed 20 mg/ 100g. According to USFDA guideline for the control of histamine production a core temperature of 4.4 ^{o}C or less should be achieved and maintained throughout handling, processing and distribution of susceptible species.

A wide variety of procedure for the determination of histamine and biogenic amines is available. Include both semi quantitative and quantitative methods. Methods based on colorimetry, fluorometry and enzyme-linked immunosorbent assay (ELISA) are available. Mostly biogenic amines including histamine is analysed by High Performance Liquid Chromatography (HPLC) methods with pre and post column derivatisation and UV–visible or fluorescence detection. LC with tandem mass spectrometry (MS/MS) can also be a useful approach for an unequivocal confirmation of the studied analytes.

Antibiotics

Illegal use of antibiotics for veterinary purposes has become a matter of public concern. Antibiotics are used in aquaculture as prophylactics, as growth promoters and for treatment of diseases. They are usually administered in feeds and most commercial shrimp feeds contain antibiotics.The feeding of antibiotics as growth promoters is associated with decrease in animal gut mass, increased intestinal absorption of nutrients and energy sparing. But inappropriate and frequently abusive, use of antibiotics can affect human health. The two major concerns are the presence of antimicrobial residues in edible tissues and the emergence of antimicrobial resistance, which represents a huge threat to public health worldwide.

The greatest potential risk to public health associated with antimicrobial use in aquaculture is the development of a reservoir of transferable resistance genes in bacteria of aquatic environments. The antibiotics lose their efficacy over time because of the emergence and dissemination of resistance among bacterial pathogens.

EU implemented “zero tolerance policy” regarding antibiotic residue. Using LCMSMS method EU laboratories are equipped to detect traces of prohibited carcinogenic antibiotics like chloramphenicol up to 0.3 ppb and nitrofuran up to 1 ppb levels. Many of the antibiotics are listed as prohibited substance in fish and fishery products. In India the tolerance limit has been set only for the following antibiotics

Antibiotic	MRL (ppm)
Tetracycline	0.1
Oxytetracycline	0.1
Trimethoprim	0.05
Oxolinic Acid	0.3

The monitoring of antimicrobial residues in fish tissues requires sensitive and selective analytical methodologies to verify the accomplishment of the legal framework and reach the desirable high standards of quality and food safety. The methods can be microbiological, immunochemical or physico chemical. European council directive 96/23/EC, 1996 gives direction on measures of monitoring residues in live and animal products. It specifies spectrometric detection, GC, HPLC, ELISA and LC-MS/MS methods.

Food additives

Food additives means substances that normally are not used independently as food or its ingredient and which, after being added to the food during its production, processing packaging, transportation or storage, remain included in the food, even in changed state. In simpler terms, food additives are the substances which are added to food by the manufacturers to facilitate processing or to improve appearance, texture, flavour and keeping quality. Functions of food additives are

- To maintain product consistency – Eg: emulsifiers, stabilizers, thickners etc
- To improve nutritional quality – Eg: vitamins, minerals
- To improve product safety and quality – Eg: preservatives, antioxidants
- To aid in process or preparations – Eg: leavening agents
- To enhance sensory characteristics of the product

Classification of food additives

Food additives are classified based on their function in food, i.e. the purpose for which the additive has been incorporated in the food.

- antioxidants
- preservatives
- food colours
- food flavours
- emulsifiers and stabilizers
- anti-caking agents
- sequestrants
- acid, bases and buffers
- anti-foaming agents
- sweeteners
- enzymes, and
- leavening agents.

⇨ Preservatives

Preservatives are substances which when added to food, retard, inhibit or arrest the activity of microorganisms such as fermentation, acidification and decomposition of foods.

In India, the preservatives have been grouped into two classes – Class I and Class II preservatives.

Class I preservatives are

Common salt 2. Sugar 3. Dextrose 4. Glucose 5. Spices 6. Vinegar or acetic acid 7. Honey 8. Edible vegetable oils

Class II preservatives are

Benzoic acid including salts thereof 2. Sulphurous acid including salts thereof 3. Nitrates or Nitrites and/or Sodium and Potassium in respect of foods like ham, Pickled meat 4. Sorbic acid and its sodium, 5. Potassium and calcium salts 6. Propionates of Calcium or sodium, 7. Sodium, Potassium and Calcium salts of Lactic acid. 8. Nisin 9. Methyl or Propyl parahydroxy Benzoates 10. Sodium Diacetate.

Sulphur dioxide, bisulphites and sulphites –

Some of the commonly using additives are detailed here.

Sulphites, as a source of Sulphur dioxide - preservation of a number of food items viz. jam, jelly, marmalade, fruit, fruit pulp and juices, syrups and sherbets, alcoholic beverages, confectionery, dry fruits and meat products. Control enzymatic and non-enzymatic browning reactions

Nitrates and nitrites – effective against bacteria like Clostridium botulinum and Staphylococcus aureus

Benzoic acid and salts - protect foods against yeasts and moulds. Benzoic acid is used in squashes, fruit syrups, cordials, juices, jams, marmalades, preserves, sweetened ready-to-serve beverages, pickles, chutneys, sauces, tomato puree and paste and fat spread

Sorbic acid and its salts - These are effective against moulds, yeasts and many bacteria. widely used for bakery and confectionery products like cakes, fillings for chocolates and various types of cheese, cheese spreads and fat spread, paneer and ready-to-eat preserved chapatis

Antioxidants

Antioxidant means a substance which when added to food retards or prevents oxidative deterioration of food. According to the FSS (Food Product Standard and Food Additive) Regulation, 2011 this does not include substances like sugar, cereal, oils, flours, herbs and spices. Under the regulation, no antioxidant other than lecithin, ascorbic acid and tocopherol shall be added to any food. However, the following antioxidants, not exceeding in concentration mentioned against each, may be added to edible oils and fats except ghee and butter, namely

1. Ethyl gallate or mixture thereof 0.01 per cent
2. Propyl gallate or mixture thereof 0.01 per cent
3. Octyl gallate or mixture thereof 0.01 per cent

4. Dodecyl gallate 0.05 per cent
5. Ascorbyl palmitate 0.02 per cent
6. Butylated hydroxyanisole (BHA) 0.02 per cent
7. Citric acid Limited by Good Manufacturing Produces (GMP)
8. Tartaric acid Limited by Good Manufacturing Produces (GMP)
9. Gallic acid 0.01 per cent
10. Resin Guiace 0.01 per cent
11. Tertiary butyl hydro quinone (TBHQ) 0.02 per cent

Food Colors

Many of the food processing operations like drying, canning, roasting, frying etc. lead to loss of the attractive natural colour of foods. Colour additives are also used in foods to correct natural variations in food colour. Food colors are used to

- to enhance colours that occur naturally but at levels weaker than those usually associated with a given food.
- to provide a colourful identity to foods that would otherwise be virtually colourless.
- to protect nutrients such as vitamins and flavours that may be affected by sunlight.
- to provide an appealing variety of foods to consumers.
- to compensate for natural or seasonal variations in food, raw material or the effects of processing and storage to meet consumer expectations.

The colouring matter in foods can be broadly classified into two groups – natural and synthetic colours. Beta-carotene, Beta-apo-8' carotenal, Methylester of Beta-apo-8' carotenoic acid, Ethylester of Beta-apo-8'carotenoic acid, Canthaxanthin, Chlorophyll, Riboflavin (Lactoflavin), Caramel, Annatto, Saffron, and Curcumin or turmeric natural colouring matter which are permitted with indication in label. Ponceau 4R, Carmoisine, Erythrosine, Tartrazine, Sunset yellow FCF, Indigo Carmine, Brilliant blue FCF and Fast green FCF are synthetic food colors permitted for use in food.

Chapter 6

Orientation to hazards - Chemical -II (Contaminants & Pesticide)

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Introduction

Recent studies on marine pollution have reported the presence of multiclass organic contaminants in coastal water as a consequence of the diverse range of anthropogenic activities within their watersheds (Munaron et al., 2012, Sapozhnikova et al., 2007). Chemotherapeutants such as certain organophosphate, carbamate and pyrethroid pesticides are being used in coastal aquaculture to manage pest and disease infestations (Rico et al., 2012). In addition, the marine environment is subject to indirect fluxes of pesticides from widespread agricultural use in nearby crops (García-Rodríguez, Cela-Torrijos, Lorenzo-Ferreira, &Carro-Díaz, 2012). Lipophilic organic contaminants of traditional concern such as organochlorine pesticides (OCs) and polycyclic aromatic hydrocarbons (PAHs) have been monitored widely in fish tissue and the marine environment (Sarkar et al., 2008). In addition to OCs and PAHs, several other classes of pesticides are becoming a point of concern because of their potential bioaccumulation in fish tissue (Chen et al., 2009).

Between 2012 and 2013, India exported 928,215 tons of marine produce with a value of $3.5 billion, which increased by 7.68% this year. The marine products from India are mainly exported to South East Asia (23.12% of the total export), the European Union (22.14%), USA (21.29%), Japan (10.61%), China (7.67%) and the Middle East (5.96%) (Source: MPEDA). Food safety regulations are becoming increasingly stringent worldwide. Japan has specified Maximum Residue Limits (MRL) for a diverse range of pesticides and contaminants (http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p). The EU legislation prohibits the presence of pesticide residues in fish and fishery products, although currently there is no specific MRL recommended (ec.europa.eu/sanco_pesticides/public/index.cfm), a default MRL of 10 ppb is applied.

Marine fishes inherently have high lipid content. During sample preparation, these lipid components often get co-extracted and interfere with the detection and quantification of target analytes by GC–MS. Several approaches have been reported to eliminate these matrix interferences, such as methodologies involving liquid–liquid partitioning, gel permeation chromatography, column chromatography, multi-stage cleanup, and low temperature cleanup (LeDoux, 2011). However these methods are time consuming and labor intensive. So far, there is limited literature available on applications of QuEChERS methodology in fish matrices that include analysis of pyrethrins and pyrethroids and a multiresidue method for 13 pesticides in fish muscle (Lazartigues et al., 2011; Rawn, Judge, & Roscoe, 2010). Recently, a QuEChERS based method was reported for the analysis of 13 flame retardants, 18 pesticides, 14 polychlorinated biphenyl (PCB) congeners, 16 polycyclic aromatic hydrocarbons (PAHs), and 7 polybrominated diphenyl ether (PBDE) congeners in catfish muscle, which uses a proprietary

zirconium-based sorbent for dispersive solid-phase extraction (dSPE) cleanup and low pressure GC–MS/MS (gas chromatography tandem mass spectrometry) for analysis (Sapozhnikova&Lehotay, 2013). QuEChERS methodology when evaluated for other high fat matrixes such as milk, egg and avocado reported high matrix interference and low recovery particularly for non-polar compounds (~27% for hexachlorobenzene) (Lehotay, Mastovska, & Yun, 2005; Wilkowska&Biziuk, 2011). Hence, at present, very few sample preparation methods deal effectively with the challenges of simultaneous analysis of a varied group of chemical contaminants in fatty fish matrix. So far, even the QuEChERS based multiresidue strategies have targeted only a limited number of compounds in fish matrix, and high matrix effect and low recoveries have been reported for several analytes (Munaretto et al., 2013; Norli, Christiansen, &Deribe, 2011). The increasing international trade of seafood and marine produces makes it necessary to screen for a wide variety of chemical contaminants in these matrices.

Definition of Pesticides

As per the World Health Organisation (WHO) 1976, Pesticides are defined as any substance or mixture of substances intended for destroying, preventing or controlling any unwanted species of plants and animals and also includes any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant used for the control of pest during production, storage, transport, marketing or processing of food for man or animal or administered to animal for the control of insect or arachnids.

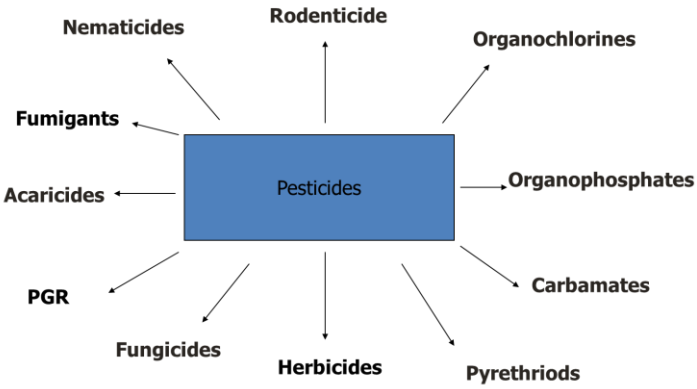

Figure 1. Major types of pesticides

Definition of Pesticide Residue

As per FAO-WHO Codex, “Pesticide residue” means any specified substances in food, agricultural commodities, or animal feed remaining as a result from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance. The term “pesticide residue” includes

residues from unknown or unavoidable sources (e.g., environmental), as well as known uses of the chemical.

Definition of MRL

MRL (Maximum Residues Level) refers to maximum permitted upper limit of a pesticide that may be found in a food or feed commodity. MRLs are not safety limits, and exposure to residues in excess of an MRL does not automatically imply a hazard to health.

Instrumental analysis of PAHs, PCBs, and Pesticides

The analyses of samples are generally performed using a GC equipped with an auto sampler attached to a triple quadrupole mass spectrometer. The analytical separation is performed using a DB-5MS (30 m × 0.25 mm, 0.25 µm) or equivalent capillary column with mid-point back flush set up for the 15 m column towards the injector port end, for which additional helium flow is supplied through a purged ultimate union. A gooseneck liner (78.5 mm × 6.5 mm, 4 mm) needs to be used. The carrier gas (Helium) flow was set at a constant rate of 1.2 mL/min for the first column, and 1.24 mL/min for the second column. The oven temperature program was set at initial temperature of 70 °C (1 min hold), ramped to 150 °C at 25 °C/min (0 min hold), then at 3 °C/min up to 200 °C (0 min hold) and finally to 285 °C at 8 °C/min (9 min hold) resulting in a total run time of 40.49 min. The transfer line temperature was maintained at 285 °C. During a 3 min post-run period, the oven temperature was maintained at 285 °C with the carrier gas flow rate in column 1 set at −3.4 mL/min.

The multi-mode inlet (MMI) is operated in solvent vent mode and 5 µL of sample was injected. The programmable temperature vaporizer (PTV) program was set at the initial temperature of 70 °C (0.07 min hold), raised to 87 °C at 50 °C/min (0.1 min hold) followed by rapid heating at 700 °C/min up to 280 °C (3 min hold). The purge flow to solvent vent was maintained at 50 mL/min, at a pressure of 11.266 psi until 0.17 min after injection. Next, the split vent was closed for 2.7 min to transfer the analytes to the column. Then, the split vent was opened to remove the high boiling matrix compounds from the inlet. The mass spectrometer was operated in MS/MS mode with acquisition starting at 4.4 min. Electron impact ionization (EI+) was achieved at 70 eV and the ion source temperature was set at 280 °C. MRM parameters of each compound have to be optimized.

Sample preparation method

Approximately 2 kg fish meat was separated from bones and skin and crushed thoroughly in a homogenizer. A subsample of 5 g homogenized meat was weighed into a 50 mL centrifuge tube, mixed with 5 mL of distilled water and vortexed for 1 min. Next, 15 mL of acetonitrile (+1% acetic acid) and 2 mL of hexane were added, and the tube was vortexed again for 1 min. Subsequently, 6 g of $MgSO_4$ and 1.5 g of NaAC were added to each tube, followed by vortexing for 2 min and centrifugation at 5000 rpm for 5 min. A portion of the middle organic layer (1.5 mL acetonitrile) was pipetted out of each tube and kept in a 15 mL centrifuge tube at −20 °C for 20 min. Adsorbents (100 mg $CaCl_2$ + 150 mg $MgSO_4$) were added to the tube for dSPE cleanup. The supernatant (1 mL) was further cleaned with 50 mg PSA + 50 mg Florisil + 150 mg C18 + 150 mg $MgSO_4$, vortexed for 1 min and, centrifuged at 10,000 rpm for

5 min. The supernatants from each tube were filtered through a PTFE membrane and analyzed by GC–MS/MS.

Method Validation

The performance of the analytical method was assessed as per the DG-SANCO guidelines for the validation of the analytical methods (Document No. SANCO/10684/2009). The following parameters were considered during the validation process.

Sensitivity

The sensitivity of the method was determined in terms of limit of detection (LOD) and limit of quantification (LOQ) of the test compounds. The LOD was determined by considering a signal to noise ratio (S/N) of 3 with reference to the background noise obtained for an unspiked matrix blank. LOQs were determined by considering a S/N of 10 with the qualifier SRM having S/N $\geqslant$ 3:1.

Matrix effect (ME)

The ME was evaluated by comparing peak areas of the matrix matched standards (peak area of post-extraction spike) with the corresponding peak areas of standards in solvent at 25 µg/kg in ten replicates. The ME was quantified as the average percent suppression or enhancement in the peak area using the following equation:

$$\text{ME } (\%) = \frac{\text{Peak area of matrix matched standard} - \text{peak area of solvent standard}) \times 100}{\text{Peak area of matrix matched standard}}$$

A negative value of ME signifies matrix induced signal suppression, whereas a positive value signifies an enhancement in signal intensity.

Accuracy-recovery experiments

The recovery experiments were carried out by spiking the homogenized fish meat (5 g) in six replicates with the test analytes under study at three concentration levels: 10, 25 and 50 µg/kg. These samples were processed following the optimized protocol and analyzed using GC–MS/MS. The quantification was performed using external calibration standards (matrix matched).

Precision

The precision in the conditions of repeatability (three different analysts prepared six samples each on a single day) and the intermediate precision (a single analyst prepared six samples each on three different days) were estimated separately at 25 µg/kg. Precision was expressed as the ratio of the reproducibility standard deviation (RSDR) to the predicted relative reproducibility standard deviation (PRSDR) and repeatability standard deviation (RSDr) to the predicted repeatability standard deviation (PRSDr) for the assessment of reproducibility and repeatability, respectively. According to Horwitz, the ratio between the calculated and the predicted values should be $\leqslant$2 (known as the HorRat value) (Horwitz & Albert, 2006). This is also applicable for the Thompson equation which suggests that at concentration below 120 µg/kg, PRSDR = 22.0 and PRSDr = 0.66 PRSDR. The Thompson equation is

claimed to be better able to account for the precision at an analyte concentration below120 µg/kg and hence in this study, the Thompson equation was followed (Thompson, 2000).

Assessment of uncertainty

The combined uncertainty was assessed as per the statistical procedure described in EURACHEM/CITAC Guide CG 4 in the same way as reported earlier (http://www.measurementuncertainty.org). The following variables were evaluated for all the test compounds: uncertainty associated with the calibration graph (u1), day-wise uncertainty associated with precision (u2), analyst-wise uncertainty associated with precision (u3), day-wise uncertainty associated with accuracy/bias (u4), and analyst-wise uncertainty associated with accuracy/bias (u5). The combined uncertainty (U) was calculated as follows:

$$U = \sqrt{u_1^2 + u_2^2 + u_3^2 + u_4^2 + u_5^2}$$

The combined uncertainty (U) was reported in relative measures as expanded uncertainty, which is twice the value of the combined uncertainty. Relative uncertainty represents the ratio of uncertainty value at a given concentration to the concentration at which the uncertainty is calculated.

Conclusion

Chemical hazards in seafood are highly important from trade, health & safety perspectives. Regulatory agencies all over the world stringently monitor residues of pesticides and persistent organic pollutants (POPs) in different food commodities. Presence of residue often results in economic loss for the exporting country. Hence it is important to develop rugged analytical methods for regulatory control and monitoring of these contaminants in seafood. Multiresidue methods can save time and money by simultaneously analyzing hundreds of compounds in a single method. However, some specific pesticides like Glyphosate, 2, 4-D, Paraquat, Diquat etc. are difficult to measure in multiresidue methods and for them single residue methods should be developed.

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Chapter 7

Orientation to Hazards: Biological I

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Fish and fishery products have gained importance in recent years because of availability of macro and micronutrients. These foods are considered safer in comparison to other meat products. Safety of fish and fishery products is a concern for human health. Various pathogenic bacteria due to unhygienic handling practices may get into the contacts of foods. The failure to prevent raw fishes and shellfish to come in contact with cooked or ready-to eat foods (cross contamination), and lack of proper temperature control are significant factors resulting pathogens to grow and become causative agents for foodborne illness. Bacterial and viral Pathogens are the primary food safety concern with regard to seafood. To prevent the outbreak of foodborne illnesses, it is crucial for food professionals to understand all aspects of biological contaminants from how they grow and reproduce to how they contaminate food and infect humans.

Biological contaminants of food are harmful and hazardous substances of biological origin in the food that can cause foodborne illness when they are consumed. Biological contaminants commonly found in seafood include bacterial pathogens, viral pathogens and parasites. Pathogen contamination and growth is often an important factor in food-borne illness. Pathogenic bacteria can cause illness in human, either by infection or intoxication. Food borne infections are caused by swallowing live pathogens that grow within the body, usually in the intestinal tract. Intoxication is a condition caused by swallowing preformed toxins i.e. toxins produced by microorganisms in the food before it is eaten. Most of the pathogenic bacteria are not present in fish caught from off-shore waters, but contamination occurs during handling of the raw material. Uncontrolled time and temperature conditions are favourable for organisms to grow and multiply at a faster rate. Food can become contaminated at any point during production, distribution and preparation. Everyone along the production chain, from producer to consumer, has a role to play to ensure the food we eat does not cause diseases.

Bacterial Pathogens:

1. *Bacillus cereus*
2. *Campylobacter jejuni and C. coli*
3. *Clostridium botulinum*
4. *Clostridium perfringens*
5. *Pathogenic Escherichia coli*
6. *Listeria monocytogenes*
7. *Salmonella* spp.
8. *Shigella* spp.
9. *Staphylococcus aureus*
10. *Faecal Streptococci*
11. *Vibrio cholerae*

12. *V. parahaemolyticus*
13. *V. vulnificus*
14. *Yersinia enterocolitica*
15. *Aeromonas spp.*
16. *Plesiomonasshigelloides*

Bacillus cereus

This is a common food contaminant and well-known causative agent of food-borne illness. Their infection is not commonly reported because of its usually mild symptoms. A fatal case due to liver failure Food poisoning caused by B. cereus may occur when foods are prepared and held without proper refrigeration for several hours before being served.

B. cereus is an aerobic spore-forming bacterium. It is commonly found in soil, on vegetables, and in many raw and processed foods. Consumption of foods that contain 10^6 CFU /g may result in food poisoning. Foods incriminated in food poisoning outbreaks include cooked meat and vegetables, boiled or fried rice, vanilla sauce, custards, soups, and raw vegetable sprouts as well as fish. Two types of illnesses have been attributed to *B. cereus*. The first is characterized by abdominal pain and diarrhoea. It has an incubation period of 4-16 hours and symptoms that last for 12-24 hours. The second is characterized by an acute attack of nausea and vomiting. It has an incubation period of 1-5 hours. Diarrhoea is not common with the second type of illness. The organism has possible severity of the emetic syndrome which emphasise the importance of adequate refrigeration of prepared food. Because the emetic toxin is pre-formed in the food and not inactivated by heat treatment, it is important to prevent growth and the production of cereulide during storage. Some *B. cereus* strains are known to be psychrotrophic and to have the highest emetic toxin production between 12- and 15°C.

Cooking of seafood does not inactivate the spores of *B. cereus* and would not be the recommended means to control this pathogen. Proper hygiene and appropriate temperature control are needed to prevent B. cereus illness. Effective control measures depend on destruction by a heat process and temperature control to prevent spore germination and multiplication of vegetative cells in cooked, ready-to-eat foods. Avoid holding cooked foods at room temperature; Use quick chill methods to cool foods below 45^0F (7.2^0C) within 4 hours of preparation; Hold/store hot foods above 140^0F (60^0C) until served, and Reheat foods rapidly to 165^0F (74^0C) or above.

Campylobacter jejuni and C. coli

These are Gram-negative, microaerophilic, curved thin rods with corkscrew motility. *C. jejuni* is widely distributed in the intestinal tract of poultry, livestock, and warm-blooded domestic animals. It is a very common and important cause of diarrheal illness in humans. Eating raw seafood is risk factor for sporadic Campylobacter infection. Symptoms include profuse diarrhoea (sometimes bloody), abdominal pain (intensity and duration can be somewhat severe), headache, weakness, and fever. Many infections occur without symptoms. *C. jejuni* is transmitted through: contaminated foods, including raw clams, mussels and oysters; person-to-person contact; and contaminated water. Cross-contamination of foods by dirty food-contact surfaces, including cutting boards and hands, may be the most frequent route of transmission. Profuse diarrhoea, abdominal pain, headache and fever and

meningitis in neonates are major symptoms because of this organism. Infective dose ranges from 500 to 10,000 cells. This organism survives refrigeration and freezing.

Hazards from *C. jejuni* can be controlled by thoroughly cooking seafood and by stressing the importance of proper (and frequent) hand and equipment washing and sanitary food-handling practices. Since the infective dose of *C. jejuni* is thought to be small, time/temperature abuse of food products is not necessary to result in this illness. Although the heat resistance of *C. jejuni* in seafood has not been determined, the reported heat resistance of this organism in other products is low (69). Preventing campylobacteriosis from consumption of raw shellfish depends on protecting shellfish growing waters from fecal contamination.

Clostridium botulinum

C. botulinum is a gram positive, spore-forming rod shaped bacteria that grows in the absence of air. *Clostridium botulinum* is a dangerous food poisoning organism and it produce a very deadly, exotoxin when grows in food. The food poisoning is known as 'botulism''. The spores are highly heat resistant. Eight different toxins such as A, B, C1, C2, D, E, F & G are known to exist. Type- E is present in sea mud and is mostly involved in botulism food poisoning in seafood. Food poisoning is due to the ingestion of toxin. Symptoms develop within 12-24 h of consuming infected food. Nausea, vomiting, fatigue, headache, paralysis, difficulty to talk, double vision and sound in the ear are the usual symptoms. Death occurs due to respiratory failure.

This organism is found throughout the environment and has been isolated from soil, water, vegetables, meats, dairy products, ocean sediments, the intestinal tracts of fish, and the gills and viscera of crabs and other shellfish. These characteristics allow it to survive normal cooking temperatures and to grow in a vacuum-packaged and modified-atmosphere environment. *C. botulinum* produces a powerful neurotoxin that causes botulism. Growth is necessary for *C. botulinum* to produce toxin. Symptoms include diarrhea, vomiting, abdominal pain, nausea and weakness. These are followed by double, blurred vision and dilated, fixed pupils. In severe cases, paralysis of the muscles responsible for breathing can cause death. The type of *C. botulinum* Type E that is most common in fish and fishery products is of particular concern because it grows at temperatures as low as 38 F and produces little noticeable evidence of spoilage. *C. botulinum* Type A is the form of this bacteria that is most common in land-based products. It is a common contaminant on processing equipment. It will grow at temperatures no colder than 50^0F and produces a putrid odour in products in which it grows. However, its spores are much more heat-resistant than the Type E form of the bacteria.

Because *C. botulinum* produces heat-resistant spores and requires the absence of oxygen for growth, botulism has been most commonly associated with improperly canned food (usually home canned). Semi-preserved seafoods, including smoked, salted and fermented fish, have also been identified as causes of botulism.

Hazards from *C. botulinum* can be controlled by inhibiting growth of the bacteria or by destroying it in seafood. Proper thermal processes for canned seafood destroy the bacteria. Heavy salting or drying to reduce the water activity below 0.93 and fermentation or acidification to below pH 4.6, are effective means of preventing *C. botulinum* growth. Maintaining proper storage temperatures alone is not considered an adequate control measure for *C. botulinum* Type E because of its ability to grow at low

temperatures and because of the severity of the illness. Nonetheless, in many products, it is an important second barrier to growth.

Proper processing under hygienic conditions and adequate retorting are suggested as remedy.

Clostridium perfringens

It is a spore forming, anaerobic (oxygen-free growth conditions) bacterium. *C. perfringens* is commonly found in soil, dust, and the intestinal tract of animals. Food poisoning caused by *C. perfringens* may occur when foods such as meat or poultry are cooked and held without maintaining adequate heat or refrigeration before serving. The illness is a self-limiting gastroenteritis with an incubation period of 8-15 hours and duration of 12-24 hours. The symptoms, which include intense abdominal cramps, gas, and diarrhoea, have been attributed to a protein enterotoxin produced during sporulation of the organism in the intestine.

The presence of small numbers of *C. perfringens* is not uncommon in raw meats, poultry, dehydrated soups and sauces, raw vegetables, and spices. Because the spores of some strains are resistant to temperatures as high as 100ºC for more than 1 hour, their presence in foods may be unavoidable. Furthermore, the oxygen level may be sufficiently reduced during cooking to permit growth of the clostridia. Spores that survive cooking may germinate and grow rapidly in foods that are inadequately refrigerated after cooking. Thus, when clinical and epidemiological evidence suggests that *C. perfringens* is the cause of a food poisoning outbreak, the presence of hundreds of thousands or more of these organisms per gram of food substantiates the diagnosis.

Control measures emphasize proper food preparation and storage techniques, especially temperature control. Control measures include: Rapid, uniform cooling of cooked foods of cooked foods to <10ºC (50ºF) within 2-3 hours; Hot holding of cooked foods at or above 60ºC (140ºF); Preventing cross-contamination of cooked foods with bacteria from raw foods by using separate food-contact surfaces for preparing raw and cooked foods items, or by thoroughly cleaning and sanitizing food contact surfaces after being used for raw products; Maintaining food preparation areas so that they are free of soil and dust; Using good personal hygiene methods, and thoroughly washing hands frequently when handling food products, especially after handling raw products and before handling cooked products.

Pathogenic Escherichia coli

E. coli are Gram-negative, rod-shaped, non-spore forming facultative anaerobic bacteria. E. coli are naturally found in the intestinal tracts of all animals, including humans. Most forms of the bacteria are not pathogenic and serve useful functions in the intestine. Pathogenic strains of E. coli are transferred to seafood through sewage pollution of the coastal environment or by contamination after harvest. *E. coli* food infection causes abdominal cramping, water or bloody diarrhoea, fever, nausea, and vomiting. There are *six categories of diarrheagenic E. coli* which include Enterotoxigenic *E. coli (*ETEC*),* Enteropathogenic *E. coli (*EPEC*),* Enteroinvasive *E.coli (*EIEC*),* Enterohemorrhagic *E. coli (*EHEC*,* Shiga toxin-producing *E. coli or* STEC*),* Enteroaggregative *E. coli (*EAEC *or* EAggEc*)* andDiffusely adherent *E. coli (*DAEC*).*

The primary habitat of the organism is intestinal tract of man and animals and its presence in food in food is generally considered as an indication of faecal contamination. Natural water get contaminated with *E. coli* either by direct contact with faeces or by mixing up with sewage. This water, when used for seafood processing, contaminates the product. Similar possibilities arise when the ice used for preservation or the utensils used for processing are contaminated with *E. coli*.

Off-shore water is generally free from E. coli, but its incidence is noted in coastal waters. Fishing in these waters or washing the boat deck and fish containers using coastal water or harbour waters are known to be the major source of contamination with E. coli. -Inadequately cleaned boat deck and containers used onboard trawldrs also act as source of contamination. If the temperature is favourable, the contaminating organism multiplies rapidly and further aggravates the situation. Generally this organism is harmless: Pathogenic strains of E.coli are considered to be harmful.

Hazards from E. coli can be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafoods below 40 F, preventing postcooking cross-contamination, and prohibiting people who are ill from working in food operations. The infective dose of E. coli is dependent upon the particular strain from only a few organisms to millions. For this reason, time/temperature abuse of food products may or may not be necessary to result in illness.

a. Maintenance of proper hygiene and sanitation ;

b. Chlorination of process water;

c. Adoption of scientific system or cleaning and disinfection;

d. Avoid fishing from near-shore waters;

e. Avoid washing the catch with coastal/harbour waters;

f. Avoid delay in processing;

g. Reduce the temperature of the material at every stage ie. <4°C.

Listeria monocytogenes

This organism is Gram-positive, micro-aerophilic, non-spore forming, and motile rods. It can survive freezing and thawing. *L. monocytogenes* grows in refrigerated temperatures (even 1°C) and it can survive both acidic and alkaline pH. This is the most heat resistant pathogenic bacteria among non-spore formers.

L. monocytogenes is widespread in nature and has been isolated from soil, vegetation, marine sediments and water. About 1% of human population is known to carry *L. monocytogenes.* Studies have indicated that *L. monocytogenes* is present in various kinds of foods including fish and shellfish. It causes listeriosis in humans. Most healthy individuals are either unaffected by *L. monocytogenes* or experience only mild flu-like symptoms. Victims of severe listeriosis are usually immune-compromised. Those at highest risk include: cancer patients, individuals taking drugs that affect the body’s immune system, alcoholics, pregnant women, persons with low stomach acidity and individuals with AIDS. Severe listeriosis can cause meningitis, abortions, septicemia and a number of other maladies, some of which may lead to death.

The greatest threat of listeriosis is from ready-to-eat products that do not require further cooking at home. *L. monocytogenes* in raw food that will be cooked before consumption is less of a concern to the food industry since the bacteria are killed during cooking. *L monocytogenes* has been isolated from raw fish, cooked crabs, raw and cooked shrimp, raw lobster, surimi and smoked fish. One of its most significant characteristics is its ability to grow at temperatures as low as 31ºF. Hazards from *L. monocytogenes* can be prevented by thoroughly cooking seafood and by preventing cross-contamination once the seafood is cooked. Since the infective dose of *L. monocytogenes* is thought to be small, time/temperature abuse of food products may not be necessary to result in illness.

***Salmonella* spp.**

Salmonella are non-spore forming, mostly motile (exception *S. pullorum* and *S. gallinarum*) facultative — anaerobic, Gram-negative rods. More than 3000 serotypes of this organism are known to exist at present. All serotypes of *Salmonella* can survive freezing at -40°C and also survive for months together at frozen condition (-18°C).

Salmonella is naturally found in the intestinal tracts of mammals, birds, amphibians and reptiles but not in fish, crustaceans or mollusks. *Salmonella* is transferred to seafood through sewage pollution of the harvest environment or by contamination after harvest.

Salmonella are enteric organisms producing enteric fever and food borne gastroenteritis. Food poisoning due to *Salmonella* is known as "Salmonellosis" infants, elderly and the under nourished are more susceptible to the disease and in such individuals salmonellosis is known to occur even from one single cell of *Salmonella*. *Salmonella* food infection causes nausea, vomiting, abdominal cramps and fever. Outbreaks of *Salmonella* food infection have been associated with raw oysters, salmon, tuna salad, shrimp cocktail, stuffed sole and gefilte fish.

Hazards from *Salmonella* can be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafood below 40 F, preventing post-cooking cross-contamination and prohibiting people who are ill or are carriers of *Salmonella* from working in food operations. The infective dose of *Salmonella* is thought to be extremely variable, relatively high for healthy individuals and very low for at-risk individuals, such as the elderly or medically compromised. For this reason, illness could result even without time/temperature abuse, but abuse has been a contributing factor in many outbreaks.

Preventive measures are Avoid fishing from polluted waters; Avoid washing with coastal/harbour waters; Avoid sorting the catch on sea beaches; Use only chlorinated water for processing and for ice manufacture; Periodical medical check-up for workers; All contact surfaces/utensils meant for processing need be cleaned and disinfected before and after use; Avoid the workers who are suffering from diarrhoea/vomiting; Before starting the work, all fish handlers may wash and disinfect their hands; Entry of rodents, wall lizards, flies etc., to the processing hall may be avoided

Shigella spp.

Shigella are Gram-negative, facultatively anaerobic, non-sporulating, non-motile, rod shaped bacteria. They are the most difficult enteric pathogens to isolate as not indigenous in foods. The disease caused by *Shigella* is generally known as `shigellosis', which causes mild diarrhea, fever, abdominal cramps and severe fluid loss. This organism are transmitted through food or water contaminated with human

excreta. Shigella is naturally found in the intestinal tract of humans.The organisms pass the acid barrier of the intestine, multiply in the gut and produce ulceration of large intestine followed by dysentery. *S. dysenteriae*causes the most severe illness. Shigella is transferred to seafood through sewage pollution of the coastal environment or by contamination after harvest. The transmission of the organism from one individual to another is by means of contaminated food, water, ice, flies, contaminated contact surface or food handlers who are carriers of this organism. They survive longest when food holding temperatures are 25°C or lower.

Shigella contamination can be prevented by eliminating human waste contamination of water supplies and by improved personal hygiene for people who are ill or are carriers of Shigella and work in food operations. Avoidance of time/temperature abuse, pest control, and Use properly chlorinated water for processing will be help to overcome this organism.

Staphylococcus aureus

Humans and animals are the primary reservoirs for *S. aureus*. *S. aureus* can be found in the nose and throat and on the hair and skin of 50 percent of healthy individuals. However, the bacteria can be found in air, dust, sewage and surfaces of food-processing equipment. *S. aureus* can produce a toxin if allowed to grow in food. The toxin is not destroyed by the cooking or canning processes. *S. aureus* has the ability to grow and produce toxins in food with very little available water (0.85 aw, 10% salt), which would prevent the growth of other pathogens. *S. aureus* food poisoning causes nausea, vomiting, abdominal cramping, watery or bloody diarrhea, and fever.

Hazards from *S. aureus* can be prevented by: minimizing time/temperature abuse of seafood, especially after cooking, and requiring that food handlers engage in proper hygiene.

It is known that contamination of food with coagulase-positive staphylococci could cause food poisoning, as the organism growing in food materials in considerable numbers, secretes exotoxin.

Habitat and source of contamination

The primary habitat of *Staphylococcus aureus* is man. This organism is present in sweat, ear gum, tears, throat, ulcers, boils and nasal cavities. It is known that 50% of human beings are carriers of this organism. Investigations carried out by CIFT have shown that 45% of seafood handlers in the processing units at Cochin are carriers of *S. aureus*.

Fish caught from the open sea doesn't contain *S. aureus*. When the material is taken onboard and handled by workers, contamination takes place. So its presence in seafood indicates lapse in maintaining personal hygiene.

Toxin production

Few Staphylococci per gram of food material may be harmless, but food poisoning outbreak may occur if the product is handled carelessly during processing, so as to allow multiplication of the organism in dangerous proportions. The organism can multiply vigorously and produce toxin at temperature near about room temperatures i.e. 30-37°C. Therefore refrigeration of the material during handling and processing is highly essential in preventing further multiplication and toxin production. The toxin once formed will not be destroyed even at 100°C even though the organisms are killed at this temperature.

It is thus evident that, once sufficient quantity of toxin is formed in food material before its consumption, food poisoning can follow even though the food material is cooked. Foods most likely to be involved in staphylococcal food poisoning are cooked and processed foods having low number of competing micro-organisms. Large number of *Staphylococcus aureus*, usually more than one million organism/g of food material must be present at one time to produce enough enterotoxin. Less than one microgram of toxin is sufficient to cause illness in a sensitive individual. Staphylococcal food poisoning is caused only by certain well defined strains of *S. aureus*; such strains are known as enterotoxigenic strains. Food-borne out breaks due to coagulase-negative strains of Staphylococci are seldom reported. *S. aureus* are known to produce 9 different types of enterotoxins designated as enterotoxin A, B, C1, C2, D, E, F, G and H. This is the most drought resistant pathogenic bacteria and they cannot compete with general bacterial flora.

Disease symptoms

Nausea, vomiting, abdominal pain, diarrhoea and subnormal blood pressure are some of the usual symptoms. It may appear within 1 - 4 h of consumption of contaminated food. Complete cure is possible within 48h.

Effect of freezing and frozen storage

The studies have shown that only 5 - 15% of *S. aureus* cells inoculated to cooked shrimps are killed during freezing at -40°C. However, during frozen storage at -18°C, there is gradual reduction and in 7 months the viability is completely lost.

Preventive measures

a. Adequate control over the health and hygiene of fish handlers

b. Refrigeration (below 4°C) of the material during handling and processing

c. Minimise time/temperature abuse of seafood, especially after cooking.

Faecal *Streptococci*

Faecal streptococci are Gram-positive, facultative anaerobic, non-spore forming non-motile and catalase negative cocci. An emerging zoonotic pathogen which infections generally occur through injuries associated with preparing whole fresh fish for cooking.

Primary habitat and source of contamination are same as in the case of E.coli. One gram of faeces contains 10^8 faecal streptococci, therefore their presence in food product is generally regarded as an indication of faecal contamination. Just like E.coli, faecal streptococci are absent in off-shore water but are present in considerable numbers in coastal waters. Unclean boat deck, utensils, water and ice are the major source of contamination.

Effect of freezing and frozen storage

Faecal streptococci are comparatively resistant to many adverse conditions. About 30% reduction of faecal streptococci takes place during freezing at -40°C, during subsequent storage at -18°C not much of reduction in count takes place even after 2 years of storage. This organism is considered as a better indicator or sanitation than E.coli, because of their resistance to sub-zero temperature.

Symptoms: causes gastrointestinal and respiratory diseases.

Preventive measures: similar to E.coli

Vibrio cholerae

V. cholerae are Gram-negative, coma shaped aerobic, non-spore forming, and motile rods. *V. cholerae* is found in estuaries, bays, and brackish waters. It is naturally occurring and is not necessarily related to sewage contamination. *V. cholerae* tends to be more numerous in the environment during warmer months.

There are a number of types of *V. cholerae*, and these produce very different symptoms. One type, *Vibrio* cholerae 01, initially causes abdominal discomfort and mild diarrhea. As the illness progresses, the symptoms may include: watery diarrhea, abdominal cramps, vomiting and dehydration. Death can occur. Susceptibility to cholera is enhanced in people who have had gastric surgery, take antacids or have type O blood. Outbreaks of this type of cholera have been associated with oysters, crabs and shrimp from the Gulf of Mexico. V. cholerae 01 has also been recovered from Chesapeake Bay waters, although no illness has been reported from that area.

Another type of *V. cholerae* non-01 causes diarrhea, abdominal cramps and fever. Nausea, vomiting and bloody diarrhea have also been reported. The severity of the symptoms is dependant, in part, upon the specific strain. In its most severe form, *V. cholerae* non-01 has resulted in septicemia (blood poisoning) in individuals with medical conditions that weaken their immune systems. The illness has been associated with consumption of raw oysters, but the bacterium has also been found in crabs.

Hazards from *V. cholerae* can be prevented by cooking seafood thoroughly and by preventing cross-contamination once the seafood is cooked. It is the causative agent of cholera. The current definition of V *cholerae* consists of the classical (non-hemolytic) and El Tor (hemolytic) biovars. The El Tor *vibrios*are generally more infectious than the classical *V. choleraeserotypes*and it can survive longer in the environment.

Serotypes

V. cholerae 01 Ogawa, Inaba and Hikojimaand V. cholerae 0139 Bengal

Those strains which are biochemically identical to *V. cholera* 01, but don't posses the 01 somatic antigens are collectively known as non-01 *V. cholerae,* previously known as non-agglutinable *vibrio*s (NAG'S) or non-cholerae *vibrio*s (NCVs). Non-01 *V. cholerae* produce mild diarrhoea. Further, this organism appears to be a hybrid of the 01 strain and the non-01 strain. Hence other serotype is named as "Bengal" for the recognition of the origin of this strain. Unlike *V. cholerae* 01, O139 organism produces a polysaccharide capsule.

Habitat

The only natural habitat of *V. cholerae* is man.

Source of contamination

Contamination occurs through food, water, flies and contaminated hands.

Symptoms

Nausea, vomiting, profuse diarrhoea, etc., develop after an incubation period of 1 – 4 days. The stool resembles 'rice water' and contains mucus, epithelical cells and a large number of *Vibrios.*

Preventive measures

a. Proper disinfection of contact surface.

b. Avoid cross contamination of cooked products

c. Strict personal hygiene of seafood handlers.

Allowable limit - should be absent.

Vibrio parahaemolyticus

V. parahaemolyticus is naturally occurring in estuaries and other coastal areas throughout most of the world. In most areas, *V. parahaemolyticus* is more numerous in the environment during the warmer months and, as a result, most outbreaks in the United States occur during the summer.

The most commonly experienced symptoms of *V. parahaemolyticus* illness include: diarrhea, abdominal cramps, nausea, vomiting and headache. Fever and chills are less frequently reported. The illness has been associated with consuming contaminated crabs, oysters, shrimp and lobster.

Hazards from *V. parahaemolyticus* can be controlled by thoroughly cooking seafood and preventing cross-contamination after cooking. Control of time/temperature abuse is also an important preventative measure.

V. parahaemolyticus is a marine pathogen present in marine and brackish-water environments. It can cause food poisoning when it is consumed in large numbers (more than 10^5/g of Kanagawa-positive strains), along with food materials. This type of food poisoning is more in countries like Japan, where there is a habit of eating un-cooked seafood. In recent years, the incidence of *V. parahaemolyticus* infection has been increasing in many parts of the world, and this has been attributed to the emergence of a new clone of the 03:K6 serotype carrying only the *tdh*gene. The onset of symptoms is within 12 h of eating infected food. They are Gram-negative, rod shaped bacteria which are non-sporulating, halophilic, motile, and oxidase-positive.

Symptoms

Abdominal pain, vomiting, diarrhoea, and fever are the usual symptoms.

Effect of freezing and frozen storage

99% of the organisms are destroyed during freezing at - 40°C and during storage at -

18°C complete destruction takes place within few days. The generation time of these organisms is only 7-10 minutes;

There are two types of *V. parahaemolyticus* are known to exist.

- Kanagawa - positive (Pathogenic)
- Kanagawa-negative (Non-pathogenic)

Isolates from clinical sources are Kanagawa- positive whereas those from marine sources are Kanagawa - negative.

Icing the material immediately after catch, washing with potable water and improvement of hygiene are considered as remedial measures.

Vibrio vulnificus

V. vulnificus is a naturally occurring marine bacterium. *V.vulnificus* requires salt for survival and is commonly isolated at salinities of 7 ppt to 16 ppt. It is primarily found in the Gulf of Mexico, but it has also been isolated from the Atlantic and Pacific oceans. The numbers of the bacterium in the environment are highest during the warmer months of April through October.

The most common symptoms include: skin lesions, septic shock, fever, chills and nausea. Abdominal pain, vomiting and diarrhea are less frequently reported. Death occurs in about 50 percent of the cases. A number of medical conditions make individuals more susceptible to the life threatening effects of this bacterium, including: liver disease, alcohol abuse, cancer, diabetes, chronic kidney disease, immunosuppressive drug or steroid usage, low stomach acidity and AIDS. V. vulnificus sepsis has been associated with the consumption of certain molluscan shellstock.

Hazards from V. vulnificus can be controlled by thorough cooking of shellfish and by preventing cross-contamination once the seafood is cooked. The risk of V. vulnificus infection may also be reduced by rapidly refrigerating oysters from the Gulf Coast during warm-weather months. Individuals in the “high risk” groups should not consume raw molluscan shellfish.

V*ibrio vulnificus*

It is an emerging pathogen, phenotypically similar to *V. parahaemolyticus.*

And is the etiological agent for 3 syndromes.

a. primary septicemia b. skin infections c. acute diarrhoea

Entry through two portals

a. Ingestion of raw sea foods

b. Exposure of skin lesions

Mortality is up to 60%. It is the part of the normal bacterial flora of estuarine and marine waters.

V. vulnificus is Gram-negative, halophilic, lactose-positive, rod shaped bacteria. All strains are pathogenic; infection dose is not known! Infection is associated with the consumption of raw seafood particularly oysters. Ten minutes treatment at 50°C proved adequate to reduce *V. vulnificus* to a non-detectable level. Icing is very effective to reduce the load of the organism. This organism is closely associated with oyster tissues and is not removed fully by controlled purification methods such as UV light assisted depuration No effective means commercially exist for elimination of the health hazard in oyster intended for raw consumption and so, it is advised to avoid raw seafood completely.

Yersinia enterocolitica

Y. enterocolitica is naturally found in soil, water and domesticated and wild animals. Yersiniosis causes diarrhea, vomiting, abdominal pain and fever, often mimicking appendicitis. Outbreaks have been associated with oysters and fish.

Hazards from *Y. enterocolitica* can be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafoods below 40 F and preventing post-cooking cross-contamination.

***Aeromonas* spp.**

The genera *Aeromonas* comprise Gram-negative, facultatively anaerobic, oxidasepositive, glucose-fermenting rod-shaped bacteria, generally motile. *Aeromonas* species viz. *A. hydrophila, A. sorbia*and *A. caviae*has been described as emerging food-borne pathogens. Besides gastroenteritis *A. hydrophila*may cause cholera like infections. *Aeromonas spp.* Are natural members of aquatic environments and is commonly found in fish and fish products of all aquatic environments. *A. hydrophila*is very resistant organism and it can survive in food items stored in cold for long period. Oysters have been implicated in food-borne disease. *Aeromonas* associated diarrhoea has been reported from different parts of India. Some *Aeromonas* spp. are psychrotrophs and some others are enteropathogenic. Studies have shown that very high percentage of the isolates from seafood produced hemolysin (79.2%) and cytotoxin (91.7%). Psychrotrophic*Aeromonas* strains are able to grow at 4-5°C and produce toxin in oysters at 5°C. Combination of chilling, salting and/or acidification is effective means of preventing the growth of *Aeromonas.*

Plesiomonasshigelloides

The genera *Plesiomonas*comprise Gram-negative, facultatively anaerobic, oxidase positive, glucose fermenting, rod shaped bacteria, generally motile. It is an emerging pathogen, mostly associated with fresh water and seawater in warm months. This organism is predominantly associated with seafood. *P. shigelloides*was implicated as the causative agent for diarrhoea after consumption of seafood in Hong Kong and USA. It cannot grow at chilled condition, but can survive. Growth can be prevented by chilling, moderate salting/acidification.

Fungal hazards

The fungi associated with foods are generally yeasts and moulds. The greatest concerns for food safety are mycotoxins e.g. aflatoxin, fusarin, patulin, etc. which are produced by moulds and may be associated with chronic illness, such as cancer. Fungi need lesser moisture for growth compared to bacteria. If the water activity (aw) is less than 0.60 there will not be any growth of fungi or other microorganisms. Water activity of biscuits is 0.30 and sugar is 0.10.

Viral Pathogens

Viral hazards

Viruses contaminate the foods same way as bacteria. It reproduces only within susceptible living cells. A ready to eat food containing a pathogenic virus is a health hazard. Viruses don't reproduce in food; it exists in foods without growing, so they need no food, water or air to survive. Viruses don't cause spoilage but may cause illness. It can survive in human intestine, water, frozen foods etc. for months. Viruses can be found in people who were previously ill. Adequate cooking can destroy it.

Viral Pathogens:

• Hepatitis A Virus

• Norwalk Virus

Hepatitis A

Virus Viruses survive better at low temperatures and are killed at high temperatures. As a result, most outbreaks of hepatitis occur during winter and early spring. Viruses can remain alive for long periods of time in seawater and have been shown to survive over one year in marine sediments.

Both raw and steamed clams, oysters, and mussels have been implicated in outbreaks of hepatitis A. Symptoms of hepatitis A include weakness, fever and abdominal pain. As the illness progresses, the individual usually becomes jaundiced. The severity of the illness ranges from very mild (young children often experience no symptoms) to severe, requiring hospitalization. The fatality rate is low, and deaths primarily occur among the elderly and individuals with underlying diseases.

Hazards from hepatitis A can be prevented by thoroughly cooking seafood and by preventing cross-contamination of cooked seafood. But hepatitis A appears to be more resistant to heat than other viruses. A laboratory study showed that hepatitis A viruses in infected oysters were inactivated after heating at 140 F for 19 minutes. Therefore, mollusks steamed only until the shells open (a common cooking practice) are not exposed to heat long enough to inactivate hepatitis A viruses.

Norwalk Virus

Norwalk virus is considered a major cause of nonbacterial intestinal illness (gastroenteritis). Illness from Norwalk virus has been associated with eating clams (raw and steamed), oysters and cockles. Norwalk virus causes nausea, vomiting, diarrhea, abdominal cramps, and occasionally fever in humans.

Hazards from Norwalk virus can be prevented by thoroughly cooking seafood and by preventing cross-contamination of cooked seafood. Additionally, a recent outbreak has demonstrated that controlling overboard discharge of untreated sewage from shellfish harvesting vessels would reduce the incidence of illness attributable to Norwalk virus.

1. Hepatitis A virus

This virus can survive in seawater and sediments for long periods (over a year). It can also survive better in lower temperature and killed in higher temperature.

Symptoms

Weakness, fever, abdominal pain and the patient gradually get jaundiced.

Thorough cooking is the preventive measure.

2. Norwalk virus

These are considered to be the major cause of nonbacterial intestinal illness (gastroenteritis). They are associated with eating raw and steamed clams or oysters etc. cause nausea, vomiting, diarrhoea, abdominal cramps and fever. This hazard can be prevented by thorough cooking and preventing cross contamination of cooked foods.

Parasites

• *Anisakis simplex*

• *Pseudoterranovadecipiens*

• *Diphyllobothrium latum*

Anisakis simplex

Anisakis simplex, commonly called herring worm, is a parasitic nematode or roundworm. Its final hosts are dolphins, porpoises and sperm whales. The larval (wormlike) stage in fish and squid is usually 18 to 36 millimeters in length, 0.24 to 0.69 millimeters in width and pinkish to whitish in color.

Anisakiasis, the human illness caused by Anisakis simplex, is associated with eating raw fish (sushi, sashimi, lomilomi, ceviche, sunomono, Dutch green herring, marinated fish and cold-smoked fish) or undercooked fish.

Parasites in fish are considered a hazard only in fish that the processor knows or has reason to believe will be served raw or undercooked. In other products, parasites are considered filth but not hazardous. The FDA has established three freezing processes to kill parasites. Freezing and storing at -4ºF (-20ºC) or below for 7 days (total time), or freezing at -31ºF (-35ºC) or below for 15 hours, or freezing at -31ºF (-35ºC) or below until solid and storing at -4ºF (-20ºC) or below for 24 hours is sufficient to kill parasites. FDA's Food Code recommends these freezing conditions to retailers who provide fish intended for raw consumption. Note: these conditions may not be suitable for freezing particularly large fish (e.g. thicker than six inches).

Pseudoterranovadecipiens

Pseudoterranovadecipiens, commonly called "codworm" or "sealworm," is another parasitic nematode or roundworm. The usual final hosts of Pseudoterranova are gray seals, harbor seals, sea lions and walruses. The larval stage in fish are 5 to 58 millimeters in length, 0.3 to 1.2 millimeters in width and yellowish, brownish or reddish in color.

These nematodes are related to Anisakis simplex and the disease associated with infections is also termed anisakiasis. These nematodes are also transmitted to humans through raw or undercooked fish. Control of Pseudoterranova is the same as for Anisakis simplex.

Diphyllobothrium latum

Diphyllobothrium latum is a cestode, or tapeworm, that parasitizes a variety of fish-eating mammals of the northern latitudes. A similar species is found in the southern latitudes and is associated with seal hosts. Cestodes have a structure that allows them to attach to the intestinal wall of their host and have segmented bodies. Cestode larvae found in fish range from a few millimeters to several centimeters in length and are white or gray in color.

Diphyllobothrium tapeworms primarily infect freshwater fish. But salmon and related fish can also carry the parasites. Diphyllobothrium tapeworms are usually found unencysted and coiled in musculature or encysted in viscera. These tapeworms can mature and cause disease in humans. These cestodes are

also transmitted to humans through raw or undercooked fish. Control of Diphyllobothrium is the same as for Anisakis simplex.

Parasitic Hazards

Parasites are organisms that need 'a host to survive, living on or within it. Human unknowingly consume microscopic and small macroscopic animals with their food. The intestinal tract is inhospitable to most of these organisms, which are either digested or evacuated in the faeces. There are two types of parasites that can infect people through food or water. There are generally (a) parasitic worms and (b) protozoan parasites.

Parasitic worms include

1. Round worms (nematodes)

2. Tapeworms (cestodes)

3. Flukes (trematodes)

For most food borne parasites, the food is part of their life cycle. Some parasites may be transmitted through food or water that is contaminated by faecal material shed by infected host.

a. Parasitic Worms

1. Anisakis simplex

A nematode commonly called as herring worms, its final hosts are dolphins, porpoises and sperm whales. Larval stages are in fish and squid. Parasites in fish are considered to be a hazard only in case the fish is eaten raw or undercooked. "Anisakiasis" is the human illness caused by this parasite. In other products parasites are considered as filth but not hazard.

2. Pseudoterranovadecipiens .

Another parasitic nematode commonly called as cod worm or seal worm. The disease caused by this parasite is also known as "Anisakiasis". The transmission and control of this organism is same as that of *Anisakis simplex.*

3. Diphyllobothrium latum

This parasitic cestode primarily infects freshwater fish. This tapeworm can mature and cause disease in human beings. These worms are transmitted to humans through raw or undercooked fish. Proper cooking can destroy it.

4. Clonorchi sinensis, Metagonimusyokagawai and Heterophyesheterophyes

These are members of a large group of trematode parasites with common characteristic of being acquired through eating raw or insufficiently cooked fish. *C. sinensis* can cause inflammatory and fibrotic changes in the bile duct, gall bladder and liver. *M. yokagawai*and H. *heterophyes*are very small flukes (1-2.5 mm in length). They burrow into the mucosa of the small intestine and produce irritation, inflammation, mucus formation and symptoms of diarrhoea and abdominal pain.

b. Protozoan Parasites

These are single celled animals.

1. Entamoeba histolytica can cause severe disease as classical amoebic dysentery which may be fatal if the parasites invade extra-intestinal tissues, such as liver, lungs, or brain.

2. Giardia lamblia associated with diarrhoea, constipation and gastrointestinal pains, rarely invade the tissues.

3. Toxoplasma gondii: Illness caused is "Toxoplasmosis", symptoms are hydrocephalus, blindness in children. These are less severe in adults. Source of infection are under cooked or raw meats i.e. pork, lamb, beef, poultry & cats. Intermediate host is domestic cat.

***4. Cryptosporidium* spp.**

Most frequently diagnosed opportunistic pathogens associated with diarrhoea and wasting syndrome in patients with AIDS. *Cryptosporidium* produces a life-threatening, prolonged cholera like illness in immuno-compromised patients. `Cryptosporidiosis' is acquired after ingesting food or water contaminated with infective *cryptosporidium* oocytes. The mean prevalence of *C. parvum* in Europe and the U.S. is between 1 and 3% and it is considerably higher in developing countries.

Proper food handling can prevent most foodborne illness and diseases. Follow WHO’s five keys to safer food:

1. Keep clean:
   - Thoroughly wash raw fruits and vegetables with tap water.
   - Keep clean hands, kitchen and chopping board all the time.
2. Separate raw from cooked:
   - Do not mix raw food and ready-to-eat food.
   - Do not mix raw meat, fish and raw vegetables.
3. Cook thoroughly:
   - Thoroughly cook all meat, poultry and seafood, especially shellfish.
   - Reheat all leftovers until they are steaming hot.
4. Keep food at safe temperatures:
   - Refrigerate cooked food within two hours of preparation
   - Never defrost food at room temperature. Defrost frozen food in the refrigerator, cold water or in the microwave.
5. Use safe water and raw materials.
   - Use safe drinking water for food preparation.

Check use-by dates and labels while buying packed food

Chapter 8

Orientation to Hazards: Biological II

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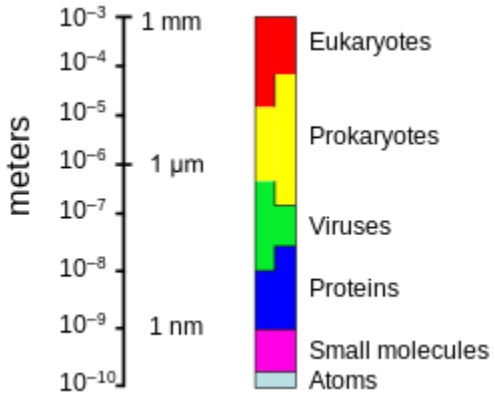
A microorganism, or microbe, is an organism of microscopic size, which may exist in its single-celled form or as a colony of cells. Technically a microorganism or microbe is an organism that is microscopic. The scientific study of microorganisms began with their observation under the microscope in the 1670s by Anton van Leeuwenhoek. The microorganisms are classified into Bacteria, Fungi, Archaea, Protists, Microscopic plants (green algae), Microscopic animals (plankton) and Virus.Microorganisms can be found almost anywhere on Earth. Bacteria and archaea are almost always microscopic, while a number of eukaryotes are also microscopic, including most protists, some fungi, as well as some micro-animals and plants.Bacteria like archaea are prokaryotic - unicellular, and having no cell nucleus or other membrane-bound organelle.

Bacteria function and reproduce as individual cells, but they can often aggregate in multicellular colonies. Some species such as myxobacteria can aggregate into complex swarming structures, operating as multicellular groups as part of their life cycle, or form clusters in bacterial colonies such as *E. coli*. Their genome is usually a circular bacterial chromosome – a single loop of DNA, although they can also harbor small pieces of DNA called plasmids. These plasmids can be transferred between cells through bacterial conjugation. Bacteria have an enclosing cell wall, which provides strength and rigidity to their cells. In general, bacteria are between 0.2 and 2.0 um - the average size of most bacteria.Research studies have shown their size to play an important role in survival over time. Due to their small size, bacteria are able to exploit and thrive in various microenvironments. The small size of bacteria is also beneficial for parasitism and oligotrophy.



The following are the major categories of bacteria based on their shapes:

a) Cocci: Cocci bacteria appear spherical or oval in shape. For the most part, the shape is determined by the cell wall of the organism and therefore varies from one type of cocci bacteria to another. Cocci bacteria may exist as single cells or remain attached to each other. Attached Cocci bacteria include: **Diplococci** bacteria - Diplococci bacteria are the type of cocci bacteria that occur as a pair (two joined cells). Some examples of Diplococci bacteria include: *Streptococcus pneumonia*, *Moraxella catarrhalis*,

*Enterococcus*spp, *Neisseria gonorrhoea*. While some of these cells may be truly round shaped, others may appear elongated (ovoid) or bean-shaped/kidney shaped. For instance, some Neisseria cells may appear round while others are bean-shaped when viewed under the microscope. **Tetrad bacteria** - Tetrad bacteria are arranged in groups of four cells. Following division, the cells remain attached and grow in this attachment.Common examples of Tetrad bacteria include: *Pediococcus*, *Tetragenococcus*. **Sarcinaesarcina/Bacteria** - Sarcina bacteria occur in groups of 8 cells. Unlike tetrads that divide into two planes, Sarcinae is produced through the perpendicular plane division. Some of the characteristics associated with these bacteria include being strict anaerobes, Gram-positive bacteria and that measure between 1.5 and 3.0 um.Examples of Sarcinae bacteria include: *Sarcinaaurantiaca*, *Sarcina lutea*, *Sarcina ventriculi*. **Streptococci Bacteria**- Streptococci bacteria are a type of bacteria that arrange in a chain form (resembling chains). A majority of these bacterial cells are also ovoid in shape and may form paired chains. As members of the family Streptococcaceae, this group of bacteria is characterized by being non-motile, Gram-positive organisms. Examples of Streptococcus bacteria include: *Streptococcus pyogenes*, *Streptococcus pneumonia, S. mutans*. **Staphylococci Bacteria**- Staphylococci Bacteria are a type of bacteria that form grape-like clusters. This type of arrangement is the result of division that occurs in two planes. Two of the main characteristics of these organisms are that they are immobile, Gram-positive bacteria. Examples of Staphylococci bacteria include: *Staphylococcusepidermidis*, *Staphylococcushaemolyticus*, *Staphylococcusaureus* *Staphylococcuscapitis*.

b)Bacillus Bacteria (Rod-Shaped): Bacillus bacteria have the following traits: Are all rod-shaped, form endospores and are facultative anaerobes. bacillus bacteria are also arranged differently. While some exist as single, unattached cells (e.g. *Salmonellaentericas*ubsp, *Bacilluscereus*, and *Salmonellacholeraesuis*), others are attached. The following are the different types of bacillus arrangements: *Diplobacilli bacteria* - Like Diplococci bacteria, Diplobacilli occur in pairs. Following cell division, the two cells do not separate and continue existing as a pair. Examples of Diplobacilli bacteria include: *Coxiellaburnetii*, *Klebsiellarhinoscleromatis*, *Moraxellabovis*. **Coccibacilli bacteria** - Compared to other bacilli, Coccibacilli bacteria are shorter in length and thus appear stumpy. Examples of Coccibacilli include: *Chlamydia trachomatis*, *Haemophilus influenza*. Unlike cocci and bacilli bacteria, some types of bacteria appear curved when viewed under the microscope. However, they vary in shape making it possible to differentiate them from each other. These include: Vibrio bacteria - Generally, vibrio bacteria are comma-shaped and thus not fully twisted (curved rods). Examples of Vibrio bacteria include: *Vibrio mytili*, *Vibrio anguillarum*, *Vibrio parahaemolyticus*, *Vibrio cholerae*. **Spirochete** - Spirochetes are characterized by a helical shape. Spirochetes are also flexible and have been shown to produce mycelium. The movement involves the use of axial filaments, which is one of the distinguishing features between the bacteria and other types of bacteria. Examples of Spirochetes include: Leptospira, Spirochaeta,
Treponema. **Spirilla** bacteria - Like Spirochetes, Spirilla bacteria possess a helical shape. However, they are more rigid and have the typical flagella found in other types of bacteria. Some examples of Spirilla bacteria include: *Aquaspirillum*, *Campylobacterjejuni*, *Spirillumwinogradskyi*.

In microbiology and bacteriology, Gram stain or Gram staining, also called Gram's method, is a method of staining used to classify bacterial species into two large groups: gram-positive bacteria and gram-negative bacteria. The name comes from the Danish bacteriologist Hans Christian Gram, who

developed the technique in 1884. Gram staining differentiates bacteria by the chemical and physical properties of their cell walls. Gram-positive cells have a thick layer of peptidoglycan in the cell wall that retains the primary stain, crystal violet. Gram-negative cells have a thinner peptidoglycan layer that allows the crystal violet to wash out on addition of ethanol. They are stained pink or red by the counterstain, commonly safranin or fuchsine. Lugol's iodine solution is always added after addition of crystal violet to strengthen the bonds of the stain with the cell membrane. Gram staining is almost always the first step in the preliminary identification of a bacterial organism. While Gram staining is a valuable diagnostic tool in both clinical and research settings, not all bacteria can be definitively classified by this technique. Acid-fast staining is the differential staining techniques which was first developed by Ziehl and later on modified by Neelsen. So this method is also called Ziehl-Neelsen staining techniques. Neelsen in 1883 used Ziehl'scarbol-fuchsin and heat then decolorized with an acid alcohol, and counter stained with methylene blue. Thus Ziehl-Neelsen staining techniques was developed. The main aim of this staining is to differentiate bacteria into acid fast group and non-acid fast groups. This method is used for those microorganisms which are not staining by simple or Gram staining method, particularly the member of genus Mycobacterium, are resistant and can only be visualized by acid-fast staining.

Growth Curve

In a closed system with enough nutrients, a bacteria shows a predictable growth pattern that is the bacterial growth curve. It consists of four different phases. Read on to learn about the phases in detail. Phases of the Bacterial Growth Curve: Upon inoculation into a new nutrient medium, the bacteria shows four distinct phases of growth. Let us dive into each of the phases in detail.

Lag Phase: The bacteria upon introduction into the nutrient medium take some time to adapt to the new environment. In this phase, the bacteria does not reproduce but prepares itself for reproduction. The cells are active metabolically and keep increasing in size. The cells synthesise RNA, growth factors and other molecules required for cell division.

Log Phase: Soon after the lag phase, i.e., the preparation phase, the bacterial cells enter the log phase. The log phase is also known as the exponential phase. This phase is marked by the doubling of the bacterial cells. The cell number increases in a logarithmic fashion such that the cell constituent is maintained. The log phase continues until there is depletion of nutrients in the setup. The stage also comes to a stop if toxic substances start to accumulate, resulting in a slower growth rate. The cells are the healthiest at this stage and researchers prefer to use bacteria from this stage for their experimental processes. Plotting this phase on the bacterial growth curve gives a straight line. Upon calculation of the slope of this line, the specific growth rate of the organism is obtained. It is the measure of divisions per cell per unit of time.

Stationary Phase: In the stationary phase, the rate of growth of the cells becomes equal to its rate of death. The rate of growth of the bacterial cells is limited by the accumulation of toxic compounds and also depletion of nutrients in the media. The cell population remains constant at this stage. Plotting this phase on the graph gives a smooth horizontal linear line.

Death Phase: This is the last phase of the bacterial growth. At this stage, the rate of death is greater than the rate of formation of new cells. Lack of nutrients, physical conditions or other injuries to the cell leads to death of the cells.

Physical factors that affect microbial growth

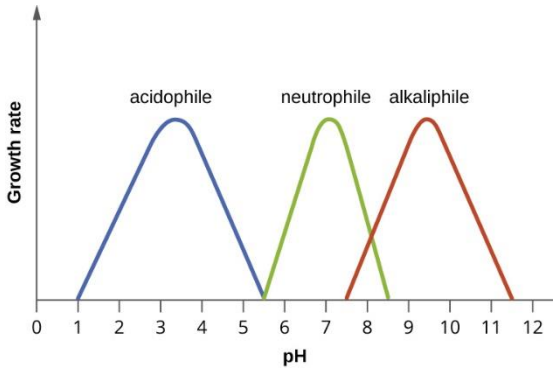
a) Temperature: Generally,an increase in temperature will increase enzyme activity. But if temperatures get too high, enzyme activity will diminish and the protein (the enzyme) will denature. On the other hand, lowering temperature will decrease enzyme activity. At freezing temperatures enzyme activity can stop. Repeated cycles of freezing and thawing can denature proteins. In addition, freezing causes water to expand and also forms ice crystals, hence cells begin to rupture. Every bacterial species has specific growth temperature requirements which is largely determined by the temperature requirements of its enzymes. PSYCHROPHILES grow best between -5^{o}C and 20^{o}C, MESOPHILES grow best between 20^{o}C and 45^{o}C and
THERMOPHILES grow best at temperatures above 45^{o}C. THERMODURIC organisms can survive high temperatures but don't grow well at such temperatures. Organisms which form endospores would be considered thermoduric. Some organisms have exotic temperature requirements. *Thermus aquaticus* is a bright orange gram negative rod isolated from hot water and steam vents at Yellowstone Park. This organism grows best at temperatures between 70-75^{o}C (158-167^{o}F). Some of its unique enzymes are in demand for molecular biological and industrial applications.
b) **Oxygen**: Microbes display a great diversity in their ability to use and to tolerate oxygen. In part this is because of the paradoxical nature of oxygen which can be both toxic and essential to life. OBLIGATE AEROBES rely on aerobic respiration for ATP and they therefore use oxygen as the terminal electron acceptor in the electron transport chain. Pseudomonas is an example of this group of organisms. MICROAEROPHILES require O_2 for growth but they are damaged by normal atmospheric levels of oxygen and they don't have efficient ways to neutralize the toxic forms of oxygen such as superoxide (O_2^-) and hydrogen peroxide (H_2O_2). The Streptococci are examples of this group. OBLIGATE ANAEROBES will die in the presence of oxygen because they lack enzymes like superoxide dismutase and catalase. Organisms like Clostridium, metabolize through fermentation and / or anaerobic respiration.
AEROTOLERANT organisms like Lactobacillus ferment and therefore do not use oxygen, however they do tolerate it. FACULTATIVE ANAEROBES are the most adaptable. They are capable of both fermentation and aerobic respiration. *Escherichiacoli* is an example of this class of organisms. ANAEROBIC PATHOGENS: *Clostridium tetani* - agent of tetanus, puncture wounds, produces a toxin which enters the spinal column and blocks the inhibitory spinal motor neurons. This produces generalized muscle spasms or spastic paralysis. *Clostridium botulinum* - this soil organism is the causative agent of botulism which typically occurs after eating home canned alkaline vegetables which were not heated enough during canning. The neurotoxin blocks transmission across neuromuscular junctions and this results in flaccid paralysis. *Clostridium perfringes* and *Clostridium sporogenes* - these organisms are associated with invasive infections known as GAS GANGRENE. *Clostridium difficile* - the causative agent of pseudomembranous colitis, a side effect of antibiotic treatment which eliminates the normal flora. MICROAEROPHILES: These organisms are all catalase negative, therefore the catalase test is useful in identification. They also have distinctive colonial morphology on blood agar which is differential for them. It is important to note if the colonies are alpha, beta, or gamma hemolytic. Group A Streptococcus - *Streptococcus pyogenes,* This beta hemolytic organism is also bacitracin sensitive. It is the cause of strep throat, rheumatic fever, glomerulonephritis and scarlet fever. Group D Streptococcus - Enterococcus - *Streptococcus faecalis*, This organism is a normal inhabitant of the large intestine. It is also a frequent cause of bladder infections. *Streptococcus pneumonia*, This

organism is a normal inhabitant of the respiratory tract. It is a frequent cause of pneumonia in people who have been compromised by other illness.

Based on the nutritional requirements, bacteria are classified as follows:

Energy source:	light:	phototrophic
	chemical:	chemotrophic
Electron source:	inorganic compounds:	lithotrophic
	organic compounds:	organotrophic
Carbon source:	CO_2:	autotrophic
	organic:	heterotrophic

Based on pH



bacterial requirements are classified as follows:

Most bacteria are neutrophiles, meaning they grow optimally at a pH within one or two pH units of the neutral pH of 7. Most familiar bacteria, like *Escherichiacoli*, *Staphylococci*, and *Salmonella* spp. are neutrophiles and do not fare well in the acidic pH of the stomach. However, there are pathogenic strains of *E. coli*, *S. typhi*, and other species of intestinal pathogens that are much more resistant to stomach acid. In comparison, fungi thrive at slightly acidic pH values of 5.0-6.0.Microorganisms that grow optimally at pH less than 5.55 are called acidophiles. Eg.*Lactobacillus* bacteria. Acidophilic microorganisms display a number of adaptations to survive in strong acidic environments. For example, proteins show increased negative surface charge that stabilizes them at low pH. Pumps actively eject H^+ ions out of the cells. At the other end of the spectrum are alkaliphiles, microorganisms that grow best at pH between 8.0 and 10.5. *Vibrio cholerae*, the pathogenic agent of cholera, grows best at the slightly basic pH of 8.0; it can survive pH values of 11.0.

Foodborne bacterial pathogens

Foodborne pathogens are mainly bacteria, viruses, or even parasites that are present in the food and are the cause of major diseases such as food poisoning. Foodborne pathogens are categorized according to the specific foods that are consumed. Foodborne illness occurs when a pathogen is ingested with food and establishes itself (and usually multiplies) in the human host, or when a toxigenic pathogens establishes itself in a food product and produces a toxin, which is then ingested by the human host. Thus, foodborne illness is generally classified into: (a) foodborne infection and (b) foodborne intoxication. In foodborne infections, since an incubation period is usually involved, the time from ingestion until symptoms occur is much longer than that of foodborne intoxications. More than 200 different food-borne diseases have been identified. Aomng them, the common pathogenic bacteria associated with the fish and fishery products includes: *Aeromonas hydrophilia*, *Bacillus anthracis, Bacillus cereus/subtilis/lichniformis, Brucella/abortus/melitensis/suis, Campylobacter jejuni/coli, Clostridium botulinum/perfringens, Escherichia coli, Enterobacter sakazakii, Listeria monocytogenes, Mycobacterium paratuberculosis, Salmonella enterica, Shigella spp., Staphylococcus aureus, Vibrio cholera, V. cholerae* non-01*, V. parahemolyticus, V. vulnificus, V. fluvialis and Yersinia enterocolitica*. *Campylobacter* sp. (mostly associated with raw or undercooked poultry) is the major foodborne pathogen, causing more than two million infections per year, while *Salmonella*, mostly found in meat, poultry, and eggs, is responsible for more than one million cases of food poisoning. *Shigella*,

Escherichiacoli (mostly found in meat and unpasteurized milk), *Clostridiumbotulinum* (often found in improperly home-canned foods), *Clostridiumperfringens*, *Yersinia*, *Vibrio cholerae*, *V. vulnificus*, *V. parahaemolyticus*, *Staphylococcus aureus*, *Bacillus* spp., and *Listeria* (in uncooked meats, vegetables, unpasteurized milk, and soft cheese) also cause foodborne disease.

The specific bacterial pathogens, isolation and identification protocols are mentioned below:

a) *Clostridium botulinum*

- **Bacteria:** Anaerobic, spore-forming, motile GPR
- **Source:** Soils, sediments, intestinal tracts of fish/mammals, gills and viscera of crabs and other shellfish
- **Illness:** Intoxication (heat-labile neurotoxin)
- **Symptoms:** Weakness, vertigo, double vision, difficulty in speaking, swallowing and breathing, respiratory paralysis
- **Foods:** Semi-preserved seafood, improperly canned foods
- **Transmission:** Spores present in raw foods
- **Control:** Proper canning, a_w<0.93, pH <4.7
- **Isolation:** Inoculate the sample into cooked meat medium and incubate for 48-72 h. Streak onto blood agar medium supplemented with gentamycin and metronidazole ans incubate the plates under anaerobic conditions in anerobic jar for 48 h at 37^{o}C. After incubation observe for the growth.
- **Toxin testing:** The toxins produced by Clostridium botulinum is tested using mouse bio assay and also by other methods such as PCR, ELISA, endopeptidase assay, lateral flow tets

b) *Clostridium perfringens*

- **Bacteria:** Anaerobic, spore-forming, nonmotile GPR
- **Source:** Soil, dust, intestinal tract of animals and humans
- **Illness:** Infection (toxin released on sporulation)
- **Symptoms:** Intense abdominal cramps and diarrhea
- **Foods:** Temperature abuse of prepared foods such as meats, meat products, and gravy
- **Transmission:** Spores present in raw foods
- **Control:** Proper time/temperature control; preventing cross-contamination of cooked foods
- **Identification:** The bacterium is mainly identified by performing biochemical tests such as Grams staining, Litmus milk test, haemolysis (double zone), CAMP test
- **Toxin testing:**Nagler test

c) *Bacillus cereus*

- **Bacteria:** Facultatively aerobic, spore-forming, motile GPR
- **Source:** Soil, dust, raw foods
- **Illness:** 1) diarrheal type (infection, heat-labile toxin); 2) emetic type (intoxication, heat-stable toxin)
- **Symptoms:** 1) profuse watery diarrhea, abdominal pain; 2) vomiting, nausea
- **Foods:** 1) vegetables, salads, meats, casseroles; 2) rice **Transmission:** Spores present in raw foods
- **Control:** time/temperature; reheat cooked foods to >165^{o} F
- **Isolation:** The bacterium is isolated on commonly used microbiological media such as nutrient agar.

C) *Campylobacter jejuni*

- **Bacteria:** Microaerophilic, motile GNR
- **Source:** Intestines of poultry, livestock, domestic animals; streams and ponds
- **Illness:** Infection (gastroenteritis)
- **Symptoms:** Diarrhea, abdominal pain, headache, weakness
- **Foods:** undercooked chicken & hamburger, raw milk & clams
- **Transmission:** Contaminated foods & water; cross-contamination; person to person
- **Control:** Proper cooking, proper hand and equipment washing, sanitary food handling practices
- **Isolation:** The bacterium is isolated from the samples by using Bolton broth incubated at 42^{o}C for 24 h followed by streaking on chromogenic media incubated under micro-aerophilic conditions. The intense red colored colonies on a translucent agar facilitates the reading compared to charcoal based agar.
- **Identification:** PCR

d) Pathogenic *Escherichia coli* O157:H7

- **Bacteria:** Facultative anaerobic, motile or nonmotile GNR
- **Source:** Intestines of animals and poultry
- **Illness:** Hemorrhagic colitis (HC), hemolytic uremic syndrome (HUS), thrombotic thrombocytopenic purpura (TTP)
- **Symptoms:** HC) diarrhea & vomiting, HUS) diarrhea & acute renal failure, TTP) diarrhea, GI hemorrhage, Brain blood clots

- **Foods:** Meat, poultry, potatoes, raw milk
- **Transmission:** Cross-contamination, sewage pollution
- **Control:** Proper cooking, temp. control, preventing cross-contamination, proper personal hygiene
- **Isolation:** The bacterium is isolated from the samples by using *E. coli* broth incubated initially at 25 ^{o}C for 2 h and at 42^{o}C for 8 h followed by streaking on chromogenic media incubated under aerophilic conditions (37 ^{o}C for 18-24 h). *E. coli* produces blue colour colonies.
- **Identification:** Biochemical tests and PCR

e) *Listeria monocytogenes*

- **Bacteria:** Microaerophilic, motile, GPR
- **Source:** Widespread in the environment
- **Illness:** Infection
- **Symptoms:** Mild flu-like symptoms to meningitis, abortions, septicemia, and death
- **Foods:** Coleslaw, raw milk, Mexican style soft cheese, smoked mussels
- **Transmission:** Cross-contamination, from raw to cooked food, contaminated raw foods
- **Control:** Proper cooking, preventing, cross-contamination, pasteurizing milk
- **Isolation:** The bacterium is isolated from the samples by using half-Fraser broth incubated at 30 ^{o}C for 24 h and later 0.1 ml of enriched broth (0.1 ml) was transferred to Fraser broth incubated at 37 ^{o}C for 24 h followed by streaking on selective media (Ottoviani and Agosti) or secondary selective media (PALCOM, OXFORD) and incubate under aerophilic conditions (37 ^{o}C for 18-24 h). β-D-glucosidase activity, common to the Listeria genus, is detected using a chromogenic substrate (X-glucoside). Its hydrolysis induces the formation of a blue to blue-green color in all Listeria colonies. PI-PLC is an enzyme only detected in pathogenic Listeria species: *L. monocytogenes* and *L. ivanovii*. AL medium contains phosphatidylinositol which, when it breaks down, produces an opaque halo around the colonies of these two bacterial species. The halo is visible after 24 hr for *L. monocytogenes* and 48 hr for *L. ivanovii*.
- **Identification:** Biochemical tests and PCR

f) ***Salmonella spp.***

- **Bacteria:** Facultative anaerobic, motile, GNR
- **Source:** Intestine of mammals, birds, amphibians and reptiles

- **Illness:** Infection (gastroenteritis)
- **Symptoms:** Nausea, vomiting, abdominal cramps, fever
- **Foods:** Poultry, poultry salads, meats, dairy products, egg products
- **Transmission:** Cross-contamination, human contamination, sewage pollution of coastal waters
- **Control:** Proper cooking, temperature control, preventing cross-contamination, personal hygiene
- **Isolation:** The bacterium is isolated from the samples by using Buffered peptone water incubated at 37^{o}C for 24 h followed by enrichment in Rappaport and Vassiliadis broth (incubation at 41.5 ^{o}C for 24 h), Muller-Kauffman Tetrathionate Novobiocin broth (incubation at 37 ^{o}C for 24 h) and later streaking on XLD agar incubated at 37^{o}C for 24 h under aerophilic conditions. On XLD agar it produces red colour colonies with black centre.
- **Identification:** Biochemical, serological and PCR

g) *Shigella spp.*

- **Bacteria:** Facultative anaerobic, motile, GNR
- **Source:** Intestine of mammals, birds, amphibians and reptiles
- **Illness:** Infection (gastroenteritis)
- **Symptoms:** Nausea, vomiting, abdominal cramps, fever
- **Foods:** Poultry, poultry salads, meats, dairy & egg products
- **Transmission:** Cross-contamination, human contamination, sewage pollution of coastal waters
- **Control:** Proper cooking, temperature control, preventing cross-contamination, personal hygiene
- **Isolation:** The bacterium is isolated from the samples by using *Shigella* broth supplemented with Novobiocin incubated initially at 44 ^{o}C for 24 h under anerobic conditions followed by streaking on MacConkey agar incubated under aerophilic conditions (35 ^{o}C for 20 h). Colonies are non-lactose fermenting (except S. sonnei) large, circular, convex, smooth, and translucent.
- **Identification:** Biochemical tests and Serological

h) *Pathogenic Staphylococcus aureus*

- **Bacteria:** Facultative anaerobic, motile, GNR
- **Source:** Intestine of mammals, birds, amphibians and reptiles
- **Illness:** Infection (gastroenteritis)
- **Symptoms:** Nausea, vomiting, abdominal cramps, fever

- **Foods:** Poultry, poultry salads, meats, dairy products, egg products
- **Transmission:** Cross-contamination, human contamination, sewage pollution of coastal waters
- **Control:** Proper cooking, temperature control, preventing cross-contamination personal hygiene
- **Isolation:** The bacterium is isolated from the samples by using Baird parker agar supplemented with egg yolk and potassium telurite incubated initially at 35 ^{o}C for 24 h under anerobic conditions. *Staphylococcus aureus* is characterized by the formation of black, shiny, convex colonies surrounded by a lightening halo of the egg yolk. Coagulase negative staphylococci are almost completely inhibited and if, however, a culture does appear, areas of thinning would be absent.
- **Identification:** Mannitol fermentation, genotypic characterisation (pvl, spa typing, SCCmec typing) and phenotypic characterization (growth on ORSAB agar)

i) ***Vibrio cholerae***

- **Bacteria:** Facultative aerobic, motile, curved GNR
- **Source:** Naturally occurring in estuaries, bays and coastal water
- **Illness:** Infection (cholera or gastroenteritis)
- **Symptoms:** 01: watery diarrhea, vomiting, abdominal cramps; non-01: Diarrhea, abdominal cramps, fever
- **Foods:** Molluscan shellfish
- **Transmission:** Contaminated water, cross-contamination from raw to cooked seafood, contaminated raw seafood
- **Control:** Proper cooking, preventing cross-contamination, harvesting from approved waters
- **Isolation:** The bacterium is isolated from the samples by using alkaline peptone water incubated initially at 37 ^{o}C for 6-18 h under anerobic conditions followed by streaking on TCBS agar incubated under aerophilic conditions (37 ^{o}C for 18-20 h). *Vibrio cholera* produces flat yellow colonies with 2-3 mm in diameter
- **Identification:** Biochemical tests, Serological and PCR

j) ***Vibrio parahaemolyticus***

- **Bacteria:** Facultative aerobic, motile, curved GNR
- **Source:** Naturally occurring in estuaries and other coastal areas throughout the world
- **Illness:** Infection (gastroenteritis)
- **Symptoms:** Diarrhea, abdominal cramps, nausea, vomiting, headache
- **Foods:** Raw, improperly cooked, or cooked and contaminated fish and shellfish

- **Transmission:** Cross-contamination from raw to cooked seafood, consumption of raw seafood
- **Control:** Proper cooking, preventing cross-contamination
- **Isolation:** The bacterium is isolated from the samples by using alkaline salt peptone water incubated initially at 37 ^{o}C for 6-18 h under anerobic conditions followed by streaking on TCBS agar incubated under aerophilic conditions (37 ^{o}C for 18-20 h). *Vibrio parahaemolyticus* produces colorless colonies with a green center.
- **Identification:** Biochemical tests, pathotyping and PCR

k) *Yersinia enterocolitica*

- **Bacteria:** Facultative aerobic, motile, GNR
- **Source:** Soil, water, domesticated and wild animals
- **Illness:** Infection (gastroenteritis)
- **Symptoms:** Diarrhea, vomiting, abdominal pain, fever
- **Foods:** Meats, oysters, fish, raw milk
- **Transmission:** Cross-contamination from raw to cooked food, poor sanitation, time/temperature abuse
- **Control:** Preventing cross-contamination, proper sanitation and food handling practices
- **Isolation:** The bacterium is isolated from the samples by using buffered peptone water incubated initially at 4 ^{o}C for 1-3 weeks under anerobic conditions or treat the samples with alkali and later streaking on CIN or mVYE agar incubated under aerophilic conditions (30 ^{o}C for 24 h). *Vibrio parahaemolyticus* produces red (red bulls eye) colonies.
- **Identification:** Biochemical tests (Urea, TSI, LIM), PYZ and AA tests, Biotyping and Serotyping, Real time PCR

Chapter 9

Packaging and Labelling requirements

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Food packaging

Packaging is the art and science of encasing food products to safeguard them during distribution, sale, and storage. It is also the process of designing and evaluating packages. Product packaging design not only lends aesthetic appeal, but also helps your products stand out from those of others. Proper packaging plays a crucial role in preservation of quality and delivery of safe, wholesome food products to the end user. Packaging has been with humans for thousands of years in one form or the other. Packaging dates back to when people first started moving from place to place. Originally, skins, leaves, and bark were used for food transport. Mesolithic humans used baskets, and neolithic humans used metal containers and discovered pottery. Four thousand years ago, sealed pottery jars were used to protect against rodents, and in 1550 BC, glass making was an important industry in Egypt. Tin-plating iron became possible in AD 1200, and as steel replaced iron this method became useful after AD 1600. In 1825, Oersted first extracted aluminum. More recently, plastics were developed, particularly the first commercial plastics in the United States around 1935–1942. Over the last three decades, packaging has grown in volume and importance into one of the most significant areas of food production.

Purpose of packaging

Packaging performs five main functions (5Ps): product containment, preservation and quality, presentation and convenience, protection, and provide storage history.

1. **Product containment**: The primary purposes of packaging are containment and protection. Containment refers to holding goods in a form suitable for transport, whereas protection refers to safekeeping goods in a way that prevents significant quality deterioration.
2. **Preservation by maintaining quality**: The second function of packaging is to control the local environmental conditions to enhance storage life and safety.
3. **Presentation and convenience**: Displaying the product in an attractive manner to the potential buyer is very important. For a package to be effective, it must present the product well and should do its own publicity. In many cases, packaging provides convenience to the consumers. Eating styles, such as ready-to-eat meals, snacks, and microwaveable ready meals, have been changed over the years, which need innovation in packaging. For children, the packaging might represent innovation or fun. Other conveniences could be ease of opening, smaller portions and tamper-proof methods.
4. **Protection during distribution and processing**: The fourth function is to protect the product during transit to the consumer. Packaging can handle better when there are challenges in food distribution chain, such as heat, humidity, or dew. It is important to be aware of the distribution challenges and designing of package to suit it.

5. **Provide storage history**: Time-temperature indicator (TTI) is effective for predicting microbial concentrations and other parameters of food quality during shipping and storage. It helps in ensuring proper handling and provides a gauge of product quality for sensitive products in which temperature control is imperative to efficacy and safety. TTIs are tags that can be applied to individual packages or shipping cartons to visually indicate whether a product has been exposed to time and temperature conditions that adversely affect the product quality. TTI could be used in chilled foods to identify the temperature abuse during storage and distribution.

Types of Packaging Materials

From skins, leaves, and bark, tremendous progress has been made in the development of diversified packaging materials and in the packaging equipment. In general, packaging materials may be grouped into rigid and flexible structures.

- **Flexible materials**: Plastic film, foil, paper and textiles are flexible materials.
- **Rigid materials**: Wood, glass, metals and hard plastics are examples of rigid materials.

Food Labelling

A label displays information regarding the product, which is typically printed on the packaging. It is a piece of paper, polymer, cloth, metal, or other material affixed to a container or article. A label may also be printed directly on the container or article. A label not only describes the product and its uses, but also provides instructions and crucial precautionary measures (if any) that need to be taken care of. It essentially informs consumers of the properties of a product.

Codex Alimentarius International Standards (FAO & WHO)

General standard for the labelling of prepackaged foods CXS 1-1985 (Revised in 2018)

This standard applies to the labelling of all prepackaged foods to be offered as such to the consumer or for catering purposes and to certain aspects relating to the presentation thereof.

General principles

Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect. Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

Mandatory labelling of prepackaged foods

The following information shall appear on the label of prepackaged foods as applicable to the food being labelled, except to the extent otherwise expressly provided in an individual Codex standard.

1. The name of the food
2. List of ingredients

The following foods and ingredients are known to cause hypersensitivity and shall always be declared:

• Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
• Crustacea and products of these;
• Eggs and egg products;
• Fish and fish products;
• Peanuts, soybeans and products of these;
• Milk and milk products (lactose included);
• Tree nuts and nut products; and
• Sulphite in concentrations of 10 mg/kg or more.

3. Net contents and drained weight

The net contents shall be declared in the metric system ("Système International" units). The net contents shall be declared in the following manner:

(i) for liquid foods, by volume;
(ii) for solid foods, by weight;
(iii) for semi-solid or viscous foods, either by weight or volume

4. Name and address

The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food shall be declared.

5. Country of origin
6. Lot identification
7. Date marking and storage instructions
8. Instructions for use

Additional mandatory requirements

- Quantitative ingredients declaration
- Irradiated foods: The label of a food which has been treated with ionizing radiation shall carry a written statement indicating that treatment in close proximity to the name of the food. The use of the international food irradiation symbol, as shown below, is optional, but when it is used, it shall be in close proximity to the name of the food.

Food packaging regulations in US

In US, the food packaging regulations are enforced by FDA (Food and Drug Administration). The FDA charged with monitoring food safety requirements caries out risk assessment as well as risk management regarding food safety and packaging. Food, Drug and Cosmetic Act 1958 enforced by the FDA is the basic regulation for Food Contact Materials (FCM).

Food packaging regulations in European Union

There is a coexistence of national legislation and community level legislation in the European region for food packaging and FCM. The regulations are directly effective in the member states. The same needs to be transposed by national parliaments for making it more effective. The EU Framework Regulation EC 1935/2004 is used for regulating the food contact materials at Union level.

Food packaging regulations in Middle East Region

The Gulf Cooperation Council (GCC) comprises of the UAE, Bahrain, Kuwait, Oman, Qatar and Saudi Arabia as its member nations. The standards and technical regulation with respect to food packaging, for GCC nations, comes under the purview of GCC Standardization Organization (GSO). These standards and regulations are also followed by Yemen. There are various standards developed by GSO, which the GCC nations must implement voluntarily. The standards must be adopted into national law to have legal effect in the Member States and Yemen.

Food packaging regulations in India

Food Safety and Standards Authority of India (FSSAI) is an autonomous body established by the Government of India under the Ministry of Health & Family Welfare. It usually sets standards for food so that there is no chaos in the minds of consumers, traders, **manufacturers** and investors. Since the FSSAI is the authority on all food-related things in India, FSSAI registration and observance of FSSAI rules is a must.

Food Safety and Standards (Packaging) Regulations, 2018

General requirements

- Every food business operator shall ensure that the packaging material used shall be in accordance with these regulations: Provided where Indian Standards are not available, then relevant International Standards may be complied with.
- Any material which comes in direct contact with food or likely to come in contact with food used for packaging, preparation, storing, wrapping, transportation and sale or service of food shall be of food grade quality.
- Packaging materials shall be suitable for the type of product, the conditions provided for storage and the equipment for filling, sealing and packaging of food as well as transportation conditions.
- Packaging materials shall be able to withstand mechanical, chemical or thermal stresses encountered during normal transportation. In case of flexible or semi-rigid containers, an overwrap packaging may be necessary.
- Food products shall be packed in clean, hygienic and tamper-proof package or container.
- The sealing material shall be compatible with the product and the containers as well as the closure systems used for the containers
- Tin containers once used, shall not be re-used for packaging of food
- Plastic containers of capacity 5 litre and above and Glass bottles, which are reused for packaging of food, shall be suitably durable, easy to clean or disinfect
- Printing inks for use on food packages shall conform to IS: 15495
- Printed surface of packaging material shall not come into direct contact with food products
- Newspaper or any such material shall not be used for storing and wrapping of food

- In case of multilayer packaging, the layer which comes in direct contact with food or layers likely to come in contact with food shall meet the requirements of packaging materials specified in Schedule I, II and III of these regulations.
- The materials listed in Schedule I, II and III of these regulations shall be compatible with their intended use as a packaging material so as not to alter the quality and safety of the food product.
- Every food business operator shall obtain the certificate of conformity issued by NABL accredited laboratory against these regulations, for the packaging material, which comes in direct contact with food or layers likely to come in contact with food to be used.

Specific requirements for primary food packaging

There are specific requirements for primary food packaging materials intended to come in contact with food products like paper and board, glass containers, metal and metal alloys and plastic materials.

Specific requirements for plastic materials

1. Plastic materials used for the manufacturing of containers for packing or storing the food products shall conform to either of the Indian Standards specifications as provided in Schedule – III

Migration limits for plastic packaging materials

2. All packaging materials of plastic origin shall pass the prescribed overall migration limit of 60 mg/kg or 10 mg/dm^2 when tested as per IS 9845 with no visible colour migration.
3. Plastic materials and articles shall not release the substances in quantities exceeding the specific migration limits (mg/Kg) as given below.

Barium	1.0
Cobalt	0.05
Copper	5.0
Iron	48.0
Lithium	0.6
Manganese	0.6
Zinc	25.0
Antimony	
Phthalic acid, bis (2-ethylhexyl) ester (DEHP)	1.5

4. Pigments or Colorants for use in plastics in contact with food products and drinking water shall conform to IS: 9833
5. Products made of recycled plastics including carry bags may be used for packaging, storing, carrying or dispensing of food products as and when standards and guidelines are framed by the Food Authority. Such packaging materials shall also comply with any other national standards/regulations as applicable

Schedule – IV: List of suggestive packaging materials

Fish and fish products or Seafood

- Glass jars with plastic (PP or High-density polyethylene (HDPE) caps
- Metal Containers with metal lid (lacquered tin containers)

- Polyethylene terephthalate (PET) punnets or containers with plastic caps
- Plastic-based multi-layered flexible laminates heat sealed pouches
- Plastic tray with overwrap

Food safety and standards (labelling and display) regulations, 2020

These regulations prescribe the labelling requirements of pre-packaged foods and display of essential information on premises where food is manufactured, processed, served and stored.

Labelling of pre-packaged foods: General Requirements

1. Every pre-packaged food shall be labelled with information as required under these regulations unless otherwise provided.
2. When a food product is sold through e-commerce or any other direct selling means, the mandatory requirements of the label as given in these regulations shall be provided to the consumer through appropriate means before sale.
3. Pre-packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
4. Any information or pictorial device written, printed, or graphic matter may be displayed on the label provided that it is not in conflict with the requirements of these regulations.
5. The particulars of declaration required under these Regulations printed on the label shall be in English or Hindi.
6. Label on pre-packaged foods shall be applied in such a manner that it will not become separated from the container.
7. Contents on the label shall be clear, unambiguous, prominent, conspicuous, indelible and readily legible by the consumer under normal conditions of purchase and use.
8. Where a package is provided with an outside container or wrapper and such container or wrapper is displayed for retail sale, it shall also contain all the declarations which are required to appear on the package except where such container or wrapper itself is transparent and the declarations on the package(s) are easily readable through such outside container or wrapper.

Labelling Requirements

Every package shall carry the following information on the label, namely, -

(1) The Name of Food: Every package of food shall carry name of the food, which indicate the true nature of the food contained in the package, on the Front of Pack:

(a) Where a food is specified by certain essential composition under Food Safety and Standards Regulations made under the Act, that establishes its identity the name provided therein shall be used;

(b) In the absence of such name, either a common or usual name or an accompanying description of true nature of food shall be used;

(c) It may additionally have a “coined”, “fanciful”, “brand” or “trade name” subject to compliance of Food Safety & Standards (Advertising and Claims) Regulation 2018.

(2) **List of Ingredients**: Except for single ingredient foods, a list of ingredients shall be declared on the label.

(3) **Nutritional information**: Nutritional Information per 100 g or 100 ml or per single consumption pack of the product and per serve percentage (%) contribution to Recommended Dietary Allowance calculated on the basis of 2000 kcal energy, 67 g total fat, 22 g saturated fat, 2 g trans-fat, 50 g added sugar and 2000 mg of sodium (5 g salt) requirement for average adult per day, shall be given on the label.

(**4) Declaration regarding Veg or Non veg**

Non-Vegetarian Food: The symbol shall consist of a brown colour filled triangle inside a square with brown outline.

Vegetarian Food: The symbol shall consist of a green colour filled circle, having a diameter not less than the minimum size specified, inside the square with green outline having size double the diameter of the circle.

(5) Declaration regarding Food Additives

(6) Declaration of name and complete address

(7) FSSAI logo and license number: The FSSAI logo and license number under the Act shall be displayed on the label of the food package in contrast colour to the background as below:

Fortified food and organic food shall be marked with the logo as specified in the schedule of these regulations. FSSAI may specify logo for any other food as decided from time to time.

1. Every package of fortified food shall carry the words “fortified with …… (name of the fortificant)” and the logo, as specified below, on the label. It may also carry a tag line “SampoornaPoshanSwasth Jeevan” under the logo.

Fortified with....
SAMPOORNA POSHAN
SWASTHA JEEVAN

.... से फोर्टिफाइड

सम्पूर्ण पोषण स्वस्थ जीवन

2. Every package of certified organic food as per Food Safety and Standards (Organic Foods) Regulations, 2017 shall carry the logo as specified below:

Jaivik Bharat

(8) Net quantity, Retail Sale Price and Consumer Care details
(9) Lot/Code/Batch identification
(10) Date Marking: “Date of manufacture or packaging” and “Expiry/Use by” shall be declared on the label. However, expression “Best before” may also be used as optional or additional information.
(11) Labelling of Imported Foods
(12) Country of Origin for Imported Foods
(13) Instructions for use
(14) Declaration regarding Food allergen
(15) Every package of food material sold in retail, but which is not meant for human consumption shall bear a declaration to this effect by a symbol. The symbol shall consist of a black colour cross inside a square with black outline having the sides of square
not less than the minimum size specified.

Principal display panel. - (1) The information required under these regulations shall be given on the principal display panel of the package or container and such information may be given in following

manner, - (a) All information should be grouped together and given at one place. Or (b) The pre-printed information be grouped together and given in one place and, Online information or those not pre-printed be grouped together in another place.

Conclusion

Food labelling and food packaging help the consumers in differentiating between various foods and finding out the best products matching their requirements. It's crucial for all the food business operators carrying out their business in India to abide by the FSSAI's Food Packaging and Labelling Regulations. There is a significant demand for getting FSSAI license or registration in India in order to run a food business. Food Labelling serves as a primary link of communication between the manufacturer and consumer and covers both food safety and information of consumer interest.

Chapter 10

Preliminary steps in HACCP implementation

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Preliminary steps are those steps that need to be completed before applying HACCP principles. These steps involve gathering information about the products and the process that need to conduct a hazard analysis. The preliminary steps in developing the HACCP plan are as follows:

1. Assemble HACCP team
2. Describe the product, intended use and consumers
3. Develop a Process Flow Chart
4. Develop a Process Description

Assemble HACCP Team

Assembling a HACCP team is an important step in building a HACCP plan. The team should consist of individuals with different specialties and experience with the process. The HACCP team should include members who are directly involved with the plant's daily operations. The team may include personnel from maintenance, production, sanitation, quality control and laboratory. The team develops the HACCP plan, write SCPs, and verify and implement the HACCP system. Hence, the HACCP team members should be knowledgeable about food safety hazards and HACCP principles.

In addition to writing and developing the HACCP plan, the HACCP team should provide oversight of the implementation of the plan into the daily operations of the facility. This includes ensuring that applicable personnel are trained appropriately to handle their required duties. Although one person may be able to analyze hazards and develop a HACCP plan successfully, many companies find it helpful to build a HACCP team. When only one person develops the HACCP plan, some key points can be missed or misunderstood in the process. The team approach minimizes the risk that key points will be missed or that aspects of the operation will be misunderstood. It also encourages ownership of the plan, builds company involvement and brings in different areas of expertise.

In small companies, the responsibility for writing the HACCP plan may fall to one person. Small companies can build their HACCP team with employees knowledgeable of various divisions, as well as owners, as members of the HACCP team.

Describe the product, intended use and consumers

The HACCP team should describe the product(s), the type of packaging, the method of distribution, the intended customer (e.g., general public, infants, elderly) and likely use of the product

(e.g., consumed without further cooking, heat-and-serve, cooked). A complete product description should include:

1. Types of seafood products (species and finished product form)
2. Sources of seafood products (wild, farm raised, from fisherman or from a processor)
3. How products are received, stored and shipped (refrigerated, frozen, canned etc.)
4. How products are packaged (e.g. reduced oxygen package)
5. How products are intended to be used (ready-to-eat, to be cooked by consumers etc.)
6. Who the intended consumers of your products are (general public, higher risk group)

Types of seafood products:

It is important to know which species (species of fish or shellfish including market name and scientific name, if necessary) are being processed in order to accurately identify potential food safety hazards. For the same reason, it is important to know the finished product form (e.g., raw, cooked, pasteurized, smoked, etc.)

Sources of seafood products:

It is important to know where the product is purchased to identify the correct potential food safety hazards – whether the product is purchased directly from the fisherman or harvest vessel; directly from the aquaculture grower or farm; from another processor; or from a combination of these sources.

Receiving, storage and shipment of product:

Identify how the fish are received/stored/shipped viz., fresh – under refrigeration; fresh – under ice or chemical coolant; frozen; canned or shelf-stable; more than one of these methods, in order to control the temperature and time for the production of safe and wholesome final product.

Packaging of the product:

It is important to know how products are received, stored, packaged, and shipped (air-permeable packaging/ reduced-oxygen packaging) to identify any potential food safety hazards during the hazard analysis.

Intended use of the products:

It is important to know how the product will be consumed (to be cooked by the consumer; ready-to-eat (RTE) raw; RTE – cooked, RTE – partially cooked; RTE – heat and serve; RTE- reheat) to identify any potential food safety hazards.

Intended consumers:

Intended consumer information needs to identify whether the end user will be the general public or a specific at-risk consumer group such as infants and the elderly. This will be relevant when identifying potential hazards during the hazard analysis.

Develop a Process Flow Chart

A flow chart provides an important visual tool that the HACCP team can use to identify and describe the process. When developing a process flow chart, it is important to include all the process steps within the facility's control from receiving through final product storage, including reworked product if applicable. Since the accuracy of the process flow is critical to conduct a hazard analysis, the steps outlined in the chart must be verified at the plant. If a step is missed, a significant food safety hazard may be missed. The HACCP team should walk through the facility and make any changes required in the flow chart. The walk-through allows each team member to gain an overall picture of how the product is made. The following is an example of a basic flow chart:

Develop a Process Description

A written process description can be a useful tool to explain what happens at each of the process steps needed to produce a product covered by a particular HACCP plan. This description can be used as a working reference for the development of the HACCP plan and to facilitate communication with company personnel and regulators. It is also important to know what occurs at each process step viz., the maximum length of time that the product could be exposed to unrefrigerated temperatures, the maximum room air temperature, or the maximum internal product temperature etc., to conduct an accurate hazard analysis.

Chapter 11

Preparation of HACCP plan

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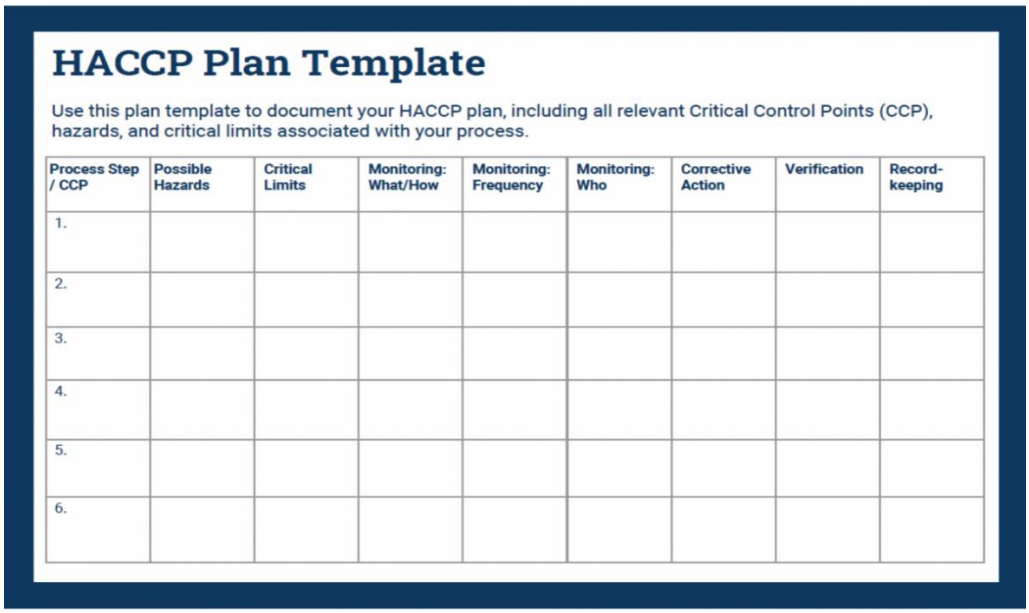
HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. **A different HACCP plan will be needed for each food product**, each processing method and each facility if the processing raises unique or individualized risks.*Writing a HACCP plan is a very crucial step in keeping control of food safety in the food industry.*

Creating a HACCP plan needs preparation and the correct mindset. A HACCP is a written plan that properly addresses the food safety risks of your food business, which requires focus and adequate knowledge about food safety and related manufacturing operations.

Making your own HACCP plan in-house promotes a sense of ownership and a general understanding of your food operations. In case of problems, you can resolve unexplained system failures if you know your plan in-depth. While making a HACCP plan from scratch can be tedious, some food companies seek the advice of independent experts such as food safety consultants from regulatory agencies in the food industry.

HACCP PLAN FORM

HACCP plan form is tool which helps to manage each CCPs. The planform will address the last five principals of HACCP. A typical planform is given in figure.



HACCP Plan Template

Use this plan template to document your HACCP plan, including all relevant Critical Control Points (CCP), hazards, and critical limits associated with your process.

Process Step / CCP	Possible Hazards	Critical Limits	Monitoring: What/How	Monitoring: Frequency	Monitoring: Who	Corrective Action	Verification	Record-keeping
1.								
2.								
3.								
4.								
5.								
6.								

Like in the worksheet, each planform should near the name and address of the production unit, name of the product, intended use of the product and target consumers and method of storage and distribution.

The plan form will help you to 1) set critical limits 2) establish monitoring procedures 3) determine corrective actions and 4) design records (to positively document that the process is in control) for identified hazards in each CCP.

The plan form has ten columns, the Column 1 in the HACCP Plan form contains the CCP's, which are identified using HACCP worksheet. Column 2 lists the hazards and critical limits are listed in column 3. Columns 4 to 7 are meant for entering monitoring procedures, in and the persons responsible for monitoring are entered. Column 8 details the corrective actions to be taken in case of any deviation. Column 9 lists the various verification procedures required to validate our HACCP plan and column 10details the relevant records which are to be maintained.

Critical Limit

A maximum and /or minimum value to which a biological, chemical or physical, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.

A critical limit represents the boundaries that are used to ensure that an operation produces safe products. Each CCP must have one or more critical limits for each food-safety hazard. When the process deviates from the critical limit, a corrective action must be taken to ensure food safety.

How to establish Critical Limits:

Critical limit for the operation may not be available readymade. They have to be fixed by conducting tests and validating them with competent laboratories. These tests may be designed and conducted in association with reputed laboratories or by consulting scientific publication, regulatory guidelines, in house experiments etc.

General source	Examples
Scientific publications	Journal articles, food science texts, microbiology texts etc.
Regulatory guidelines	National/ International guidelines, BIS, EIA/MPEDA publications, tolerance and action levels, FDA or EU guidelines, tolerance and action levels
Subject experts	CIFT, CIBA, CMFRI, thermal process authorities, consultants, food scientists, microbiologists, universities etc.
Experimental studies with validated data	In house experiments, Accredited laboratories

A few examples of critical limits are given below

Hazard	CCP	Critical Limit
Microbial Pathogens	Cooking	85oC for 3 minutes for elimination if pathogens from shrimp
Microbial Pathogens	Drying	a_w<0.7
Microbial Pathogens	Acidification	Batch schedule- pH<2, time 28 h

We should understand that a variety of options are available for managing and controlling a hazard. Only experience and practicality will help you to select the best control measure that has to be adopted.

Monitoring:

Monitoring is the process by which hazard control is effected by ensuring the operations is well under critical limit. It is a planned sequence of observations or measurements to assess whether a CCP is under control. Monitoring also helps to produce an accurate record of operation, which will be useful verification.

Monitoring procedures can either be qualitative or quantitative, Sensory observation for decomposition is an example of a qualitative observation, whereas a temperature reading form a thermometer is a quantitative observation. Monitoring can be performed either in a continuous or in a periodic (non-continuous) basis. It is always desirable to have a continuous monitoring procedure, however, if it is non continuous, procedures should be reliably indicate that the hazard is under control. The means by which the observation is done should be given in the HACCP plan. Monitoring should be done on a real time basis, so that corrective actions can be taken in time, whenever deviations are observed.

Monitoring a CCP can be categorised into five viz. visual observations, sensory evaluation, physical measurement, chemical testing and microbiological examination. Visual monitoring needs no expensive equipment and may not even require highly specialized staff. Sensory evaluation can sometimes provide a quick indication of loss of control. If can be used to check the quality of incoming raw materials. Bad odours van also provide a quick indication of loss of control Physical measurements, such a temperature, pH, water activity, humidity can means to control a particular CCP. Rapid chemical tests (eg. Chlorine level in water) are useful as means of monitoring CCPs. Microbiological testing and detailed chemical analysis are of limited use in monitoring CCPs. It can be employed for the testing of raw materials before starting processing, and for testing critical finished products (eg. Ready to eat fish curry) before release. Monitoring also provides a record that products were produced in compliance with the HACCP plan. This information is useful in the verification of the HACCP plan as discussed in principle 7.

Components of Monitoring System

The monitoring procedure ensures that the required control measures are effective and hazards are kept below critical limits. This is done in the plan form by identifying following parameters:

- What will be monitored (Direct/Indirect). (Column4)
- How the critical limits and control measures will be monitored (column 5)

- How frequently monitoring will be performed (Column 6)
- Who will perform the monitoring (Column 7)

What will be monitored

It can be a measurement of a product characteristic or a processing

- Measurement of boiler compartment temperature
- Measurement of the pH of pickle
- Measurement of conveyor belt speed

It can also a subjective measurement which involves observation of a control measure to manage hazard.

Examples

- Checking that a supplier's certificate accompanies a lot of raw material.
- Auditing the farm premises to check whether the fish farmer is using the permitted antibiotic and whether he applies it as per guidelines.

How Critical Limit and Control Measures will be monitored?

Monitoring must be designed to provide rapid (real-time) results. There is no time to lengthy analytical testing because critical limit failures must be detected quickly and an appropriate corrective action instituted before distribution.

Examples

- Time and temperature using a calibrated thermometer and stopwatch.
- Water Activity (a_w) using a calibrated RH meter
- Acidity (pH) using a calibrated pH meter
- Visual observation for subjective evidences like supplier's guarantee, freshness using sensory evaluation *etc.*

Frequency of monitoring

As mentioned above, monitoring can be continuous or non-continuous. Where possible, continuous monitoring should be used. Continuous monitoring is possible for many type of physical and chemical parameters.

Examples of continuous monitoring include:

- The time and temperature of a batch cooker process for IQF shrimps may be continuously monitored and recorded on a temperature-recording chart.
- Checking for presence of metals in frozen shrimp blocks using a metal detector.

Examples of non-continuous monitoring include:

- Routine. Daily checks for temperature of stored fish waiting for processing.
- Periodic sensory examination for decomposition in histamine forming seafood

Who will do the Monitoring?

Assignment of the responsibility for monitoring is an important consideration when developing a HACCP plan.

Individuals assigned to CCP monitoring can be:

- Line personnel,
- Equipment operators,
- Supervisors,
- Technologist

Corrective Actions

Corrective actions are predetermined procedures to be adopted when critical limits at a CCP is compromised. These procedures should restore process control and state clearly the method of disposing the product produced during the deviation.

An effective corrective action plans must:

- Correct and eliminate the cause of the noncompliance to assure that the CCP is brought back under control.
- Segregate, assess and determine the disposition of the noncompliant product.

All corrective actions taken must be documented. Documentation will assist the firm in identifying recurring problems so that the HACCP plan can be modified. Additionally, corrective action records provide proof of product disposition.

An example of disposition procedure for an affected product is given below:

- Isolating and holding product for safety evaluation. If the product was found to be safe, release the product.
- Diverting the affected product or ingredients to another line where deviation would not be considered critical.
- Reprocessing.
- Destroying product.
- It may be necessary to determine the cause of the deviation to prevent future recurrence. A critical limit failure that was not anticipated or reoccurs should result in an adjustment to the product or process or a re-evaluation of the HACCP plan.

Verification Procedures

Verification are those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan. The purpose of the HACCP plan is to prevent food-safety hazards, and the purpose of verification is to provide a level of confidence that the plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process, and is being followed.

Parts of Verification:

- Validation
- CCP verification activities
  - Calibration of monitoring devices
  - Calibration record review
  - Targeted sampling and testing
  - CCP record review
- HACCP system verification
  - Observations and reviews
  - Microbiological end-product testing
- Regulatory agencies

Validation:

The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards. Validation can be performed by the HACCP team or by an individual qualified by training or experience. Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

Verification of CCPs Verification activities developed for CCPs are essential to ensure that the control procedures used are properly functioning and that they are operating.

- **Calibration**

Verification activities at CCPs include calibration of monitoring devices

To ensure the accuracy of the measurements taken with traceability. Calibration is conducted

To verify that monitoring results are accurate.

Calibration of CCP monitoring equipment is fundamental to the successful implantation and operation of the HACCP plan. If the equipment is out of calibration, then monitoring results will be unreliable, Frequency of calibration should also be influenced by equipment sensitivity

- **Calibration Record Review**

  Reviewing the equipment calibration records involves checking the dates and methods of calibration and the test results

- **Targeted Sampling and Testing**

  Verification may also include targeted sampling, testing and other periodic activities, Vendor compliance may be checked by targeted sampling when receipt of material is a CCP and purchase specifications are relied on as critical limits. Typically, when a monitoring procedure is not as stringent as desire, it should be coupled with a strong verification strategy.

- **CCP Record Review**

At least two types of records are generated at each CCP: monitoring and corrective action. These records are valuable management tools, providing documentation that CCPs are operating within established safety parameters and that deviations are handled in a safe and appropriate manner. However, records alone are meaningless unless someone in a supervisory capacity reviews then on a periodic basis to "verify" that the HACCP plan is being followed.

HACCP System Verification

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system. The frequency of the system wide verification should be yearly (at a minimum) or whenever there is a system failure or a significant change in the product or process. The HACCP team is responsible for ensuring that this verification function is performed. Often, the HACCP team will contract an independent third party to conduct the system-wide verification.

Activities

- **System Verification Activities**

Systematic verification activities include on-site observations and record reviews. Reviews are usually performed by an unbiased person who is not responsible for performing the monitoring activities. System verification should occur at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

- **End-product Microbiological Testing in HACCP Verification**

  As explained in Chapter2, microbiological testing is ineffective for routine monitoring by can be used as a verification tool. Microbiological testing can be used to determine (e.g., during verification audits or on periodic basis that the overall operation is under control)

  Record-keeping procedures

  Accurate record keeping is an essential part of a successful HACCP program. Records provide documentation that the critical limits have been met or that appropriate corrective actions were taken when the limits were exceeded. Likewise, they provide a means of monitoring so that process adjustments can be made to prevent a loss of control.

  Four kinds of categories are kept as part of the HACCP system.

  1. HACCP plan and support documentation used in developing the plan
  2. Records of CCP monitoring
  3. Records of corrective action
  4. Records of verification activities

Conclusion

HACCP was designed to prevent hazardous products from leaving the manufacturing or processing facility. The key to the success of HACCP is employee training, behaviour and attitude. Some companies are under the misconception that they already have al HACCP plan because they are adequately controlling all areas where safety could be compromised. The difference is that, rather than monitoring isolated processing steps, an HACCP approach controls the entire production process as an integrated system.

Although HACCP provides insurance that fish is safe, there is no way to completely eliminate all hazards. HACCP is most effective when used with other control systems. Total Quality Management programs and Standard Operating Procedures should be used along with HACCP to improve product safety, product quality, and plant productivity by providing intimate knowledge of the production process, production environment and processing equipment.

Chapter 12

Overview of ISO 22000:2018 FSMS

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ISO 22000:2018 is the latest global food safety management system (FSMS). This standard replaces the old ISO 22000:2005. ISO 22000:2018 was published in 19 June 2018. The aim of the standard is to harmonize the requirements for 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 22000:2018 applies 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 farm-to-table.

ISO (international Organization for Standardization) is a non-governmental organization (NGO) established in 1947. The head quarter is in Geneva, Switzerland. It has a membership of around 160 national standards institutes from countries in all regions of the world. ISO 22000 was developed by a working group (WG) under ISO Technical Committee 34 (Food Products). This working group evolved into ISO sub-committee (SC 17). This subcommittee is responsible for the management of the ISO 22000 family of standards.

Due to the ever-growing global population and raising demand for food to meet the requirements, made food safety a very important aspect. In the manufacturing process it is vital to ensure that the products delivered to consumers do not interfere with the consumers' health adversely. If the production system fails to comply with the food safety regulations, that will lead to the transmission of foodborne illness.

Food Supply chain:

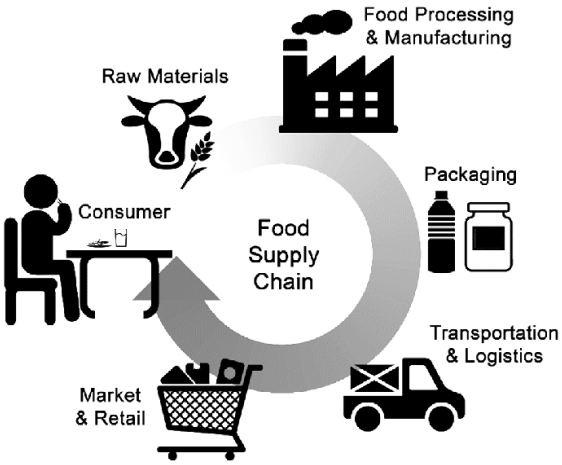

Fig. 1. Food Supply Chain

Food supply chain or food system refers to the processes that describe how food from a farm ends up on our tables. The processes include production, processing, distribution, consumption and disposal. Every step of the supply chain requires human and/or natural resources. In the food supply chain, food moves from producer to consumer via the processes of production, processing, distribution, retailing and consumption; At the same time, money that consumers pay for food moves from consumers to producers in the reverse process.

Fig.2.Movements of food and money in a simple food supply chain

According to World Health organization reports, about 2 million death occur every year from contaminated food or drinking water. Around 600 million cases are caused by 22 different enteric diseases (disease caused by intestinal infection) and among that about 52000 deaths are caused by enteric disease caused by *Salmonella typhi.* Over 40% people suffering from enteric diseases caused by consumption of contaminated food were children under the age of 5 years.

ISO 22000

ISO 22000 is a global standard for Food Safety Management Systems (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. ISO 22000 (Food safety management systems -- Requirements for any organization in the food chain) describes the requirements for a food safety management system. The standard is utilized with ISO 22002-1 (Prerequisite programmes on food safety - Part 1: Food manufacturing) to form the technical basis for a Global Food Safety Initiative (GFSI) recognized audit scheme known as FSSC 22000 ISO 22000:2018 is having high level structure with a different approach to understand risk i.e. It is having a risk-based approach. As a result of the high-level structure, the clauses of the standard are largely changed compared to the previous version. The main clauses of high-level structure are as follows:

1. Scope
2. Normative references
3. Terms and Definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Process approach

ISO 22000:2018 adopts a process approach when developing and implementing a FSMS and improving its effectiveness to enhance production of safe products and services while meeting

applicable requirements. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the food safety policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle, with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results. The recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the food chain.

Plan-Do-Check-Act cycle

The PDCA cycle can be described briefly as follows:

Plan: establish the objectives of the system and its processes, provide the resources needed to deliver the results, and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where relevant) measure processes and the resulting products and services, analyse and evaluate information and data from monitoring, measuring and verification activities, and report the results;

Act: take actions to improve performance, as necessary.

The process approach uses the concept of the PDCA cycle at two levels. The first covers the overall frame of the FSMS (Clause 4 -7 and Clause 9 - 10). The other level (operational planning and control) covers the operational processes within the food safety system as described in Clause 8. Communication between the two levels is therefore essential. So, the Plan-Do- Check- Act (PDCA) cycle of ISO 22000:2018 is having 2 separate cycles working together to handle management system and principles of Hazard Analysis and Critical Control Point (HACCP) respectively. The operation process, clearly deals with key points -Critical Control Points(CCPs), Operational Pre-requisite Programmes (OPRPs) and Pre-requisite Programmes (PRPs).

Risk-based thinking

Risk-based thinking is essential for achieving an effective FSMS. In ISO 22000:2018, risk-based thinking is addressed on two levels, organizational and operational,which is consistent with the process approach.

Organizational risk management:

Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. In the context of organizational risk management, a positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities. Addressing risks establishes a basis for increasing the effectiveness of the FSMS, achieving improved results and preventing negative effects.

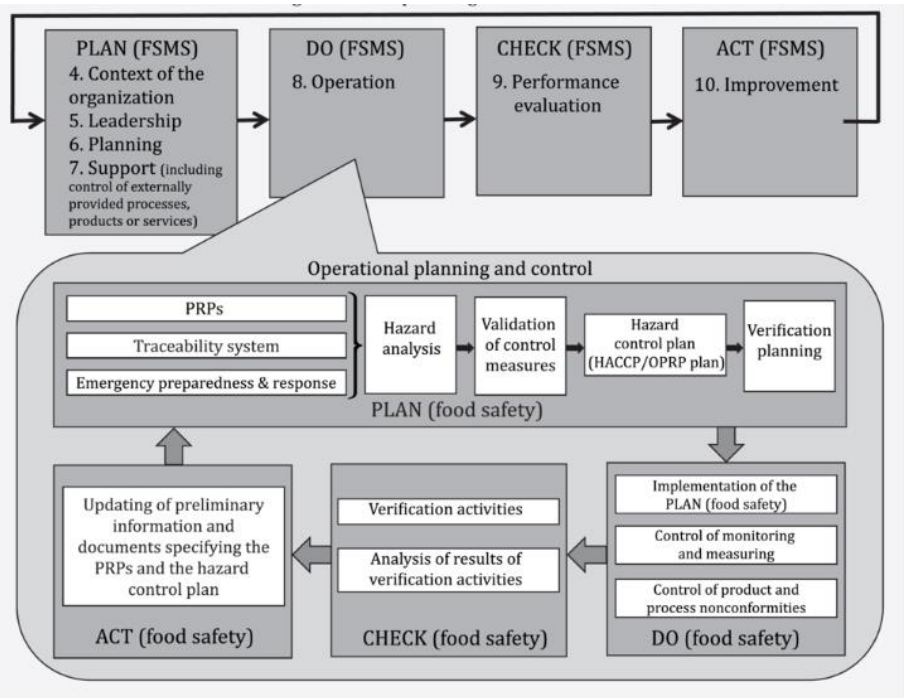

Fig Organizational planning and control of ISO 22000:2018 (*source:ISO 22000:2018- Food safety management systems)*

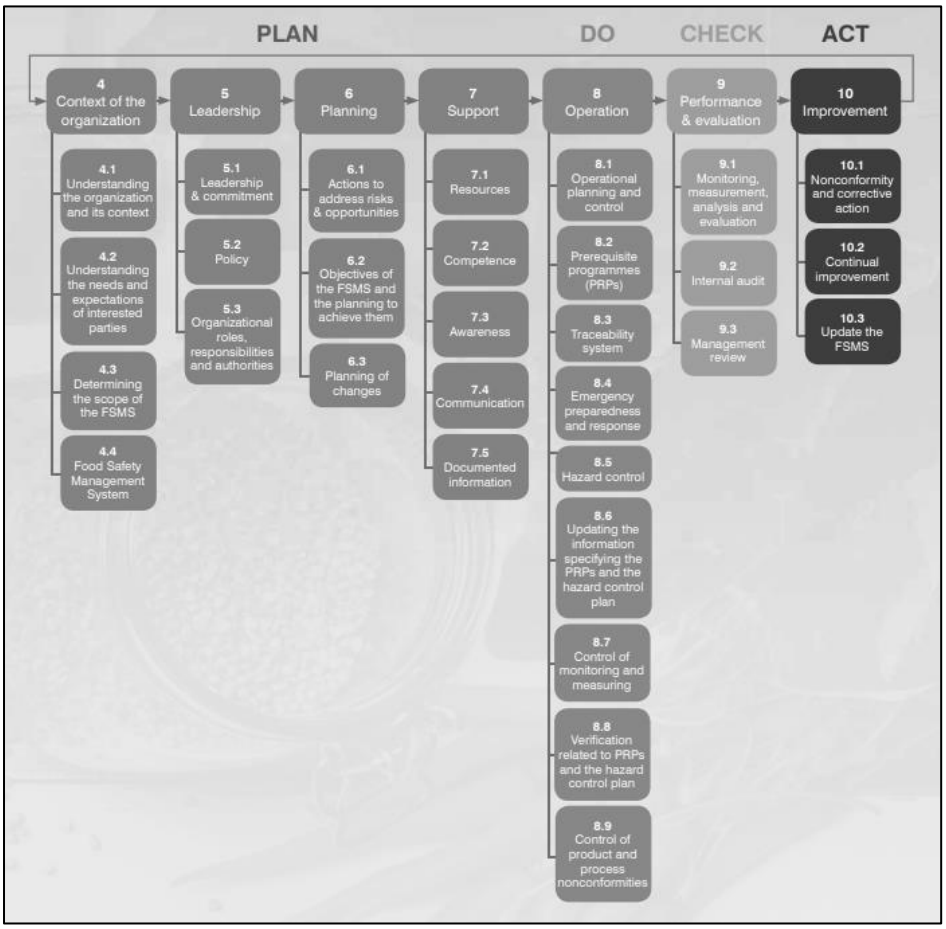

Fig.3. PDCA cycle of ISO22000:2018 (*source: NQA-ISO-22000-Implementation-Guide)*

Hazard analysis — Operational processes:

The concept of risk-based thinking based on the HACCP principles at the operational level is implicit in ISO22000:2018. The subsequent steps in HACCP can be considered as the necessary measures to prevent hazards or reduce hazards to acceptable levels to ensure food is safe at the time of consumption. Decisions taken in the application of HACCP should be based on science, free from bias and documented. The documentation should include any key assumptions in the decision-making process.

Relationship with other management system standards:

ISO 22000:2018 has been developed within the ISO high level structure (HLS). The objective of the HLS is to improve alignment between ISO management system standards. It enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its FSMS approach with the requirements of other management systems and supporting standards. ISO 22000:2018 is the core principle and framework for FSMSs and sets out the specific FSMS requirements for organizations throughout the food chain. Other guidance related to food safety, specifications and/or requirements specific to food sectors can be used together with this framework.

In addition, ISO has developed a family of associated documents. These include documents for:

- prerequisite programmes (ISO/TS 22002 series) for specific sectors of the food chain;
- requirements for auditing and certification bodies;
- traceability.

Key changes in ISO 22000:2018

These are some of the key changes to consider:

Changes due to the adoption of HLS

Clause no. 4- Business Context and interested parties.

4.1 - for systematic determination and monitoring of the business context

4.2 - introduces demands to identify and understand factors that can (potentially) affect the ability of Management System to reach the intended results.

Clause no. 5 - Strengthened emphasis on leadership and management commitment:

5.1- new demands to actively engage and take accountability for the effectiveness of the management system.

Clause no. 6 - Risk management

6.1 - companies to determine, consider and, where necessary, take action to address any risks that may impact (either positively or negatively) the ability of the management system to deliver its intended results.

6.2 - Strengthened focus on objectives as drivers for improvements

Clause no. 7 - Extended requirements related to communications

7.4 - “mechanics” of communication, including determination of what, when and how to communicate

7.5 - Documented information shall be controlled to ensure it is adequately protected (ref. 7.5.3). The explicit requirement to have a documented procedure has been removed.

Clause no. 9 - Performance evaluation

Other changes that are specific to ISO 22000 and food safety management

- The PDCA cycle: the standard clarifies the Plan-Do-Check-Act cycle, by having two separate cycles in the standard working together: one covering the management system and the other, covering the principles of HACCP.
- The scope now specifically includes animal food: food for animals not producing food for human consumption. Feed is intended to be fed to food producing animals.
- Some important changes in the definitions: 'Harm' is replaced by 'adverse health effect' to ensure consistency with definition of food safety hazard. The use of 'assurance' highlights the relationship between the consumer and the food product, based on the assurance of food safety.
- Communicating the food safety policy – Clause no. 5.2.2: Explicitly requires the management to facilitate understanding of the food safety policies by employees.
- Food Safety Management System Objectives: Establishing objectives for the food safety management system is further specified in Clause no. 6.2.1 and includes items as e.g. 'consistent with customer requirements', 'monitored' and 'verified'.
- Control of externally-provided processes, products or services – Clause no. 7.1.6- introduces the need to control the suppliers of products, processes and services (including outsourced processes) and to ensure adequate communication of relevant requirements, to meet the food safety management system requirements.

Food Safety Management System (FSMS)

The adoption of a food safety management system (FSMS) is a strategic decision for an organization that can help to improve its overall performance in food safety. The potential benefits to an organization of implementing a FSMS based on this document are:

a) the ability to consistently provide safe foods and products and services that meet customer and applicable statutory and regulatory requirements;

b) addressing risks associated with its objectives;

c) the ability to demonstrate conformity to specified FSMS requirements.

ISO 22000:2018 employs the process approach which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. This process approach enables an organization to plan its processes and their interactions. The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on. Risk-based thinking enables an organization to determine the factors that could cause its processes and its FSMS to deviate from the planned results, and to put in place controls to prevent or minimize adverse effects.

ISO 22000:2018, the following verbal forms are used:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;

- “can” indicates a possibility or a capability.

“NOTES” provide guidance in understanding or clarifying the requirements in this document.

FSMS principles

Food safety is related to the presence of food safety hazards at the time of consumption (intake by the consumer). Food safety hazards can occur at any stage of the food chain. Therefore, adequate control throughout the food chain is essential. Food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a FSMS that combines the following generally recognized key elements:

- interactive communication;
- system management;
- prerequisite programmes;
- hazard analysis and critical control point (HACCP) principles.

In addition, ISO 22000:2018 is based on the principles that are common to ISO management system standards. The management principles are:

- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

Benefits of FSMS

FSMS is a preventive approach to food safety, having conformance to legal and regulatory requirements. The implementation of FSMS increases the credibility and reputation of the organization. It also enhances the customer satisfaction and increases the profitability of the company.

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

Chapter 13

.Key elements, Terminologies and Scope of FSMS

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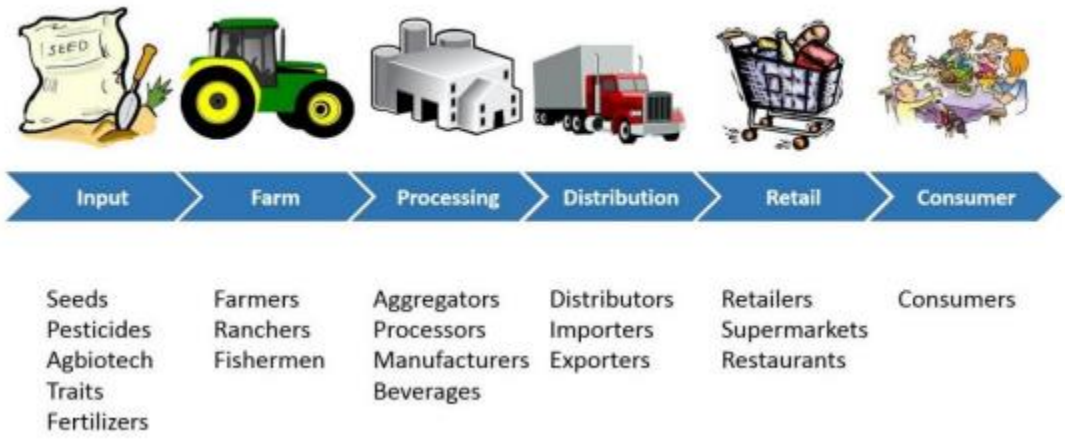
Introduction

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

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

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



<u>Organizations within the food chain range from:</u>

- feed producers and primary producers through food manufacturers,

- transport and storage operators,

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

- service providers.

Interactive communication

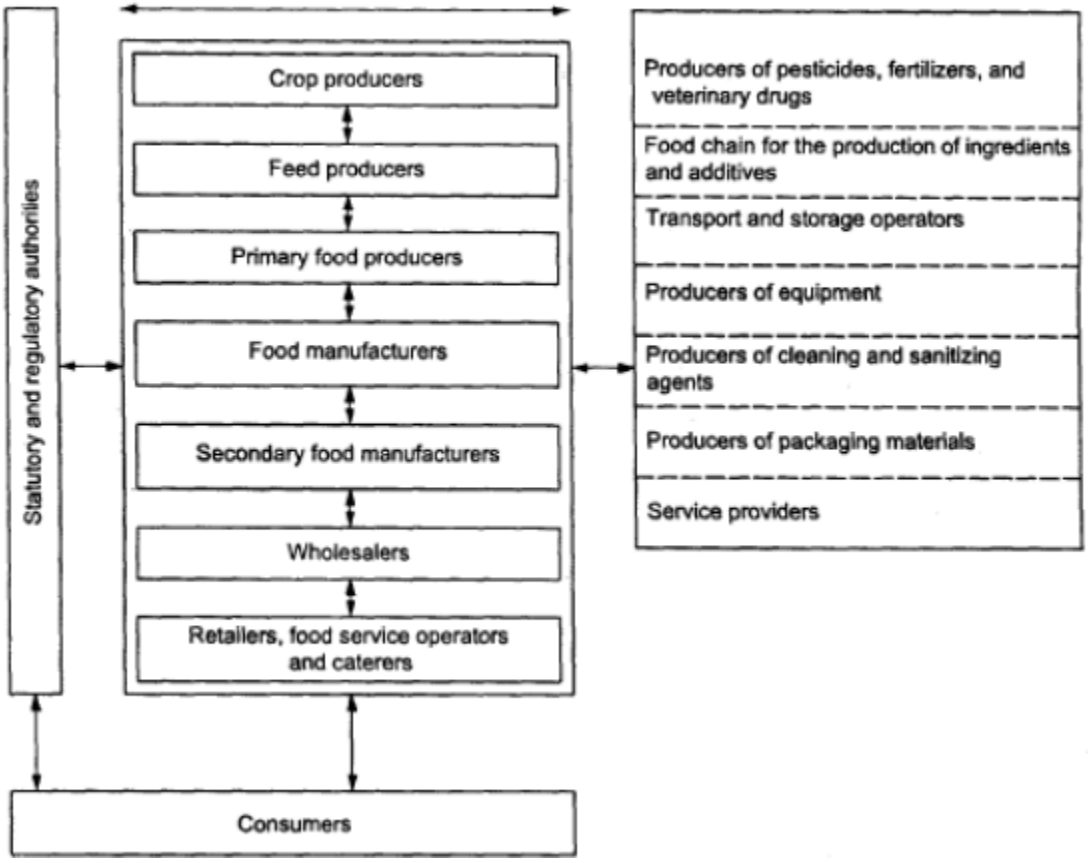
• Communication along the food chain is essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain.

• This implies communication between organizations both upstream and downstream in the food chain.

• Communication with customers and suppliers about identified hazards and control measures will assist in clarifying customer and supplier requirements.

• Recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the chain in order to deliver safe food products to the final consumer.

• An example of the communication channels among interested parties of the food chain is shown here.



System management

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

• This International Standard can be applied independently of other management system standards. Its implementation can be aligned or integrated with existing related management system requirements.

• Organizations may also utilize existing management system(s) to establish a food safety management system that complies with the requirements of this International Standard (ISO: 22000-2005/2015).

• It combines the HACCP plan (12 steps) with prerequisite programmed (PRPs).

• Hazard analysis is the key to an effective food safety management system, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures.

Prerequisite programme

• Standard operating procedure (SOP)

• Sanitation standard operating procedure (SSOP)

• Good Agricultural Practice (GAP)

• Good Veterinarian Practice (GVP)

• Good Manufacturing Practice (GMP)

• Good Hygienic Practice (GHP)

• Good Production Practice (GPP)

• Good Distribution Practice (GDP)

• Good Trading Practice (GTP) HACCP principles

• Principle 1: Conduct a hazard analysis

• Principle 2: Determine critical control points (CCPs)

• Principle 3: Establish critical limits

• Principle 4: Establish monitoring procedures

• Principle 5: Establish corrective actions

• Principle 6: Establish verification procedures

• Principle 7: Establish record-keeping and documentation procedures

Scope

a) To plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance to their intended use;

b) To demonstrate compliance with applicable statutory and regulatory food safety requirements;

c) To evaluate and assess mutually agreed customer food safety requirements and demonstrate conformity with them;

d) To effectively communicate food safety issues to interested parties within the food chain;

e) To ensure that the organization conforms to its stated food safety policy;

f) To demonstrate conformity to relevant interested parties;

g) To seek certification or registration of its FSMS by an external organization, or make a self-assessment or self-declaration of conformity to this document.

Terminologies

Acceptable Level

Level of a food safety hazard not to be exceeded in the end product provided by the organization

Action Criterion

Measurable or observable specification for the monitoring of an OPRP

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

Audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

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

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

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

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

Competence

Ability to apply knowledge and skills to achieve intended results

Conformity

Fulfilment of a requirement Contamination Introduction or occurrence of a contaminant including a food safety hazard in a product or processing environment

Continual Improvement

Recurring activity to enhance performance

Control Measure

Action or activity that is essential to prevent a significant food safety hazard or reduce it to an acceptable level

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

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

Correction

Action to eliminate a detected nonconformity

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

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

Corrective Action

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

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

Note 2 to entry: Corrective action includes cause analysis. Critical control point CCP Step in the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level, and defined critical limit(s) and measurement enables the application of corrections

Critical Limit

Measurable value which separates acceptability from unacceptability

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

Documented Information

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

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

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

Effectiveness

Extent to which planned activities are realized and planned results achieved

End Product

Product that will undergo no further processing or transformation by the organization

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

Feed

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

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

— food is intended for consumption by humans and animals and includes feed and animal food;

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

Flow Diagram

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

Food

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

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

— food is intended for consumption by humans and animals and includes feed and animal food;

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

Animal Food

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

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

— food is intended for consumption by humans and animals and includes feed and animal food;

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

Food Chain

Sequence of the stages in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption

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

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

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

Food Safety

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

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

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

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

Food Safety Hazard

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

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

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

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

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

Management System

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

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

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

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

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

Policy

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

Interested party (preferred term)

Stakeholder (admitted term)

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

Lot

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

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

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

Monitoring

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

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

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

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

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

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

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

Nonconformity

Non-fulfilment of a requirement Objective Result to be achieved

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

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

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

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

Operational Prerequisite Programme OPRP

Control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level, and where action criterion and measurement or observation enable effective control of the process and/or product

Organization

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

Outsource

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

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

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

Prerequisite programme PRP

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

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

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

Process

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

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

Requirement

Need or expectation that is stated, generally implied or obligatory

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

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

Risk

Effect of uncertainty

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

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

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

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

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

Significant Food Safety Hazard

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

Top Management

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

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

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

Traceability

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

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

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

Update

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

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

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

— retain is to keep something that is retrievable.

Validation

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

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

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

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

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

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

Verification

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

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

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

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

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

Reference:

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

○

Chapter 14

ISO 22000Series of standards on PRPs

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Prerequisite Programs (PRPs)

PRPs are the 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.

Prerequisite requirements - ISO 22000

ISO 22000 requires that the organization establishes PRP programs to control the likelihood of introducing contamination through the work environment. ISO 22000 identifies areas and programs that must be considered during the development of PRPs. Examples: pest control programs, personnel hygiene and lay-out of premises. However, the standard leaves the responsibility for developing the details of the program to the organization; it does not give specific requirements for the PRPs, organization needs to determine the appropriate PRPs according to the requirements.

To give companies a guidance on prerequisite programs, ISO has published a technical specification, ISO/TS 22002-1 "Prerequisite programs on food Safety-Part 1: food manufacturing". ISO/TS 22002-1 and is intended to be used with the ISO 22000 standard, and gives more detailed requirements for food manufacturers to follow when developing and implementing PRPs. Unlike ISO 22000, which applies to all organizations in the food chain, ISO 22002 applies only to Manufacturers of food.

ISO 22002 Technical Specifications (TSs) are guidance documents, not intended for certification, but intended for assisting an organization in establishing, implementing and maintaining prerequisite programmes (PRP) in accordance with ISO 22000ISO/TS 22002-1:2009 specifies requirements for establishing, implementing and maintaining prerequisite programmes (PRP) to assist in controlling food safety hazards. ISO/TS 22002-1:2009 is applicable to all organizations, regardless of size or complexity, which are involved in the manufacturing step of the food chain and wish to implement PRP in such a way as to address the requirements specified in ISO 22000:2005, Clause 7. ISO/TS 22002-1:2009 is neither designed nor intended for use in other parts of the food supply chain. Food manufacturing operations are diverse in nature and not all of the requirements specified in ISO/TS 22002-1:2009 apply to an individual establishment or process. Where exclusions are made or alternative measures implemented, these need to be justified and documented by a hazard analysis, as described in ISO 22000:2005, 7.4. Any exclusions or alternative measures adopted should not affect the ability of the organization to comply with these requirements.

ISO/TS 22002-1:2009 specifies detailed requirements to be specifically considered in relation to ISO 22000:2005, 7.2.3:

a) construction and layout of buildings and associated utilities;

b) layout of premises, including workspace and employee facilities;
c) supplies of air, water, energy, and other utilities;
d) supporting services, including waste and sewage disposal;
e) suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;
f) management of purchased materials;
g) measures for the prevention of cross-contamination;
h) cleaning and sanitizing;
i) pest control;
j) personnel hygiene.

In addition, ISO/TS 22002-1:2009 adds other aspects which are considered relevant to manufacturing operations:

1) rework;
2) product recall procedures;
3) warehousing;
4) product information and consumer awareness;
5) food defence, bio vigilance, and bioterrorism.

STANDARDS BY ISO/TC 34/SC 17 -Management systems for food safety

There are 11 standards and/or project under the direct responsibility of ISO/TC 34/SC 17 secretariat, as follows:

1. ISO 22000:2018- Food safety management systems — Requirements for any organization in the food chain
2. ISO/TS 22002-1:2009 -Prerequisite programmes on food safety — Part 1: Food manufacturing
3. ISO/TS 22002-2:2013 -Prerequisite programmes on food safety — Part 2: Catering
4. ISO/TS 22002-3:2011 -Prerequisite programmes on food safety — Part 3: Farming
5. ISO/TS 22002-4:2013 -Prerequisite programmes on food safety — Part 4: Food packaging manufacturing
6. ISO/TS 22002-5:2019 -Prerequisite programmes on food safety — Part 5: Transport and storage
7. ISO/TS 22002-6:2016 -Prerequisite programmes on food safety — Part 6: Feed and animal food production
8. ISO/AWI 22003-2 -Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems — Part 2: Requirements for bodies providing audits of food safety management system elements in conjunction with safe food product/process certification
9. ISO/CD 22003-1 -Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems — Part 1: Requirements for bodies providing audit and certification of food safety management systems
10. ISO/TS 22003:2013 -Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems
11. ISO 22005:2007 -Traceability in the feed and food chain — General principles and basic requirements for system design and implementation

Reference: ISO/TC 34/SC 17 – Management System for Food Safety

Chapter 15

Process of certification, accreditation, and benchmarking of FSMS standards

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Certification

Certification, according to ISO/IEC 17000:2004, is "third party attestation related to products, processes, systems or persons." According to The Global Food Safety Initiative (GFSI) Guidance Document Accreditation is a process by which an authoritative body gives formal recognition of the competence of a certification body to provide certification services against an international standard.

Certification process enable an organization to comply with the customer requirements/buyer specification. Certification ensure independent check of conformity and indicates an effective Food Safety Management System. Certification provides a competitive advantage for the firm, improve the firm's reputation and provides a worldwide recognition. The process of certification involves the following steps:

1. Request for registration
2. Document review
3. Pre-assessment
4. Registration audit
5. Corrective action
6. Registration decision
7. Certification, publicizing the registration
8. Maintenance of registration & Surveillance audit

The Global Food Safety Initiative (GFSI) is a division of the Consumer Goods Forum and a collaboration of retailers, manufacturers and food service companies that has been working on harmonization of food safety standards. GFSI benchmarks the various food safety standards against a basic set of criteria. Standards meeting the criteria are recognized. Many large retailers and manufacturers are requesting their suppliers to register to a GFSI recognized scheme. One of the benchmarked standards is FSSC 22000.

Food Safety System Certification (FSSC) 22000 is an ISO 22000 and PRP based certification scheme for food manufacturers. It includes both the requirements for a Food Safety Management System found in ISO 22000 and the requirements for Prerequisite Programs found in TS/ISO 22002-2. ISO and FSSC have the same food safety management system requirements. They differ in the way they define PRP requirements:

ISO 22000 requires that PRPs, appropriate to the organization and product, are implemented to control the likelihood of introducing hazards. The standard does not specify required PRPs and details of the PRPs, but asks the organization to consider and use appropriate information (statutory,

regulatory and customer requirements and more). FSSC 22000 has the above requirements, but includes the TS/ISO 22002-1 which gives specific requirements for PRPs that manufacturers must address.

The Foundation Food Safety System Certification 22000 (FSSC 22000) offers a complete certification Scheme for the auditing and certification of Food Safety Management Systems (FSMS) or FSMS and Quality Management Systems (FSSC 22000-Quality).The Scheme uses international and independent standards such as ISO 22000, ISO 9001, ISO/TS 22003 and technical specifications for sector specific Pre-Requisite Programs (PRPs), such as ISO/TS 22002-1 for certification. These standards were developed through a wide and open consultation with a large number of international stakeholders. Besides these standards, the Scheme also contains additional requirements known as FSSC Additional Requirements.

Through meeting the Global Food Safety Initiative (GFSI) Benchmarking Requirements, the FSSC 22000 Scheme meets the highest standards globally leading to international food industry acceptance. The FSSC 22000 Scheme sets out the requirements for Certification Bodies, Accreditation Bodies and Training Organizations to develop and implement its operations for auditing and certification of food safety management systems of organizations within the entire food supply chain. The issued certificate confirms that the organizations food safety management system is in conformance with the Scheme requirements and that the organization is able to maintain compliance with these requirements. To get ISO 22000 or FSSC 22000 certification, the organization need to implement food safety management system processes to meet the requirements of the standard. The FSSC 22000 certification process involves the following steps:

The Scheme documents contain the requirements for organizations in the food and feed supply chain to gain certification. They shall be used by the applicant organization to assess, develop, implement and improve its food and feed safety management system prior to application for certification. The requirements of the food and feed safety management system also serve as the normative documents for certification of the organization. The normative documents shall be used to assess the continuous compliance of the food and feed safety management system of the applicant organization with the required performance.

FSSC 22000 certification have general rules for all categories, and specific rules for individual categories. The FSSC 22000 certification scheme outlines the requirements for the audit and certification of food safety management systems (FSMS) or FSMS and Quality Management Systems (QMS) of organizations in the food supply chain. The certificate confirms that the organization’s FSMS (FSSC 22000) or FSMS and QMS (FSSC 22000-Quality) is in conformance with the Scheme requirements

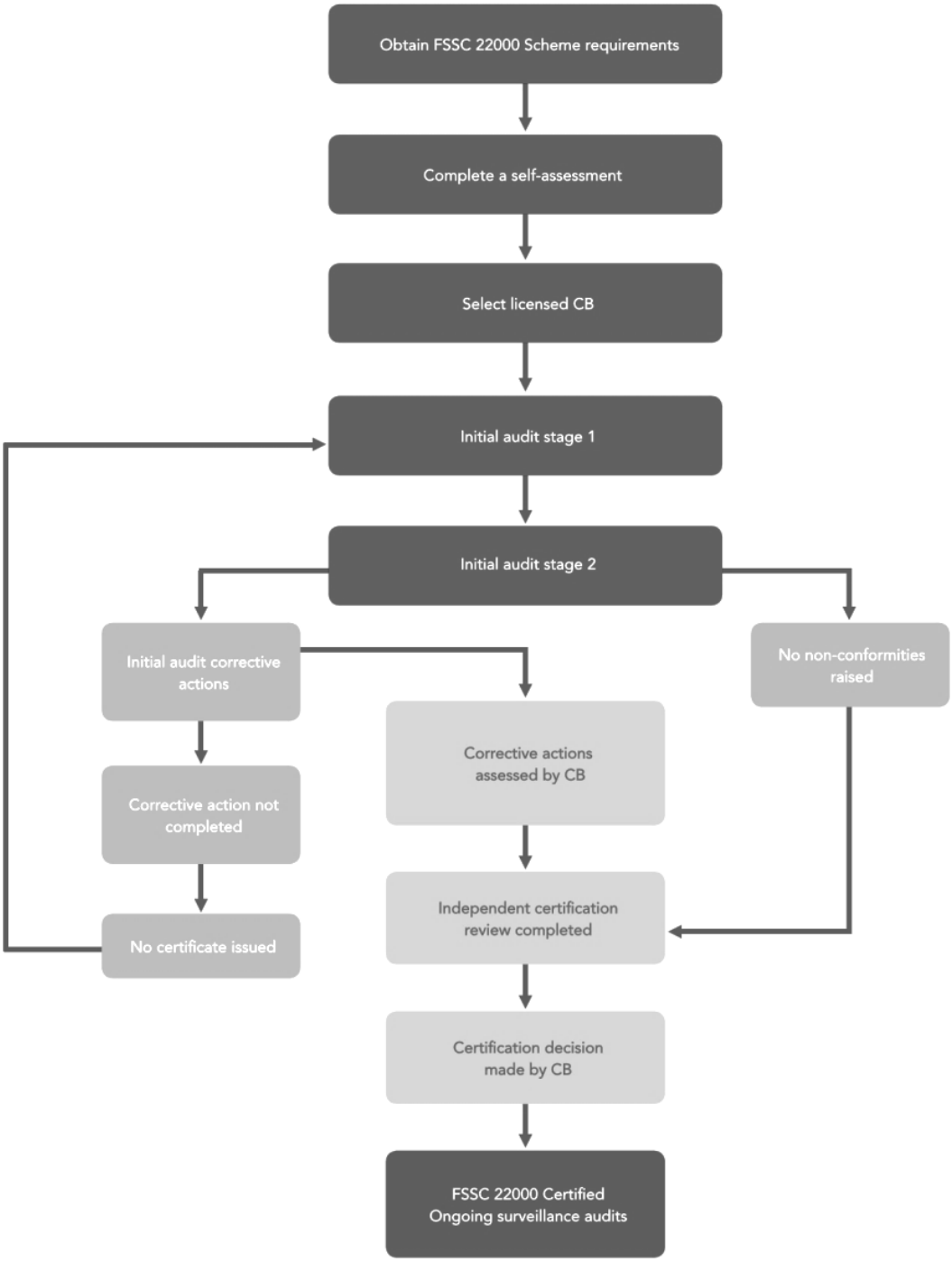

Fig1. Process flow for FSSC 22000 certification

. The Scheme is based on the publicly available standards/technical specifications:

• ISO 22000 requirements for any organization in the food chain;

• ISO 9001 requirements (where FSSC 22000-Quality is required);

• Relevant prerequisite programs (PRPs) based on technical specifications for the sector (e.g. ISO/TS 22002-x; PAS xyz); and

• FSSC 22000 Additional Requirements as determined by our stakeholders.

The Scheme provides a voluntary certification model that can be applied across the entire food supply chain. It can cover supply chain sectors where specific prerequisite programs (PRPs) have been developed and accepted. The aim of the Scheme is to ensure that it continuously meets international food industry requirements resulting in a certification that assures that organizations provide safe food to its customers.

The specific Scheme objectives are to:

a) establish and maintain an accurate and reliable Register of certified organizations that have demonstrated to comply with the Scheme requirements;
b) promote the accurate application of food safety and quality management systems;
c) promote national and international recognition and general acceptance of food safety and food safety quality management systems;
d) provide information and campaigns on food safety and quality management systems;
e) provide support for the certification of food safety management systems in the field of food safety and quality

Nature of the scheme:

The Scheme provides an independent ISO-based Scheme for third party auditing and certification. The Scheme:

a) incorporates ISO standards, sector specific technical specifications for PRPs, market driven additional requirements as well as statutory and regulatory requirements;
b) is recognized by the Global Food Safety Initiative;
c) allows the integration with other management system standards such as environmental, health and safety etc.;
d) is governed by a non-profit Foundation and managed by an independent Board of Stakeholders;
e) increases transparency throughout the food supply chain;
f) offers a “FSSC 22000 Register of certified organizations” which is publicly accessible

The Scheme is intended for the audit, certification and registration of organizations for the various food chain (sub)categories such as farming animals for meat/milk/eggs/honey, farming of fish and seafood, processing of perishable animal products, processing of perishable plant products, processing of ambient stable products, production of feed etc.

Accreditation

While, accreditation activities are conducted by Accreditation Bodies (ABs), which are not-for-profit organisations, either government owned or under agreement with government, charged with ensuring that participating Certification Bodies in the country are subject to oversight by an authoritative body. ABs may not be high profile in each country, but play a key role in the accredited certification process and ensuring international consistency in conformity assessment. GFSI recognises two ISO standards for accreditation purposes. One is ISO/IEC Guide 65, and the other ISO/IEC 17021, supplemented by ISO/TS 22003. Both of these standards contain similar operational requirements for a certification body. They both address issues of preventing conflict of interest, managing customer information, properly qualifying personnel, auditor calibration, and many other aspects involved with the certification process. Both ISO/IEC Guide 65 and ISO/IEC 17021/ISO22003, require the accreditation body to observe auditors in the field as well as conduct a detailed office review of policies,

procedures, and document control. It is only after the successful assessment of auditors and the certification body operations that accreditation can be granted.

ISO/IEC 17021 covers conformity assessment of 'management systems", and is applied in combination with ISO/TS 22003, which covers audit and certification of food safety management systems. ISO 17021/ISO 22003 is not product specific. While, ISO/IEC Guide 65, is concerned with verifying that particular products or services meet specified requirements. The Accredited Certification framework is a tried and tested process that applies credibility and robustness to third party food certification audits. The process is continually under review and revision by GFSI to ensure fitness and appropriateness to food safety certification and the GFSI objectives.

Benchmarking

Benchmarking is the process by which companies look at 'best practice' in the industry and try to imitate such strategies and procedures. Benchmarking enables identification of the gap between current and optimal, or 'best practice' performance levels. The Benchmarking requirements are built through consensus of experts and members and based on internationally-recognised standards such as ISO and Codex Alimentarius. The Global Food Safety Initiative (GFSI) Benchmarking requirements were first created in 2001 by a group of retailers motivated by the necessity of harmonising food safety standards across the global supply chain. These requirements are frequently updated with input from food safety experts around the world to keep up to date with food safety trends. The main objectives are objectives:

1. Reduce food safety risks by delivering equivalence and convergence between effective Food Safety Management Systems.
2. Manage cost in the global food system by eliminating redundancy and improving operational efficiency.
3. Develop competencies and capability in food safety to create consistent and effective global food systems.
4. Provide a unique international stakeholder platform for collaboration, knowledge exchange and networking.

Four popular GFSI benchmarked schemes available to food manufacturers viz. the BRC Global Standard for Food Safety, Food Safety System Certification (FSSC) 22000, International Featured Standards (IFS) Food standard, and Safe Quality Foods (SQF) Food Safety Code for Manufacturing. Benchmarking document requires scheme owners to develop standards that contain a core set of FSMS programs based on current, global regulation/ guidance and industry best practices. Some of these programs include a food safety (HACCP) plan, good manufacturing practices (GMPs), food defence plan, food fraud vulnerability assessment, and supplier management program. Each scheme offers a unique structure, set of requirements, and protocol for assessing a manufacturing site's food safety system to meet GFSI requirements. The BRC, IFS, and SQF schemes are product and process certification schemes, set forth specifications for the production of food products. FSSC 22000 is a management system certification scheme, sets forth requirements for implementing a system of policies and objectives that direct and manage food safety activities of the site.

FSSC 22000 includes the requirements of ISO 22000:2005 in addition to sector specific prerequisite programs (defined in ISO technical specifications) and nine additional requirements as stated in part II of the FSSC 22000 standard. ISO 22000:2005 is divided into five main sections covering (1) General requirements of FSMS, (2) Management responsibility, (3) Resource Management, (4)

Planning and realization of safe products (including HACCP), and (5) Validation, verification and improvement of the FSMS.

The GFSI Benchmarking requirements are always evolving. They are continually kept updated, adapting to changes in industry and government, reflecting best practices across the board from individuals to institutions. GFSI-recognised certification covers the entire Supply Chain – from Farm to Fork to ensure food safety.

References:

1. GFSI benchmarking requirements
2. Global Food Safety Initiative- Enhancing Food Safety Through Third Party Certification

Chapter 16

Traceability system in FSMS

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Introduction:

The horse meat scandal is known across world. This involved food products across Europe which was labeled as beef where it contained horse meat. Profit driven malpractice was identified by Irish food inspectors who revealed in mid-January 2013 that they had found horse meat in frozen beef burgers. This leads to the path for authentication of food products and open the horizon of thought of people to suspect about crime against food safety and human health. Such food frauds are being carried out in all kind of food stuffs including seafood. Seafood comprises of various species and after their processing it is very hard to know which species it is made of until it is not tested with modern analytical tools.

Food fraud

Food fraudis a significant and growing problem, driven by globalization, economic opportunity, and the low probability and severity of punishment. Analytical verification of food fraud and food authentication is needed to support proper food safety management systems. Food fraud is designed to increase the perceived value of both food and ingredients and is a growing concern in our global food supply**.**

“Consumers expect safe and nutritious foods. They also expect all participants in the supply chain to have effective practices in place that allow for the rapid identification, location, and withdrawal of food lots when problems are suspected or confirmed. The increased focus on food safety and consumer awareness raises the need for the identification and adoption of business practices that will aid the ability of the trading partners in the food industry to track and trace a product throughout the supply chain” (FAO, 2017).

A few of the recent, and possibly well-known, occurrences of food fraud include:

- Melamine or cyanuric acid found in infant formula and pet foods
- Fake food and alcohol seizures in EU borders
- Kiwi wine company accused of complex food fraud
- Exporting falsified hazelnut products to Germany from Georgia
- 75% seafood samples mislabeled with cheaper fish in place of more expensive across Canadian cities.
- Mislabeled giant squid as octopus in North America

DRIVERS for Food fraud

- Deliberate criminal fraud for financial gain (adulteration/substitution – premium products)
- Rising commodity prices
- Shortage of supply
- Raw material quality due to poor yields and variable composition
- Avoidance of tariffs
- Sustainability fishing

***Seafood Authentication*:**

Process that verifies that a food is in compliance with its label description is called as Authentication. This is necessary to preventing Food Fraud and quick Recalls of products distributed in markets.

Traceability is vitally important for food safety as well as operational efficiency. This will help to pinpoint the source of the issue and the scope of any potential incident.

Any deliberate action of businesses or individuals to deceive others in regards to the integrity of food to gain undue advantage. Types of food fraud include but not limited to: adulteration, substitution, dilution, tampering, simulation, counterfeiting, and misrepresentation. There are more than 8,100 (up to 2017) papers dealing with food authenticity have been recorded in the Science Direct database

***Seafood Traceability*:**

Seafood Traceability cab be defined as track and trace a product throughout the supply chain. This requires reliable analytical methods that can give a decisive answer about the authenticity of foodstuffs. This can also be called as measuring features that can discriminate foods of different origins.

There are certain authenticity indicators which includes Rare earth elements and precious metals, Microbial fingerprinting, Metabolomics fingerprinting and Sensory analysis

Food Traceability (terms & definitions)

- **Tracking" or "Tracing forward":** refers to pursuing in the downstream direction
- **"Tracing" or "Tracking back":** refers to pursuing in the upstream direction
- **Traceability system:** A series of mechanisms for traceability, by which "identification", "link", "records of information", "collection and storage of information", and "verification" are performed.
- **Traceable unit:** The unit used for identification. This unit is used when tracing and tracking. In some cases, a lot works as a unit and in others, an individual and/or individual product works as a unit

Timeline (Traceability and Authentication Definition)

1994: ISO 8402 Definition of Traceability-"The ability to trace history, application and location of an entity by means of recorded identification"

1998: Denis (1998) Definition of Food Authentication- "Food authentication is the process by which a food is verified as complying with its label description"

2002: The Food Safety Agency (FSA) basic characteristics for traceability system-
(1) Identification of units/batches of all ingredients and products
(2) Information on when and where they are moved and transformed
(3) A system to link these data

2004: CAC Definition of food Traceability-"The ability to follow the movement of a food through specified stages of production, processing and distribution"

2005: ISO 9000 Definition of Traceability-"The ability to trace the history, application or location of that which is under consideration"

2016: Danezis et al. defined Food Authentication as "Food authentication is the process that verifies that a food is in compliance with its label description. This may include, among others, the origin, production method, or processing technologies

Traceability systems in practice

The key factors to successfully implementing a traceability system within the seafood processing establishments include

• Full details of suppliers of raw materials and ingredients.

• Identification of individual batches by product coding till dispatch from factory

• Maintain batch separation throughout the processing and storage.

• Linking batch codes to production records for each process in the establishment.

Of the various different methods by which traceability can be achieved the following are provided as examples;

• Paper-based traceability

• Bar code/scanner systems

Technology-Enabled Traceability

Data Elements Specific data captured through the traceability system (e.g. origin, water usage, etc.)

Unique Identifiers An assigned unique identifier to the individual food product for tracking along the supply chain; examples include RFID tag or barcodes

Sensor Technology Real-time tracking of identified data elements through supply chain; enables automated data capture

Distributed Ledger Technology Enables easier aggregation, integration, analysis and sharing of data; today, ledgers are often completed using suboptimal paper based systems but can be significantly improved through technology adoptions

There are 7 principal ways a food or food ingredient can be adulterated to increase its perceived value:

1. Substitution
2. Unapproved Enhancements
3. Concealment
4. Mislabeling
5. Dilution
6. Counterfeiting
7. Gray Market

CURRENT FOOD AUTHENTICITY CHALLENGES

CATEGORY	**EXAMPLE**
Origin of food from sustainable sources	Palm oil, fish, exotic meats
Method of food production	Organic food
Substitution - Quantification of ingredients	Meat species in processed foods
Designation of geographical origin (Food Information legislation)	Meat, fish , composite foods
Specialty foods	Vanilla, saffron, honey, balsamic vinegar, Basmati rice
Adulteration - Alcoholic and nonalcoholic beverages	Fruit juices, wine, spirits
Miscellaneous	High protein foods

ANALYTICAL WAYS:

1. DNA-methods: DNA-based methods for food authentication depend on the highly specific amplification of DNA fragments by the Polymerase Chain Reaction (PCR). The advantage of genomics is that it can amplify minute traces of nucleotide material. The sensitivity of these methods are high since the amount of analyte required is in nanogram (ng).
2. Stable isotope analysis: The isotopic ratios are applicable to food authentication because stable isotope ratios change with the climatic conditions, geographical origin, soil pedology, and geology of the locations of food ingredients origin. The analysis of isotopic ratios uses various methods such as Isotope Ratio Mass Spectrometry (IRMS), Multi Collector – Inductively Coupled Plasma – Mass Spectrometry (MC-ICP-MS), and Thermal Ionization Mass Spectrometry (TIMS).
3. Proteomics: proteins can act as markers for many properties of the food products all along the food chain from farm to fork, and therefore proteomics can be applied for a systematic search of new marker proteins or peptides. Proteomics identifies specific products encoded by DNA. The sensitivity is very high since the amount of required material can be as small as a few cells.
4. Metabolomics: Metabolomics deals with the study of multiple metabolites in a cell, a tissue or an organism. Ultra-high performance liquid chromatography (UHPLC), high-resolution mass spectrometry (HR-MS) and software programs to process the large analytical data sets can be used.
5. Spectroscopy: Spectroscopy, in particular vibrational spectroscopy, is a fast and inexpensive method for both the assessment of food quality and food authenticity. Novel instrumental techniques combined with chemometric methods have enabled the development of rapid methods that apply multivariate (MVA) analysis, to near infrared (NIR) and mid infrared (MIR) data to analyze food matrices.
6. Metagenomics/Next Generation Sequencing: Metagenomic and metatranscriptomic have great potential in becoming valuable options for detecting food authenticity for a specific food product. Traditional DNA barcoding methodologies based on PCR and Sanger sequencing has limitation being low-throughput. Such limitations has been overcome by high-throughput NGS technologies including metagenomic approaches, which provide more information food product.
7. Sensory analysis: Traditionally reliable results in sensory analysis require a well-trained panel of human assessors. Organoleptic test panels comprise a set of techniques for accurate measurements of human responses to foods. Appearance, aroma, flavor and texture properties are important characteristics determining the quality authenticity of food products. These panels require extensive training of judges, adequate replication and detailed statistical analysis of the observations.

Current work – supporting testing and enforcement

Meat speciation

- DNA quantitation breed authentication
- Detection of offal and serum in meat products

- Gelatine speciation (water-retention, chicken plumping agents)

Fish speciation

- Geographic traceability
- EU harmonisation of fish DNA methods
- Nitrogen factors for fish quantitation

Technical Challenges in detecting Food Malpractices

- **3 key difficulties:**

1. Issue is linked to a legal requirement, standard or guidance; conclusion must be beyond reasonable doubt, but data interpretation is made against a background of analytical uncertainty, natural variation etc

2. Finding a marker that characterises the food, one of its ingredients, the adulterant(s), or the processing, production or geographic origin

3. Availability of authentic samples (databases)

Emerging authenticity indicators

Sl. No.	Indicators	Remarks
a.	**Rare earth elements and precious metals:**	○ Elemental fingerprinting targets groups of elements including macroelements (such as calcium, sodium, potassium), trace-elements (such as selenium, zinc, copper), rare earth elements (REEs, such as cerium, samarium and lanthanum), or other ultra-trace elements (such as precious metals platinum or gold) ○ ICP-MS (Inductively coupled plasma mass spectrometry) and ICP-OES (Inductively coupled plasma - optical emission spectrometry) can be used exclusively
b.	**Metabolomic fingerprinting:**	○ Quantitative analysis of the complete metabolome or selected subsets is called Metabolomics. ○ Metabolomics uses mostly nuclear magnetic resonance (NMR) and mass spectrometry (MS) analytical technologies ○ Gas chromatography mass spectrometry (GC–MS), Liquid chromatography mass spectrometry (LC–MS), ultra performance liquid chromatography (UPLC), QTOF-MS and Orbitrap-based technologies, High-Resolution MS (HRMS), Vibrational spectroscopic techniques (near-infrared or NIR, mid-infrared or MIR, and Raman spectroscopy
c.	**Microbial fingerprinting:**	○ Assessment of geographical origin can be achieved through microbial fingerprinting in non-processed foods (fruits, fish, wine, yoghurt).

		○ Microflora was found to be specific of the production system and microbial fingerprints were shown to differ between organically and conventionally grown fruits ○ Polymerase chain reaction-denaturing gradient gel electrophoresis technique, PCR-DGGE is usually used for microbial fingerprinting
d.	**Sensory analysis:**	○ Specialized panelists required with total sensory experience of food combines aroma, taste, texture, temperature, spiciness, appearance. ○ The instrumental sensory techniques electronic tongue (e-tongue), electronic nose (e-nose), electronic eye (eeye) and gas chromatography olfactometry (GCO) are used for objective sensory evaluations.

Opportunities and challenges for Food Authentication

Food authentication is an interdisciplinary area where has input from instrumentation, biology, informatics, mathematics and statistics, agriculture, and food technology are needed.

- Vast volumes of data are generated, but our ability to manage and analyze these date are falling behind the ability to generate these data.
- Mass spectrometry is a frontline technology rapidly replacing other methods in many fields of food science.
- Multi-analyte capabilities are essential for food authentication studies since they provide more descriptors and thus facilitate better classification.
- Programs are being developed and implemented to reduce food fraud, but these programs must continue to evolve in order to keep pace with the ingenuity of food fraud perpetrators.

Opportunities and challenges for Food Traceability

Global supply chain is complex system. Hence ensuring it as effective practices in place is an on-going challenge. One of the biggest traceability challenges goes back to recordkeeping. Without effective procedures to capture multiple dimensions of product information, it becomes difficult to track products and comply with recall requirements. One problem that hinders traceability and increases the scope and cost of recalls is the lag time between when a problem occurs and when a company detects it. Government regulation requires businesses to implement a food traceability system (record system, recall system, etc.)

Development of information technology supports implementation of food traceability system (IoT, Bigdata, machine learning, etc.) is the need of hour for effective implementation of traceability system for any food products.

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Chapter 17

Seafood Export and Trade Issues

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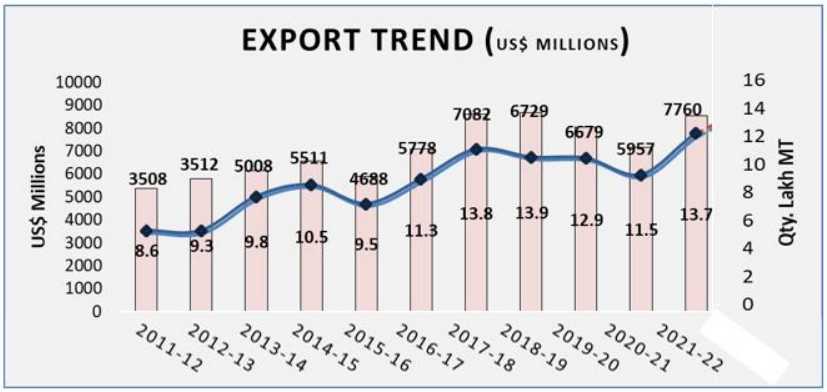
In 2021-22 India exported to 123 countries and the top 5 countries are USA, China, Japan, Vietnam and Thailand. The following figures illustrates the export performance of the marine products from India

Export Performance of Marine Products



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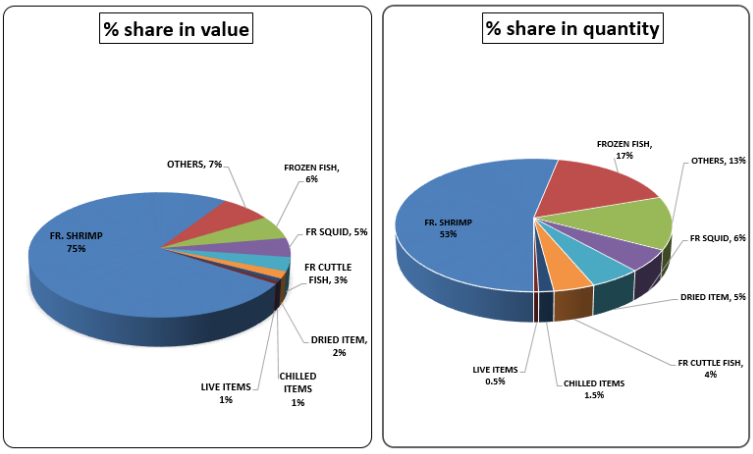

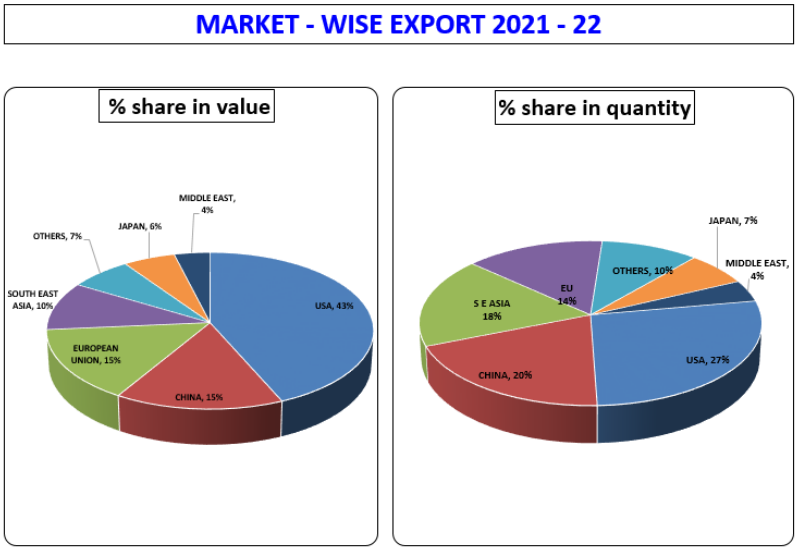

Sanitary & Phytosanitary measures

The word Sanitary means that measures relating to human or animal life or health while Phyto sanitary means those relating to plant life or health. There are three international standards setting bodies specifically mentioned in the SPS agreement. These are often referred as **"Three sisters"** and they are as follows:

1. **The International plant protection convention (IPPC) - dealing with plant health**
2. **The World Organization for Animal Health (OIE) – dealing with animal health**
3. **The Codex alimentarius Commission (CODEX) – dealing with food Safety**

World Trade Organization recommends that members must not use SPS measure that are Unnecessary, not science based, arbitrary or which constitutes a disguised restriction on International Trade. The key points of SPS are as follows:

- The SPS agreement recognizes the need for WTO members to protect themselves from the risk posed by the entry of pests and diseases but also seeks to minimize any negative effects of SPS measures on trade.
- The health aspect of SPS agreement basically means that WTO members can protect human, animal or plant life or health by applying measures to manage the risk associated with imports.
- The measures usually take the form of quarantine or food safety requirements.

Terms used in SPS agreement

Harmonization

WTO members are encouraged to base their SPS measures on international standards, guidelines & recommendations where they exist . The SPS Committee promotes and monitors international harmonization.

Equivalence

SPS agreement requires importing WTO members to accept the SPS measures of exporting WTO members as equivalent, if the exporting country objectively demonstrate to the importing country that its measures achieve the importing country's ALOP (Appropriate Level Of Protection).

Appropriate Level Of Protection (ALOP)

ALOP is the level of protection deemed appropriate by the WTO members to protect human, animal or plant life or health within its territory

Risk Assessment

The evaluation of livelihood of entry, establishment or spread of a pest or disease within the territory of an importing WTO member according to SPS measures which might be applied and of the associated potential biological and economic consequence.

OR

The evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease –causing organisms in food, beverages or feedstuffs.

Risk assessment is essentially the process of gathering scientific evidence and relevant economic factors on the risks involved in allowing a particular import to enter a country.

An importing member is likely to seek information on matters such as the pests or diseases that might be associated with the commodity for which permission to import has been sought, and if they are present in the exporting country, the type of question that might be asked as below:

- Does the pest or disease occur in your country?
- Have the pests or diseases been controlled?
- Are they restricted to particular parts of the country?
- How effective are procedures applied to ensure that the products for export are free from pests, diseases and other contaminants?

Regional conditions

WTO members are required to recognize the concepts of pest / disease-free areas and areas of low pests / disease prevalence.

Exporting WTO members claiming pest / disease-free areas or areas of low pests/disease prevalence must demonstrate to the importing WTO member that such areas are, and are likely to remain, pests / disease free areas of low pest / disease prevalence.

Transparency

SPS agreement requires WTO members to provide information on their SPS measures and to notify changes in the SPS measures. WTO members are required to publish their SPS regulations.

The notification requirements are met through a national notification authority. Each WTO member must nominate a national enquiry point to deal with SPS related queries from other WTO members.

The World Organization for Animal Health (OIE)

The objective of the world organization for Animal Health (OIE) include ensuring transparency in the global animal disease and zoonosis situation, publishing health standards for trade in animals and animal products, promoting veterinary skills, improving the safety of food of animal origin and promoting animal welfare through a **science based approach.**

OIE standards, guidelines and recommendations are contained in the **aquatic animal health code** and the **manual of diagnostic tests for aquatic animals.**

CODEX

- Codex has a dual mandate to protect the health of consumers and to ensure fair practices in the food trade.
- Codex develops and encourages implementation of standards, codes of practice, guidelines and recommendations covering all aspects of food safety, including handling and distribution.

SPS – Notification – Australia

Notification No. G/SPS/N/AUS/298 dt. 09/07/2012 (Bio security bill and the inspector general of Bio security bill)

As per Bio Security advice 2009/25, the imported prawns –

1. be sourced from a country or zone that is recognised by Australia to be free of WSSV, YHV, TSV and NHPB – Necrotising Hepetopancriatis Bacterium (the last disease agent, for unfrozen product only); or
2. have the head and shell removed (except for the last shell segment and tail fans) and, if not from a disease free source, have each batch tested on arrival with negative results for WSSV, and YHV; or
3. be 'highly processed', that is head and shell-off (except for the last shell segment and tail fans), and coated for human consumption by being breaded or battered, marinated in a wet or dry marinade, marinated and placed on skewers or processed into dumpling, spring roll, samosa, roll, ball or dim sum-type product; or
4. be cooked to a standard where all protein is coagulated and no uncooked meat remains.

Aquatic animal health certificate for import of seafood

The Canadian Food Inspection Agency (CFIA) brought out guidelines for import of aquatic animals on 10th December 2011 with amendments to Health of animals act. These new guidelines are operational from 10th Dec 2012.

As per this guidelines every consignment of aquatic animal into Canada must be accompanied with an aquatic animal health certificate by the competent authority for aquatic animal health services of the country of origin.

The aquatic animal health certificate must clearly certify **zoo sanitary requirements,** packaging and shipping requirements by competent authority.

Imposition of stringent standards for fish and fishery products by developed countries

The higher standards imposed by the developed countries becoming a major threat to exports of developing countries.

MRL of Ethoxyquin in shrimps under the Food Sanitation Law of Japan

Japanese authority responsible for ensuring the quality of imported food products into Japan has unexpectedly started examining the shrimp consignments from India for Ethoxyquin since August 2012. Japan have adopted the default standard as 0.01 ppm, as designated for parameters or residues that do not figure in the positive list introduced by Japan in 2006. Japan has fixed MRL for fish at **1ppm** whileNo MRL was fixed for shrimp.

Registration of Overseas enterprises and exporting companies in importing countries

The recent requirements of registration under US food safety modernization act and the AQSIQ of China is leading to procedural issues and adding documentation costs for seafood exporting countries in Asia including India. European Union, Russian Federation, Brazil, China etc. are following such kind of registration procedures in their countries to import the seafood from India. Some of these countries also reserve the right to inspect the establishments in India although stringent regulations are in place in India.

ITC HS

ITC-HS Codes or Indian Trade Classification based on Harmonized System of Coding was adopted in India for import-export operations. Indian custom uses an eight digit ITC-HS Codes to suit the national trade requirements. ITC-HS codes are divided into two schedules:

- Schedule I - Describe the rules and guidelines related to import policies
- Schedule II - Describe the rules and regulation related to export policies

The total number of chapters in the schedule I is 98. The chapters are further divided into sub-heading under which different HS codes are mentioned. Export Policy Schedule II of the ITC-HS code contains 97 chapters giving all the details about the guidelines related to the export policies. The marine products mainly come under chapter 03 and 16.

List of marine products coming under various HS code (4 digit level) is as below

Chapter	HS Code (4 digit level)	Description
03	0301	Live fish
	0302	Fish, fresh or chilled, excluding fish fillets and other fish meat of heading 0304
	0303	Fish, frozen, excluding fish fillets and other fish meat of heading 0304
	0304	Fish fillets and other fish meat (whether or not minced), fresh, chilled or frozen
	0305	Fish, dried, salted or in brine; smoked fish, whether or not cooked before or during the smoking process; flours, meals and pellets, of fish fit for human
	0306	Crustaceans, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine; smoked crustaceans, whether in shell or not, whether or not cooked before or during the smoking process; crustaceans, in shell, cooked by steaming or by boiling in water, whether or not chilled, frozen, dried, salted or in brine; flours, meals and pellets of crustaceans, fit for human consumption
	0307	Molluscs, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine; smoked molluscs, whether in shell or not, whether or not cooked before or during the smoking process; flours, meals and pellets of molluscs, fit for human consumption
	0308	Aquatic invertebrates other than crustaceans and molluscs, live, fresh, chilled, frozen, dried, salted or in brine; smoked aquatic invertebrates other than crustaceans and molluscs, whether or not cooked before or during the smoking process; flours, meals and pellets of aquatic invertebrates other than crustaceans and molluscs, fit for human consumption

Chapter	HS Code (4 digit level)	Description
05	0508	Coral and similar materials, unworked or simply prepared but not otherwise Worked; shells of molluscs, crustaceans or echinoderms and cuttle-bone, unworked or simply prepared but not cut to shape, powder and waste thereof
	0511	Animal products not elsewhere specified or included; dead animals of chapter 1 or 3, Unfit for human consumption: **Products of fish or crustaceans, molluscs or other aquatic invertebrates; dead animals of Chapter 3** ***(Fish nails, fish tails and other fish waste)***
12	1212	Locust beans, seaweeds and other algae, Sugar beet and sugarcane, fresh, chilled, frozen or dried, whether or not ground; fruit stones and kernels and other vegetable Products (including unroasted chicory roots of the variety cichorium intybus Sativum) of a kind used primarily for human consumption, not elsewhere specified or included : ***Seaweed***
13	1302	Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products : ***Agar-agar, Kappa Carrageenan***
15	1504	Fats and oils and their fractions, of fish or marine mammals, whether or not refined, but not chemically modified
16	1604	Prepared or preserved fish; caviar and caviar substitutes prepared from fish eggs
	1605	Crustaceans, molluscs and other aquatic invertebrates, prepared or preserved
23	2301	Flours, meals and pellets, of meat or meat offal, of fish or of crustaceans, molluscs or other aquatic invertebrates, unfit for human consumption; greaves : **Fish meal unfit for human consumption**
	2309	Preparations of a kind used in animal feeding: **Feeds for fish (prawn, etc.)**

Trade agreements: Review & Execution

Trade agreements	Way Forward
1. India - Japan CEPA 2. India - Korea CEPA 3. India - EU BTIA 4. India - Peru FTA 5. India - Mauritius CECPA 6. India - EFTA 7. RCEP Negotiation 8. India Australia Free Trade Agreement 9. India New Zealand Free Trade Agreement 10. India Canada Free Trade Agreement 11. India MERCOSUR Free Trade Agreement 12. India Eurasian Economic Union Trade Agreement	• **India EU FTA** : Early execution of India-EU FTA and reduction of tariff is urgently required for better market access of Indian seafood in EU. • **India-Korea CEPA**: It is understood that during previous review the duty for frozen shrimp was agreed to be reduced to 0% by South Korea with a quota restriction. This may be urgently brought into effect for getting duty benefit for exporting to South Korea. **This review and execution of FTA's on a fast track mode will facilitate India's export to these markets.**

Strategies to overcome SPS issues:

Various strategies to overcome the SPS agreement related issues are as follows:

- Prevent the usage of banned antibiotics like chloramphenicol, nitrofuran *etc.,* in food producing animals
- Competent authority needs to take steps to create aquatic disease-free areas/zones/region
- Use SPS as tool to counter the countries who are using SPS as a tool to restrict the trade
- Raise the SPS issues in bilateral trade meetings for market access
- Raise the SPS issue sin WTO SPS Committee meetings; and
- Active Indian participation in CODEX, OIE & IPPC proceedings

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Chapter 18

Establishment of FSMS in Seafood Industry:

Indian perspective

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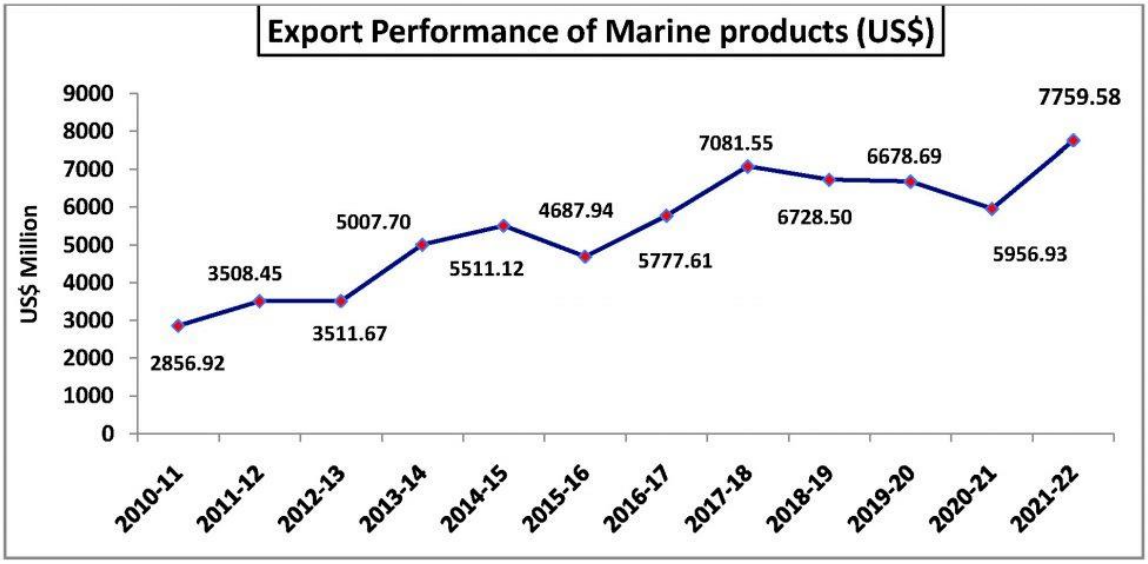
1. INTRODUCTION

Indian Fishery trade has expanded considerably in recent decades and this has been an important source of foreign exchange for the country, with total earnings of US$ 7.74 billion in 2022.The growth was 30% higher compared with 2020-2021 in dollar terms. This marked a quantum jump over the achievements during the previous years despite challenges of Covid 19 pandemic and other hurdles related to logistics, biosecurity and sustainability.

Table.1: Export Performance During 2021-22 compared to 2020-21

Export Details	2021-22	2020-21	Growth %
Quantity in Tons	13,69,264	11,49,510	19.12
Value in Crores	57,586.48	43,720.98	31.71
USD in Million	7,759.58	5,956.93	30.26
Unit Value (USD/Kg)	5.67	5.18	9.36



India is the second largest fish producing country in the world accounting for 7.56 per cent of global production. The seafood processing and export industry contributes significantly to the Indian economy in terms of employment and foreign exchange earnings. The fisheries and aquaculture

production contributes around 1% to India's Gross Domestic Product (GDP) and over 5% to the agricultural GDP. The marine product exports from India is targeted to reach USD 14 billion by 2025.

Frozen shrimp continued to be the major item of export in terms of quantity and value, accounting for a share of 53.18% in quantity and 75.11% of the total USD earnings. **Other Items** constituted by Surimi and Surimi analogue (imitation) products was the second largest category by US$. *Frozen Fish* is at the third largest position, *Frozen squid* & cuttlefish have shown a positive export trend.

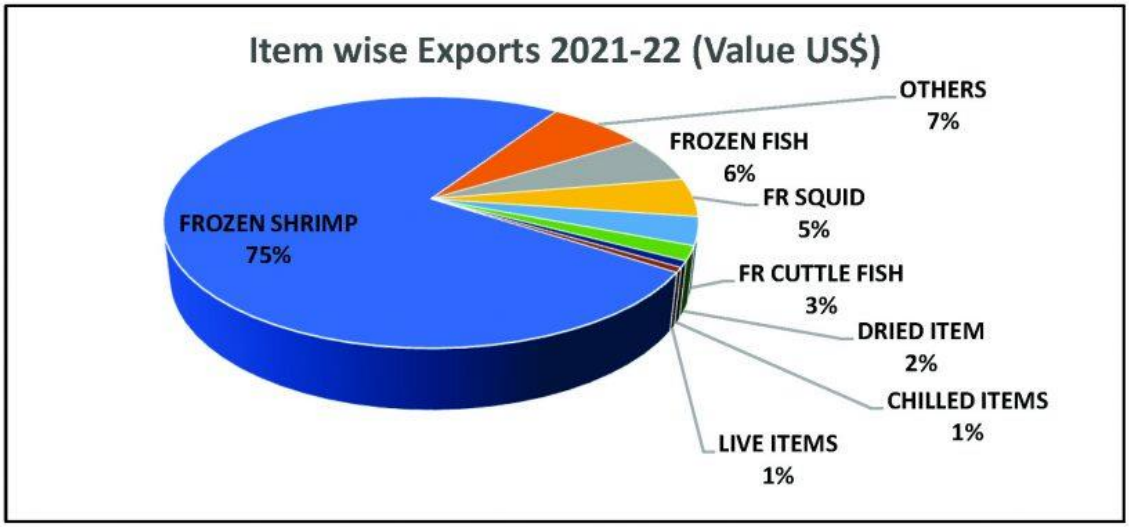


Figure.2 Item wise exports 2021-22 (Value US$)

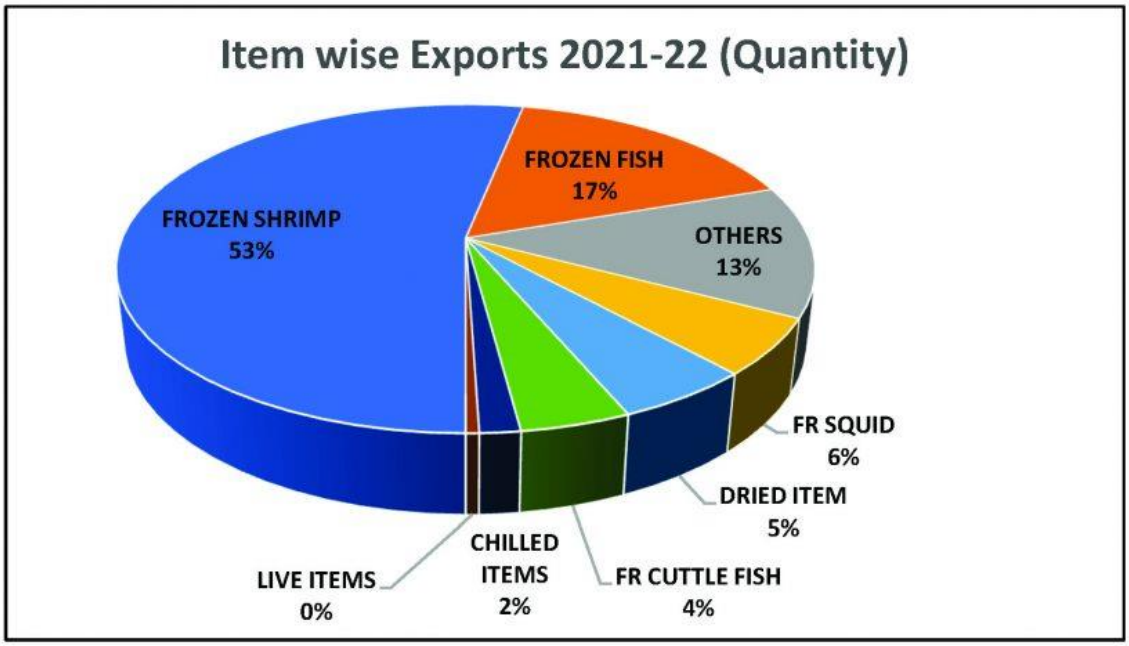


Figure.3 Item wise exports 2021-22 (Quantity)

Market wise export Details

India exported marine products to 123 countries

Historically, Indian exports of fish and fishery products have been directed at 3 major markets: the European Union (EU), Japan, and the United States. However, the Indian export destinations changed significantly over the years. *USA* retained the title as the major importer of Indian seafood with a share of 43.45% in terms of USD earnings. *China* continued to be the second largest market destination for Indian Seafood with a share of 15.14% in USD earnings. *European Union* continued to be the third largest destination for Indian Seafood with a share of 14.98% in USD. *South East Asia* is the fourth largest market destination of Indian Marine products accounting for a share of 10.04% in USD terms.

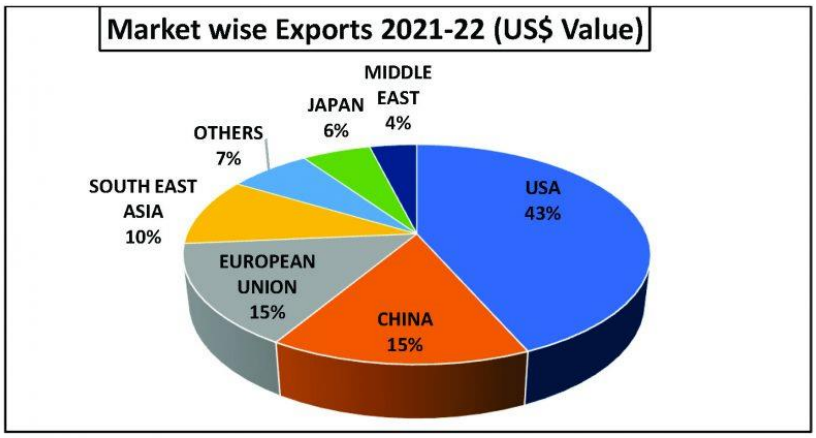


Figure.4 Market Wise Exports 2021-22 (Value US$)

Figure.5 Market wise Exports 2021-22 (Quantity)

Historically, India has faced a number of challenges meeting hygiene requirements forfish and fishery products in its major export markets, especially the EU and US. Throughout the 1980s and early 1990s, the major source of problems for Indian exporters was the US. While the processing sector expanded rapidly through the 1990s, hygiene controls did not keep pace with emerging requirements in India's major export markets. Since the mid-1990s,the major concern has been compliance with the

EU's requirements for hygiene throughout the fish supply chain, alongside the U.S. requirements for HACCP to be implemented in fish processing facilities.

2. EVOLUTION OF QUALITY CONTROL SYSTEMS IN INDIA – GOVT INITIATIVES

When India started exporting frozen seafood in 1953, there was no scientific quality control system prevailing. Later, Govt. of India decided that the consignments exported from India have to meet certain predetermined and specified standards of quality. Compulsory pre-shipment inspection of frozen shrimps was introduced on 15' September 1964 as per the provision of section 6 of the export (Quality control and Inspection) Act 1963. According to this system of inspection, the exporters willingly subjected their products to prescribed standards. Then, the export of marine products was brought under compulsory inspection system with effect from 15"' March 1965. In 1969, the scheme was taken over by Export Inspection Agency (EIA). Bacteriological requirements were added in 1975 .

In the consignment inspection, for a commodity to be inspected under this system, the exporter applies to the EIA for inspection and issue of export certificate. The inspection agency carried out inspection adopting laid—down techniques to ascertain whether they met the prescribed standards. Based on the inspection results, certificate of export worthiness was issued by the EIA. The end product might have been produced to the notified requirements and it cannot enquire into the conditions under which these products had been manufactured. In 1977, a revised notification was introduced stipulating various requirements to be implemented by the processing units for ensuring hygiene and wholesomeness of the product. Under the provisions of the notification of the In-process Quality Control (IPQC) scheme of fish and fishery products, a panel of experts had been constituted to assess the facilities prescribed therein. Based on the recommendations of the panel, the units were declared as approved or non-approved.

Another change was the introduction of a new system- Modified In-process Quality Control (MIPQC) scheme. For the approval under this system of inspection, it is the sole responsibility of processors themselves to exercise total surveillance of their units under the guidance of Export Inspection Agency to ensure organoleptic and bacteriological quality of the product. However, in the case of all the above systems of inspection, the Export Inspection Agency issues certificate of export worthiness. The Pre-Shipment Inspection and Quality Control manual published by EIA from time to time gives the instructions and procedures to be followed under this scheme.

Subsequent to the rejection of a few tonnes of Indian shrimps by Japanese Quarantine Authority due to the contamination of cholera germs, Vibrio cholerae detected in frozen shrimp consignments exported to Japan more stringent measures were taken by the EIA. Modified In-process Quality Control scheme is re-titled as In Process Quality Control, under this scheme. Only those processing units already approved under QCIA system and have some additional infrastructure facilities are allowed to export. This modified system of IPQC scheme was introduced as per the notification of Government of India dated 9.4.1988. The IPQC system was re-titled as Quality Control Inspection in Approved Units (QCIA). The establishment of HACCP cell by the Government of India in 1996 to assist the effective implementation of HACCP in the fishing industry is marked as the first proactive move by the Indian government to enhance food safety controls in the fish and fishery products sector.

3. DETENTIONS AND REJECTIONS OF INDIAN SEAFOOD IN INTERNATIONAL MARKETS

With the entry of WTO as an international regulatory body on the transnational trade of goods and services, the global trade environment has undergone a drastic change and has impacted India's export of marine products too. Consequently, the agreement on Sanitary and Phytosanitary (SPS) measures has emerged as a major determinant to the flow of agricultural products, particularly marine products to the international market. (Shinoj, Ganesh Kumar, Joshi &Dutta, 2009). Inspite of the comprehensive food safety measures initiated by the Indian government, rates of border rejections have increased over time. Although seafood exports from India is witnessing a phenomenal growth, quality issues are also on the rise.

Food safety requirements related to general hygiene and specific microbiological and chemical contaminants in fish and fish products are subject to change over time in response to emerging problems, advances in scientific knowledge, consumer concerns, and political pressures. Recognizing this, various countries have put in place stringent rules and regulations to ensure the quality of imported fish and fishery products.

Regulatory requirements for fish quality have been laid both for sale within the country(FSSAI), and for export by the national authorities(Export Inspection Council), and the importing countries European Union(EU Directives), China (GACC), US (Food & Drug Administration), Saudi Arabia(SFDA), Russia(FSVP), specific requirements for Japan, Australia etc.

Sl No	Hazard category	Specific cause for RASFF alert
1.	Residues of veterinary drugs	Furazolidone (AOZ),Nitrofurazone(SEM), Oxytetracycline, Chloramphenicol, Leuco malachite green
2.	Non pathogenic microorganisms	High aerobic plate count, Coliforms, Enterobacteriacea, Enterococci
3.	Pathogenic micro organisms	Vibrios, Salmonella, Listeria
4.	Heavy metals	Cadmium, Mercury, Lead
5.	Food additives & flavourings	Ascorbic acid, Sodium carbonate, Sulphite residues, Allura red, Sorbic acid, E160b Annatto, Bixin/Norbixin, E122 Azarubine
6.	Biocontaminants	Histamine
7.	Labelling	Insufficient/incorrect labelling
8.	Adulteration fraud	Improper Health certificate
9.	Packaging defects	Defective packaging / Pest infestation
10.	Organoleptic aspects	Altered organoleptic characteristics &abnormal smell, spoilage & temp control
11.	Virus	SARS COV 2 virus
12.	Foreign bodies	Faeces: defective packaging and infested with insects, foreign body(scraps of paper, cardboard, wire ,wool, hair and insects)

4. THE EVOLUTION OF PRIVATE/VOLUNTARY CERTIFICATIONS IN KERALA SEAFOOD EXPORTINDUSTRY.

Major share of the Kerala seafood export is contributed by marine capture, with exports dominated by frozen shrimp and cephalopods. With the diversification of Indian marine exports and the increase in the export of processed and value-added seafood, the challenges due to food safety are also on rise. Concerns over numerous rejections of Indian seafood exports on food safety rounds have generated greater attention to pervasive food safety problems in the supply chain including high levels of chemical residues, presence of heavy metals, and microbial contamination. The supermarket sector has risen to have an important impact and often dominant share of food retailing, commonly 70 per cent in developed countries (FAO, 2011a). The present seafood value chain in Kerala is buyer driven or direct network.

The exporters have little bargaining power and get subjected to pressure from the importers and chain managers to change the production method, cut labour cost, impose new standards related to safety, quality etc. so that the retailer can maximize the commercial advantage of the relationship. (Somasekharan, Harilal& Thomas 2015).

The food quality and safety management systems have evolved as the key driver for the organization and management of food production systems in the agribusiness and food industry. Particularly for high value agricultural and food products food safety and quality concerns dominate the competition than the price (Busch & Bain, 2004). The widespread adoption of these FSMS by the food retail and commercial sectors has led to the proliferation of such systems, each with its own standards, accreditation, auditing and certification processes. Private food standards are playing an increasingly important role in food safety governance and determining market access in international trade. The adoptions of these standards in agribusiness are so widespread that they have become de facto mandatory as ignoring them is tantamount to losing a significant share of the market (Bush and Bain, Henson, 2007: Fuchs &Kalfagianni, 2010). These labelling and certification programmes can be considered as an important strategy for diversifying a product to make it seem different from others.
Private food safety standards are generally set by private firms and standard setting coalitions and aim to facilitate supply chain management within an increasingly globalised and competitive international food market. The main drivers for the proliferation of these private food safety schemes have been: the clear assignment of legal responsibility to food chain operators for ensuring food safety; increasingly global and complex supply chains; and, increasing consumer awareness of food and food systems and their impact on health and, in particular, on food safety (FAO, 2010).

Private/voluntary food safety certifications in Kerala seafood export sector started from 2001. Every fish processing establishments, that has implemented the mandatory HACCP based quality and safety management programme, get certified by these private certifying bodies too. The exporting companies opting for the private food safety systems were on rise since 2001.

RELEVANCE OF FOOD SAFETY CERTIFICATIONS

A food business having a food safety certification assures to the consumers and the marketplace that it has successfully met the requirements of a national or an internationally recognised best practise approach. Effective food standards and control systems are required to protect food production within

the country as well as to facilitate trade with other nations. All food manufacturers are required to meet the given standards of quality and safety, and need to have their products regularly tested. Food Safety Certification validates that the food business is managed by following healthy practices that ensure safety and quality.

Advantages of an FSMS

- Continuous prevention of foodborne illness and related public relations disasters.
- Food safety compliance during routine inspections.
- Improved inventory control.
- Reduction in product loss.

More consistency in product preparation and improved product quality.

5. FSMS CERTIFICATIONS

The FSMS certifications most prevalent are ISO 22000:2015,(International Organisation for Standardisation), BRC (British Retail Consortium), FSSC 22000(Food Safety System Certification), IFS(International Featured Standards), & GAA-BAP (Global Aquaculture Alliance/Best Aquaculture Practices)

There has been a shift in the preference for the newly certified companies to FSSC 22000 which combined ISO 22000 with PAS220:2008 and five additional requirement. The number of BAP certifications also shows a recent hike with the increase dependency on aquacultured products to meet the buyer demands. 25% of the total seafood exporting firms in Kerala are certified against any one of the private /voluntary standards and the process is still going on.

Companies that choose to become certified have a choice among different private standards, hence a regime of competition exists among standards. In some cases, companies go for multiple certifications too, 50% of the certified companies in Kerala own multiple certifications. 90% of the certified companies supplied the processed or value added seafood products to the buyers who supplied to the large supermarkets in the developed countries and the rest of the 10% companies supplied the products directly to the markets with their packaging specifications and logo.

5.1. International Organisation for Standardisation

ISO, the International Organization for Standardization, is an organisation editing several standards regarding processes and systems for many different businesses. ISO 22000:2015 is a quality management system addressing food safety issues in food production and can be applied to all types of organization in the food chain. ISO 22000 integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by the Codex Alimentarius Commission. ISO 22000 requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed. ISO 22000:2015 is not recognized by GFSI due to the lack of technical specification for sector PRPs.

5.2. British Retail Consortium (BRC)

Developed by the British Retail Consortium for companies providing retailer branded products in 1996 to use their due diligence defense as per the legal requirements of EU General Product Safety Directive and the United Kingdom Food Safety Act in a food safety failure. It is a global standard that covers manufacturing, storage and distribution, packaging, and consumer products. The BRC standard for food safety is based on systems for quality management , HACCP and GMP and includes requirements for routines regarding quality management (BRC Global Standards,2011).

5.3. Food Safety System certification 22000 (FSSC 22000)

FSSC 22000 is developed by the Foundation of food safety certification, with the support from Food and drink industries of the European Union (CIAA) (Bureau Veritas, 2007). The FSSC 22000 combines the ISO 22000 FSMS with a set of prerequisite program requirements (ISO/TS 22002:1:2009 (PAS 220/2008)). PAS 220 was developed to specify requirements on prerequisite programs (PRP) to control food safety hazards during the food processing and to support management systems implemented to fulfill the ISO version. FSSC can be applied to a wide range of food manufacturing organisations irrespective of their size or complexity.

5.4. International Features Standard (IFS)

Developed by German retailers group in 2003 to audit food manufacturer's product, food safety and quality of processes. IFS have developed standards not only for food safety but for logistics, household and personal care products, brokers and wholesale business (IFS, 2010).

5.5 Best Aquaculture Practices

The certification scheme developed by the Global Aquaculture Alliance (GAA) is one of the most significant aquaculture schemes in terms of volumes and global coverage. The standards cover requirements for environmental sustainability, community and social welfare,animal welfare, food safety and traceability in a certification programme for aquaculture facilities. Certified producers are entitled to use the "BAP certification mark"; a label attached to products from certified fish farms. Both farms and processing facilities can be certified.

COMPARISON OF GFSI SCHEMES

Table 1 Key Features of Private Food Safety Standards and Related Schemes prevalent in Keralacompared with relevant Codex standards (FAO, 2010)

	GFSIbenchmarkedSchemes				**InternationalStandards**	
	BRC	IFS	FSSC22000	GAA-BAP	ISO22000	CODEX HygienePrinciples&otherrelevantcodes
Geographic focus	British market	German, French andItalian	Europe	International	International	International

		market				
Owners	British retailmembersand tradeassociations	German,Frenchand Italianretailassociations	Foundationfor Food SafetyCertification	Non-ProfitTradeAssociation	InternationalStandards Organization	FAO/WHO
Members include	Tesco,Sainsbury's,Marks andSpencers	Carrefour,Tesco, Ahold,Wal Mart,Metro,MigrosandDelhaize	Standardbased on ISO22000 &BSI PAS220	Standardsbased onISO19011:2002 ISO/IEC Guide7:1994 ISO/IEC Guide65:1996 ISO/IEC Guide17065:2012 ISO/IEC Guide2:2004 ISO9000:2005 GFSI GuidanceDocument-Issue5 and Issue6	105 memberbodies (oneper country)from Publicand privatesector. Pluscorresponding andsubscribingmembers	180 Membersstates Plusobservers
Endusers (who applythestandard)	Foodmanufactures	Foodmanufactures	Foodmanufactures	Foodmanufactures	Entire foodchain	Entirefoodchain

Table2 GFSIrequirementscoveredintheKeyGlobalFoodsafetystandards(www.sgs.com)

GFSIRequirements	FSSC22000	BRC	IFS	GAA-BAP
	FSMS	Food Safety and QualityManagement System	Quality Management System	Quality Management System

Food SafetyManagementSystem	Management responsibility	Senior managementcommitment andcontinualimprovement	Seniormanagementresponsibility	Managementresponsibilityandcommitment
	Management ofresources	Personnel	Resource management	Resource management
	Planning andRealisationofsafeproducts	Food Safety and QualityManagement System,Productcontrol	Productionprocess	Purchasing andspecification
	Validationverification andimprovement ofFSMS	Internal audit, correctiveandpreventiveactionandcalibration	Measurement,analysis andimprovement	Correctiveandpreventiveaction
Good Manufacturing Practices(GMP), GoodDistribution Practices(GDP), GoodAgricultural Practices(GAP)	Planningand Realisationof SafeProducts PAS220	Sitestandard,Product control,Processcontrol, Personnel	Humanresources, Foodhygiene requirements (Clauses4.6-4.18)	FoodSafety (Clauses5.5-5.12)
HazardAnalysisCritical ControlPoint	Planningand Realisationof SafeProducts Validation,VerificationandImprovement of FSMS	Foodsafetyplan-HACCP	HACCP	Foodsafety-HACCP compliance, Control of non-conformity

6. CONSTRAINTS FACED BY EXPORTERS IN FSMS IMPLEMENTATION

1. Non Harmonisation of standards
2. Recurring Cost of Certifications
3. Inadequate Trained Manpower
4. Insufficient Financial Resources
5. Infrastructure and Lay out

The developing countries including India are mainly concerned about the investment andrecurrent cost of compliance involved in establishing these private food safety standards andcertifications. The lack of administrative, technical and scientific capacities to comply withemerging requirements also presents potentially barriers (Jaffee and Henson, 2004). Indianseafood exportsector however considersthesefood safety standardsasan opportunity, inspite of the arguments that are prevailing in the international markets as to whether these foodsafety standards facilitate trade or serve as a However, the stakeholders in the private sector strongly vouch thatfactoriescertifiedwithISO/EU/BAP/BRC etc have an edge over the others.

7.Outlook for 2022-23

Department of Commerce has fixed an ambitious target of US$ 8,868 million for marine products export for 2022-23, which require a growth rate of about 15% over the previous year to achieve the target. To achieve this target, joint efforts by the government and private sector is required.

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Chapter 19

Innovative Extension Approaches for Technology Dissemination in Fisheries

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Status and trends in aquaculture and fisheries

In the context of current challenges in food production, nutritional security, social transitions and growing climate uncertainties, fish and aquatic animals play important role to maintain the status quo. Global fish production has attained a target of 179 million tonnes in 2018 with an average annual growth of around 6 % in aquaculture and is expected to be increased to the extent of 186 million tonnes by the end of 2030. On the contrary, the trend of Indian fisheries has achieved a big leap in fish production during last seven decades witnessing a quantum leap in production i.e. from 0.75 million tonnes (1950-51) to 14.2 million tonnes (2019-20). Today, it shares about 7.7 % of the total global fish production and has established its dominance in global fisheries scenario as the 3rd largest in total fish production and 2nd in aquaculture production with an average annual growth rate of 14.8%. Out of total global production, around 87 % (156 million tonnes) accounted for human consumption covering more than 3.1 billion people in world (FAO, 2016). Mostly the developing countries account for over 60% of global fish catch, about 50% of global fishery exports in value terms and more than 60% in quantity.

In the livelihood sector, at global level about 59.6 million people are directly employed in fisheries and aquaculture at global level and more than 200 million engaged along the value chain in various upstream and downstream activities from production to distribution (FAO, 2016). In India, it provides livelihood security to more than 25 million (2018-19) of fishers and fish farmers at the primary level and almost twice along the fisheries value chain. Besides, about 84 percent of the globally engaged population in fisheries and aquaculture sector are in Asia, followed by Africa (almost 10 percent), and Latin America and the Caribbean countries (4 percent).

Despite the significant contributions of this sunrise sector, global debates on fisheries issues and policies appear to be dominated by concerns over environmental sustainability, overfishing and overcapacity. In this context, it is alarming to note that the sector has not received adequate attention from the social scientists to understand its various socio-economic dynamics to prove the fisheries sector as a potential driver of local and national economic development.

Problems in small scale fisheries

Small-scale fisheries are normally characterized by low capital input activities, low capital investments, lack of equipment and labor-intensive operations followed by traditional fishers. They also usually operate as semi-subsistence, family-based enterprises, where a share of the production is kept for self-consumption (Garcia et al., 2008). Traditional fishers dominate the marine sector and they are socially deprived, educationally weak with very high occupational rigidity. There is inequity in the distribution of yield and effort in marine fishing in case of traditional fishing communities. They are unorganized with least social security. The informal social security system in the form of sharing of

earnings among the community prevailing in the traditional fishing is hardly seen in the mechanized fishing. There are also huge regional variations in productivity among them.

Technologies are the main drivers of growth. Hence, systematic technological interventions backed by appropriate policy and institutional support are vital for making the aquaculture operations sustainable and economical. Generally, the technologies and trade interventions reinforce each other which can be characterized as skill-based, cost effective, capital intensive, cost-sharing; which can bring a change in the performance of the sector. Hence, there is an urgent need to reform that agriculture allied sectors in holistic, scientific and systematic approach to meet the recent challenges due to climate change and global competitiveness so as to achieve sustainable production and growth under different agro-climatic conditions. Keeping eye upon this, some of the advanced extension techniques have been suggested for an accelerated fishery development with focus on poverty alleviation of poor fishers.

Revamping extension systems for sustainable fisheries

The role of extension in fisheries cannot be ignored. Strong extension system is the key to bring the desired changes to meet the present day challenges related to sustainable fisheries. Basically, the end product of the fisheries extension system is to work with fisheries within an agro-climate and economic environment by providing suitable technologies to enrich knowledge and upgrade skills to improve better handling of natural fish resources and applying the cutting-edge technologies to achieve desired production level. Extension system plays a pivotal role in empowering fishers and other stakeholders to make fish farming more participatory, demand-driven, knowledge intensive and skill supportive for disseminating most appropriate technical, management and marketing skill to improve profitability in fisheries that can overcome the emerging challenges and concern, thus developing a synergistic pathway for enhancing productivity along with quality produce in order to sustain production base and ensure ecological and livelihood security. The extension system needs to disseminate a broad array of information starting from farm to fork in an integrated manner for safe delivery from field to the consumer considering all the aspects of conservation and production technologies, post-harvest management, processing and value addition. Such knowledge based decision should be incorporated in reshaping of extension approaches. In present scenario, the extension system envisages a transformation from technology driven to market driven extension, where fishers would give emphasis on commercialization of fish and fish based products, maintenance of quality, fulfilling consumers' demands, etc., in the program planning process for the effectiveness of any extension programme.

Advanced extension techniques for technology dissemination in fisheries

With the advent of global competitiveness and market liberalization, our prevailing extension system has become defunct, which needs to be strengthened with innovative extension techniques to tackle the interwoven challenges in fisheries viz., enhancing production, climate change, weather aberrations, dwindling resources, quality and safety of products, growing market demand, entrepreneurial opportunities in fisheries, conservation of environment and international trade promotion etc.; so that fishers can adjust their production portfolio keeping eye upon the emerging trends in food consumerism in domestic as well as global markets. In India, in the course of development, many different models for transfer of technology have been tested and some robust extension approaches have been tested and validated. Furthermore, the frontline extension system of the country has been revisited and

sharpened through fishers oriented approaches for technology adaptation and dissemination. As a result, the extension system in India has been designed to move beyond technology and beyond commodity through reciprocal fishers-research-extension linkages for sustainable growth and livelihood security of the farmers. In order to streamline this mechanism, a conceptual framework has to be developed in response to recognizing and considering different livelihood assets viz., human, social, physical, natural and financial resources. In general, fish farmers suffer from lack of access to appropriate services like credit, inputs, market, extension, technologies etc. Therefore, participatory technology development and participatory extension approaches emerged as a part of integration of the 'interdependence model' and the 'innovation systems framework' that offered more inclusive ways of involving the institution in technology generation, customization and diffusion. Some of the following innovative and advanced extension techniques validated through research systems must be adopted on trial basis to make fisheries more lucrative and sustainable.

a. Asset Based Community Development (ABCD) approach

Conventionally, poor people consider themselves as the impoverished population with certain needs for development that can only be resolved by various supporting agencies. But Asset Based Community Development (ABCD) approach intends for the development of community based on the principle of identifying and mobilizing individual and community 'assets', rather than focusing on problems and needs. It is an extension approach in which a community's micro-assets are linked with its macro environment. It believes that communities can initiate and sustain the process of growth and development themselves by recognizing and harnessing the existing, but often unrecognized assets, and thereby promoting local economic potential to drive its development process (Rans & Green, 2005). The approach is optimistic in nature, because the focus is on 'what is possessed by the community, rather than the problems of the community." The focal point in this approach is asset and not the need of the community. Assets of individuals, associations and institutions are identified after an extensive survey and assets are then matched with the need of the people to empower communities to control their futures and create tangible resources such as services, funds and infrastructures etc. (Foot and Hopkins, 2010. In fishery, ABCD approach gives greater emphasis on reducing the use of external inputs and on a high degree of social mobilization in which the assets of the poor (social, physical, financial as well as human) can be utilized to bring sustainable livelihoods in fisheries through number of different fishery related activities.

Five Key Assets in ABCD

As per ABCD approach there are 5 categories of asset inventories such as individuals, associations, institutions, physical assets and connections

1. **Individuals:** Every individual has got certain assets, gifts and qualities; such individual is at the center of ABCD approach.
2. **Associations**: Groups of people working with a common interest are critical to community mobilization.
3. **Institutions:** The assets of institutions help the community capture valuable resources and establish a sense of civic responsibility.
4. **Physical Assets**: Physical assets such as land, buildings, space, and funds are other assets that can be used.

5. **Connections:** These are the exchange between people sharing their assets by various methods.

b. Rural Advisory Services (RAS)

Rural Advisory Services (RAS) refer to all the different activities that provide the information and services needed and demanded by farmers and other actors in rural settings, to assist them in improving their livelihoods by developing their technical, organizational and management skills and practices (GFRAS, 2011; FAO, 2010). RAS must be designed to provide the information related to farm, organization, business management etc. recognizing the diversified actors involved in extension and fields advisory works (public, private, civil society); knowing the need of fishers, fish farmers' producer organizations (FFPOs), fishermen cooperatives and rural communities beyond technology related information and explaining them the role of facilitation and brokerage in rural development and value chains. In the case of aquaculture, large-, medium- and small-scale fishers need different types of RAS support. The large aquaculture farms are mostly self-reliant and need only regulatory support, while medium-sized farms need mobilization and facilitation support in addition to regulatory support. Small aquaculture farms need more education and input provision alongside facilitation (Kumaran, 2014). Timely sharing of research recommendations can address the problem of technology information for the fishers. In this direction, innovative extension strategies are being formulated keeping the fishers' needs and capacities in mind to pass on appropriate technologies by combining Internet, telecommunications, video, and print technologies that may bridge the information gap and empower fishers to make better production and marketing decisions (McLaren et al. 2009).

In fishery sector, RAS helps in

- Providing management and business development support appropriate to the scale, resources and capacities of each fisherman.
- Better understanding markets (prices, products, seasonality, standards, value addition etc.) related to fish and fish products.
- Linking fishers to other stakeholders involved in provision of varied support and services.
- Creating platforms to facilitate interaction and sharing among the various stakeholders including FFPOs to ensure coordinated support to fishers.
- Exploiting information communication technologies (ICTs) to provide fishers with a range of information related to weather, prices, extension programmes and generic information regarding fisheries.
- Facilitating the formation of FFPOs and also collaborate with FFPOs to strengthen the demand and supply side of RAS.
- Promoting institutional and policy change to enable and support small-scale fishery.

RAS encourages the formation/ organisation of groups by involving individual fishers, who have little influence over the social, economic and political processes affecting them, but as a group/ organizations and networks they can deal with their specific challenges. This can act as a platform to articulate concerns, exchange knowledge, influence policies and engage in collective action so that their livelihood remains sustainable and profitable. Effective formation of Rural Resource Centres (RRCs), Fishermen Cooperative Society, Fish Farmers' Producers Organisations (FFPOs) can be instrumental

by galvanizing collective action in order to ensure better access to markets and to support innovation by their members in related activities (Sundaram, 2014).

c. Model Village System of Extension (MVSE) approach

MVSE is an integrated and holistic extension approach where community participation is prioritized for suitable technological interventions in the fisheries to bring all-round development in fisheries sector in terms of socio-economic upliftment, technological empowerment, self-governance thereby enhancing the futuristic knowledge base and skills through participatory framework. MVSE emphasizes on involvement of all stakeholders in the process to converge their activities with a stake in the food value chain linking producer to consumer. Nevertheless, MVSE is an action research taken up in fishers' farm based on the principle of leveraging the activities, investments and resources from outside agencies/ externally aided projects resulting higher productivity, ensuring food security and sustainable improvement in overall quality of life by promoting leadership, self-dependency of the community in food chain. Economically viable, ecologically compatible and socially acceptable suitable technologies are successfully intervened in a cluster approach through participatory mode by integrating the multi-disciplinary research. The cluster of villages is adopted as model village, the success of which is later replicated to other villages. The village is developed as a commodity village branding for a particular commodity in the market.

MVSE approach works on the following principles:

- Promotes self -governance among the fishers
- Skill improvement and leadership development among the fishing community.
- Establishing linkage through pluralistic convergence of multiple stakeholders associated in the sector.
- Encouraging the market opportunities through commodity based village development (CBVD).

d. Farmers Field School (FFS) approach

The FFS extension approach is an alternative to the top down extension approach which was evolved as a method to solve complex field level issues in fisheries sectors. FFS aims to build fishers' capacity to analyze their production systems, identify problems, test possible solutions, and eventually encourage the participant member to adopt the practices most suitable to their farming systems (FAO, 2003 c). This is a learning-by-doing approach which emphasizes group observation, discussion, dissection, modification, and promotes field-based experimentation, analysis for collective decision making followed by actions. The FFS approach is an innovative, participatory and interactive learning approach that emphasizes problem solving and discovery-based learning. FFS also provides an opportunity to fishers to practice and evaluate sustainable resource use technologies, and adoption of new technologies by comparing with their conventional technologies developed in congruent with their own tradition, culture and resource use pattern. The goal of FFS approach is such that, after observing and comparing the results of field level experiments, fishers will eventually "own" and adopt improved practices by themselves sidelining the conventional ones without any external compulsion. Field day is being organized at the end of the season to give visibility to the entire activities to convince the non-adopters. Exchange visits with other FFS is also encouraged to learn by association and comparison A group of 20-25 fishers can form a Farm School under the guidance of a FFS facilitator. Extension workers, NGO workers, fishermen co-op members or previously trained fishers can become Farmer

Field School (FFS) facilitators. The facilitators are trained by master trainers, who have expertise in the particular subject matter. FFS is a time bound activity usually covering one production cycle or a year.

It is also significant to note that irrespective of the merits of the technology, the acceptance to technologies is influenced by the extension methods. Farmer Field School (FFS) model has been accepted as a good extension technique because of its exclusively participatory nature. FFS was also found to be effective in avoiding barriers like socio- economic constraints, infrastructure problem and incompatibility of technology for the adoption of sustainable fishery practices.

The basic component of FFS is setting up of a Participatory Comparative Experiment (PCE), commonly referred to as Participatory Technology Development (PTD), whereby the fishers put the FFS concept into practice under close monitoring and supervision by the FFS members. A PCE can be developed in the field of agriculture, livestock, fishery, forestry, agro-forestry, livelihood system and others.

Principles of Farmer Field School (FFS)are as follows: -

- Field is the learning place.
- Emphasizes hands on and discovery-based learning.
- Farmers become experts.
- Integrated and learner defined curriculum.
- Doing is better than learning/ seeing.
- Experiences are the start of all learning.
- Link to actual field situations and should be relevant to local needs and problems.
- Participatory monitoring and evaluation.
- Fishermen are decision makers.

e. Market Led Extension (MLE) approach

In order to make farming more enterprising, extension professionals need to be pro-active beyond the regular objective of maximizing the productivity of the fishers by transferring improved technologies rather fishers should be sensitized on various aspects of farming like culture, harvest, quality, processing and value addition, consumer's preference and market intelligence. This will help the fishing community to realize high returns for the produce, minimize the production costs, and improve the product value and marketability that may lead to realize the concept of doubling farmers' income (DFI). With the globalization of agriculture, emphasis on productivity and profitability to the farm enterprises has been increased and, therefore the demand- driven agriculture (and allied sectors) has led to the paradigm shift from production-led extension to market- led extension. There are many challenges in the agricultural marketing system, which can be resolved through the efforts of market- led extension models.

In this approach, fishers are viewed as 'Fish-entrepreneurs' who expects high returns 'Rupee to Rupee' from his produce by adopting a diverse basket of package of practices suitable to local situations/ farming systems with optimum cost benefit ratio (C:B ratio) ensuring maximum share of profit by exploring the market demand. Goal of market led extension is to facilitate fishers to get better price. Market led extension focuses on harnessing the ICT tools to access market intelligence including likely

price trends, demand position, current prices, market practices, communication network, etc. besides production technologies.

For farmers, as the extension system is more credible source of farm technologies, the extension personnel ought to be knowledge- and skill-oriented in relation to production and marketing of agro-enterprises. Thus, revamping the extension system will have a catalytic role for ushering in farmer-led and market-led extension; which can subsequently alleviate poverty and ensure livelihood security. In the light of this, the challenge remains to motivate the extension personnel to learn the new knowledge and skills of marketing before assigning them marketing extension jobs to establish their credibility and facilitate significant profits for the fishing community. SWOT analysis of the market, Organization of Farmers' Interest Groups (FIGs), capacity development, establishing linkage and synergy, harnessing ICTs, digital marketing etc are the competencies required by the extension personnel in order to effectively implement market led extension.

f. Digital Extension approach

Extension reforms brought a transformation in fishery extension system through introduction of Information and Communication Technologies (ICTs). The ICT-enabled extension system referred to as Digital Extension has the potential for enabling the empowerment of fishing communities by improving their access to information and sharing knowledge with innovative e-agriculture initiatives (Saravanan, 2010a).

With the phenomenal growth in information and communication technology, use of ICT application in agriculture and allied sectors will bring remarkable change in the attitude and knowledge level of user. Basic requirement is to provide most appropriate information in such a capsule that can be easily understood and used by them. This approach will strengthen the extension system for better dissemination of technology. Hence, along with ICT-based advisory services, input supply and technology testing need to be integrated for greater impact and content aggregation from different sources require to be sorted in granular format and customized in local language for rapid adoption of technologies (Balaji et al., 2007&Glendenning and Ficarelli, 2011).

The effectiveness of this innovative extension approach depends on capacity building, people's participation along with government initiative to provide strong infrastructure to be worked with the cutting-edge technologies. The farmer friendly technology dissemination process needs to be handled with careful planning by the incorporation of information communication technology. The use of ICT application can enhance opportunities to touch the remote farmers to live in close proximity of the scientific input. The computer based web portals namely aAQUA, KISSAN Kerala, TNAU AGRITECH Portal, AGRISNET, DACNET, e-Krishi, ASHA, India Development Gateway (InDG) portal, Rice Knowledge Management Portal (RKMP), Agropedia, KIRAN, AGMARKNET, ITC-e-Choupal, Indiancommodities.com, Mahindra Kisan Mitra, IFFCO Agri-Portal, Agrowatch Portal, iKissan, etc. along with some mobile based Apps like mKRISHI® Fisheries, riceXpert, Pusa Krishi, Krishikosh, m4agriNEI, CIFTFISHPRO, CIFT Lab Test, CIFTraining etc. launched in India are some of the successful digital intervention for technology dissemination.

The use of internet, mobile and video- conferencing assists the IT enabled farmers to utilize the facilities for their favors for which the most suitable permanent infrastructure is the basic requirement. Strong linkages need to be established between direct ICT interventions and it should be part of the national level program on holistic agricultural development.

g. Disruptive Extension:

Recently, a new extension technique christened as 'disruptive extension' comes into limelight which is considered as an innovative extension approach that creates a new paradigm of extension that eventually disrupts an existing approach followed by extension professionals in the field of agriculture and allied sectors with a pre-conceived idea about the field level problems. It is an entrepreneurial oriented sustainable extension system that can be able to transform every link in the food chain, from farm to fork, pond to plate and deck to door. It is a combination of different innovative extension techniques like ABCD, CRE (cost-recovery extension), MVSE, CBVD etc. blended with suitable conventional approaches, the fulcrum of which lies between resource exploitation on one side and resource conservation on another side that influence the livelihood security and technology sustainability for small scale farm holders. It deals with the following principles:

- Importance of good governance in agriculture (and allied fields) that considers the resource rights of the farmers.
- Emphasis on growing interest among the stakeholders by explicit analysis of field level issues for technology adoption.
- Potential to resolve the social conflicts for equal access to community resources through Memorandum of Understanding (MOU).
- Based on cost recovery mechanism.
- Ensure commitment to optimum resource management and maximum economic benefit to improve food security.
- Provision of community based social insurance.
- Maintaining the sustenance of the technology supports through custom hiring approach.
- Focus on pluralistic convergence of different partners to build a network of linkage with various entities around the farm households.
- Encouraging the farmers-scientist interaction for technology development, assessment and application through Farmers' FIRST approach.

Fisheries embraces diverse actors in its endeavour to support their livelihood system giving an impact in food and nutritional security. At the same time, the contribution of women fishers also cannot be ignored particularly in on-farm operations, harvesting, post-harvest management, processing etc., especially in fishery and animal husbandry sector. Hence, in today's scenario innovation in extension is the key to address the growing challenges, which need to be validated, integrated and scaled up and further recommended for large scale implementation by the policy makers. The advanced techniques of extension should be based on capacity building, skill development, people's participation along with government initiative to provide policy support in line with the cutting-edge technologies. Much effort has been initiated in going beyond the farm and the fishers and focus on beyond the technology to a wider innovation system.

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Hazard Analysis Worksheet

Firm Name	**Product Description:**
Firm Location	**Method of Storage & Distribution:**
	Intended Use & Consumer:

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Signature				Date	

HACCP Plan Form

Firm Name	Product Description
FirmLocation	Method ofStorage&Distribution
	IntendedUse&Consumer

CriticalControl Point(CCP)	SignificantHazard(s)	Critical Limitsforeach ControlMeasure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			

Signature:	Date:

HACCP Plan Form

Firm Name	**Product Description:**
Firm Location	**Method of Storage & Distribution:**
	Intended Use & Consumer:

Critical Control Point (CCP)		
Significant Hazard(s)		
Critical Limits for each Control Measure		
Monitoring	**What**	
	How	
	Frequency	
	Who	
Corrective Action		
Verification		
Records		

Signature:	**Date:**