FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

Training Manual
Food Safety Supervisor Course
Special – (Level 3) – Manufacturing
Fish and Fish Products

Contents

- HACCP manufacturing and HACCP Implementation of Important Control Measures
- HACCP Plan

Disclaimer: The content of this handbook/ manual is only for training and capacity building purpose, and is not intended to substitute applicable law, which may be referred separately.

Welcome to the manual –

The manual is designed for small, medium and large-scale Fish and Fish products processors and manufacturers.

This manual explains General Requirements on Hygienic and Sanitary Practices to be followed by all Food Business Operators engaged in Fish and Fish Products establishments, as per Food Safety & Standard Act, 2006.

This manual presents bare minimum requirements of Food Safety and Hygiene to be followed by Food Business Operators along with Industry best practices.

Learning Outcome –

The objective of this manual is to train the personnel, about food safety and hygiene requirements which are to be followed in their businesses and who can be designated as Food Safety Supervisors in the Fish &Fish Products establishments. The Food Safety Supervisors (FSS) may interpret these requirements according to the size and type of their establishment.

The desired outcome of this manual is better understanding of food safety and hygiene requirements and high standards of food safety practices in the industry.

The Food Safety Supervisors (FSS) of Fish and Fish Products Industry are to be trained on:

General Requirements on Hygiene and Sanitary Practices, as per "Part II of Schedule 4" of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html) under Food Safety & Standards Acct,2006.

(http://www.fssai.gov.in/home/fss-legislation/food-safety-and-standards-act.html

And Industry Best Practices as applicable to Fish and Fish Products.

Rationale: The GMP, GHP and HACCP implementation will help establishments prevent physical, chemical, biological hazards resulting from the environment and processes.

What the law says -

The establishment in which Fish and Fish Products is handled, processed & packed, by the food business operator and the persons handling them should conform to the sanitary and hygienic requirement, food safety measures and other standards as specified below. It shall also be deemed to be the responsibility of the food business operator to ensure adherence to necessary requirements.

In addition to standard requirements by FSSAI, the food business operator shall identify steps in the activities of Food businesses, which are critical to ensure food safety, and ensure that safety procedures are identified, implemented, maintained and reviewed periodically.

In India, the mandatory sanitary and hygiene requirements for food business operators are- "Part II of Schedule 4" of Food Safety and Standards (Licensing & Registration of Food Businesses) Regulations, 2011 (http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html) under Food Safety & Standards Acct,2006.

(http://www.fssai.gov.in/home/fss-legislation/food-safety-and-standards-act.html).

For the ease of understanding, the relevant sections from Part II of Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011 has been segregated as per flow of operations in the Fish and Fish products industry.

Section A - Introduction to Food Safety

A1 KEY DEFINITIONS

A2 FOOD SAFETY AND HAZARDS

A3 FOOD SPOILAGE

A1 Key Definitions for Fish and Fish Products Processing

1. **Biotoxins** - Poisonous substances naturally present in fish and fishery products or accumulated by the animals feeding on toxin-producing algae or in water containing toxins produced by such organisms.
2. **Chilling** - The process of cooling fish and shellfish to a temperature approaching that of melting ice
3. **Candling**- Passing fillets of fish over a translucent table illuminated from below to detect parasites and other defects
4. **Clean water** - water from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish, shellfish and their products intended for human consumption
5. **Cleaning** - The removal of soil, food residues, dirt, grease or other objectionable matter
6. **Contaminant**-Any biological or chemical agent, foreign matter, or other substance not intentionally added to food that may compromise food safety or suitability.
7. **Contamination** - The introduction or occurrence of a contaminant in fish, shellfish and their products
8. **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. For the purposes of this Code, a control measure is also applied to a defect.
9. **Corrective action** - Any action to be taken when the results of monitoring at the CCP indicate a loss of control. For the purposes of this Code, this also applies to a DAP
10. **Decomposition** - The deterioration of fish, shellfish and their products including texture breakdown and causing a persistent and distinct objectionable odour or flavor
11. **Dressed** - That portion of fish remaining after heading and gutting
12. **Disinfection** - The reduction by means of chemical agents and/or physical methods in the number of micro-organisms in the environment to a level that does not compromise food safety or suitability
13. **Defect** - A condition found in a product that fails to meet essential quality, composition and/or labeling provisions of the appropriate Codex product standards.
14. **Dewatering** - Removal of excess wash water from the minced fish flesh
15. **Diseased fish** - A fish on or in which pathological changes or other abnormalities that affect safety and quality are apparent
16. **Fish** - Any of the cold-blooded (ectothermic) aquatic vertebrates. Amphibians and aquatic reptiles are not included.
17. **Feed additives** - Chemicals other than nutrients for fish that are approved for addition to their feed.
18. **Fish farm** - An aquaculture production unit (either land- or water-based); usually consisting of holding facilities (tanks, ponds, raceways, cages), plant (buildings, storage, processing), service equipment and stock.
19. **Fish feed** - Fodder intended for fish in aquaculture establishments, in any form and of any composition
20. **Hazard** -A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

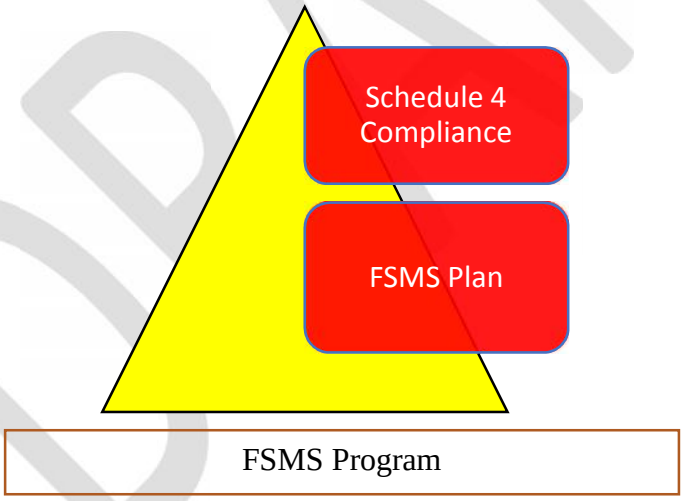
21. **Inedible**- Inspected and judged by a competent person, or otherwise determined by the competent authority to be unsuitable for human consumption.
22. **Minced fish** -Comminuted flesh produced by separation from skin and bones
23. **Ready to cook**- "Ready to Cook" means that the food or a material in the food must be brought to a temperature sufficient to kill any pathogenic microorganisms before it is safe to consume
24. **Shellfish**- Those species of aquatic molluscs and crustaceans that are commonly used for food.
25. **Trimming** - The process of removing any signs of blood, membrane or remnants of the gut which may be attached to the shell
26. **Whole fish (or round fish)**- Fish as captured, ungutted

A2 Food safety and Hazards

Food Safety means assurance that food is acceptable for human consumption according to its intended use.

As per FSS Act 2006, Food Safety Management Systemmeans the adoption of Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business.

For the purpose of this document and all assessments conducted there under, the definition of FSMS shall be read as the above and the requirements for this be taken as that defined under **Schedule IV & Critical Control Point**.



Schedule IV

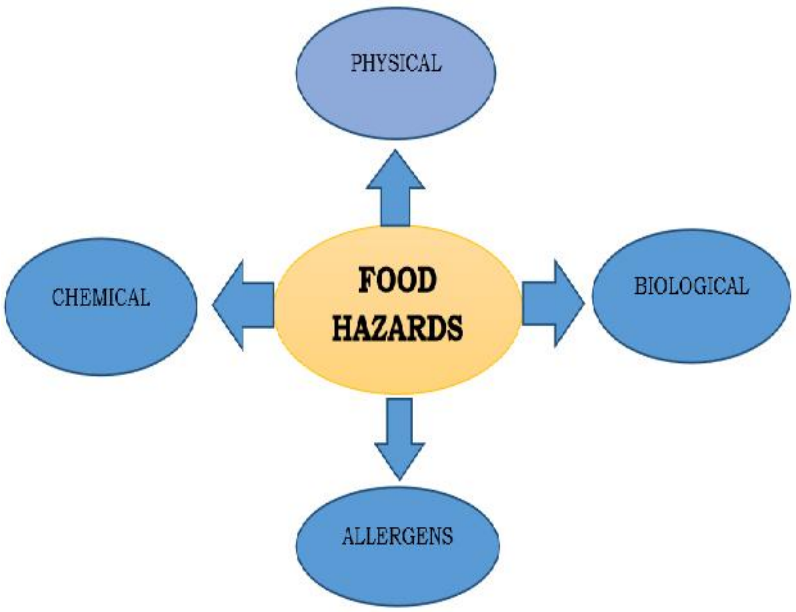
1. **Why?** Section 16 of the FSSA, holds FSSAI responsible for regulating and monitoring the manufacture, processing, distribution, sale and import of food so as to ensure safe and wholesome food.

2. **How?** By introducing basic hygiene and safety requirements in the form of Schedule IV

3. **Where in FSSR?** The Schedule IV has been mandated for compliance by introducing it as a licensing requirement/condition under the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

Food Safety hazard

Food Safety Hazard means biological, chemical (includes allergen) or physical agent in food, or condition of food, with the potential to cause an adverse health effect. There are majorly four types of hazards



Types of Food Hazards

Physical Hazards -Any foreign object (inanimate) found in the food or a naturally occurring object (metal, hard plastic), that poses a hazard is called as Physical Contamination or Hazard.https://www.google.co.in/url?sa=i&rct=j&q=&esrc=s&source=images&cd=&cad=rja&uact=8&ved=0ahUKEwjf9eC0td7YAhWJgbwKHfn6AK0QjRwIBw&url=https%3A%2F%2Fwww.123rf.com%2Fphoto_30150442_the-picture-is-show-of-physical-hazards.html&psig=AOvVaw3_50kRHaht6GbrzWB4P-LI&ust=1516258537931257

Common Physical Hazards include:

- Metal fragments: Hard or sharp objectives
- Glass
- Bone/ Shells
- Chipped pieces from equipment
- Metal from trolleys, hooks, SS Knives, screw, bolt
- Blades
- Plastic or chipped pieces of disposables
- Lint and threads
- Band- aids
- Hair (human)
- Finger nails
- Jewellery pieces
- Stone
- Objectionable matter (viscera, scales, skin, etc.), formation of struvite crystal

Control Measure for Physical Hazards-

Glass Policy: All glasses and windows in the production areas need to be of safe break type either by providing a protective covering or unbreakable glass/ plastic. In case of any glass breakage the glass shouldn't break and fall into the products. Tube lights and other lighting fixtures to be safe break-even clocks placed need to be safe break.

Jewellery Policy: No Worker, working in a processing or handling area is supposed to put on any type of Jewellery. Jewellery could be hazardous and a strict Jewellery Policy should be defined for men and women employees to adhere. By considering religious view mangalsutra can be allowed by taking proper precautions.

Plastic Policy: Various plastic items are used during process and storage e.g. bottles, scoops, lab items (beaker, jars and test tubes etc.). A strict Plastic Policy could be drawn to avoid any contamination of food products from these plastic items.

Visitors Policy: To prevent any contamination from the visitors, a Visitor's Policy to be in place. All visitors shall declare their health status if they are suffering from any contagious disease such as cold, diarrhea etc. Provide giving instructions to visitors as to what are the basic requirements during visit to the fish and fish product Industry should be followed.

Chemical Hazard- Naturally occurring and process induced chemical substances that can cause a food borne illness are called as Chemical Contaminant or Hazard.

Intentionally added--Preservatives, Nutritionally additives & Color additivesabove the specified limit as per the FSS (Food Additive) Regulation.

Unintentionally added

- Antibiotics and other veterinary drugs residues
- Naturally Occurring Toxins Substances (NOTS)
- Heavy metals
- Chemicals used like:
  1. Cleaning and sanitizing chemicals residues
  2. Chemical contaminants from packing and food contact materials
  3. Lubricating material such as Grease and Oils

Control Measures:

Chemical contamination-

Adequate physical separation should be maintained between other non-edible chemicals and food items. All possible measures should be developed and effectively implemented to avoid any chance of cross contamination.

Pesticides, Insecticides and Veterinary Drug Residues-

- Approved Supplier.
- Certified Agencies for Pest Control
- Feed Control

Chemical Additives-

- Chemical additive concentration need to be controlled and approved levels shall be maintained.

Packaging Material-

- Food grade packaging material to be used.

Lubricants, Grease-

- Vehicle inspection should be conducted regularly.
- Also control on cleanliness should be maintainedfrom supplier's end.
- Inspection to be carried out at each and every step under preventive maintenance plan.

Heavy metals-

- Periodic water testing is necessary for control and monitoring.
- Birds to be procured from approved supplier
- Preventive maintenance of all equipment's should be followed as per defined frequency.

Biological hazardsare organisms, or substances produced by organisms, that pose a threat to human health. They are a major concern in food processing because they cause most food borne illness.

Biological hazards include pathogenic parasites, bacteria and viruses. These hazards can come from raw materials or from food processing steps. Fish caught from off shore waters are free from almost all pathogens, except *Vibrio parahaemolyticus* and *Vibrio vulnificus*, because these organisms are part of the normal bacterial flora of marine and brackish water environments.

Biological hazards are-

Parasites– Parasitic Worms (including Nematodes, Cestodes, Trematodes); Protozoan Parasites (Entamoeba histolytica, Giardia lamblia etc.)
Bacteria – Aeromonas hydrophyla, Clostridium botulinum, Vibrio parahaemolyticus, Vibrio cholerae, Vibrio vulnificus, and Listeria monocytogenes etc.
Viruses - Hepatitis A, Calicivirus, Astrovirus, Norovirus etc.
Fish Poisoning – Ciguatera fish poisoning, Scromboid Poisoning, Shellfish Poisoning etc.

Mechanism of Food Borne Disease

Food Borne Infections - This result when a person consumes food containing pathogens; which grow in the human intestine and cause discomfort or disease. Typical symptoms of a food borne Infections do not appear immediately.

Food Borne Intoxications - This result when a person consumes food containing toxins in it; that cause discomfort or disease. Typical symptoms of a food borne Intoxication appear quickly.

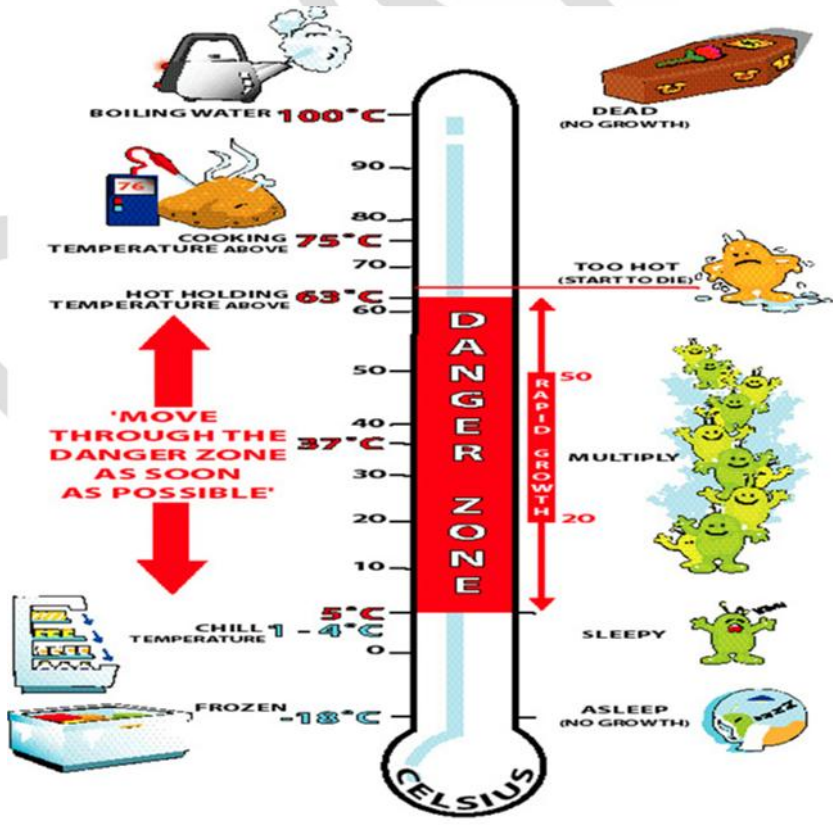
Food Borne toxin are mediated infections, that result when a person consumes food containing toxins produced by the pathogens in it; which grow in the human intestine and produce toxins that cause discomfort or disease.

Conditions favouring growth of Microorganisms

FAT TOM

Conditions	Definition
Food	Food borne Microorganisms draw nutrients from Potentially hazardous foods
Acidity	Food borne Microorganisms grow well between the pH range of most foods
Temperature	Microorganisms grow well between the temperature range of 5°C – 60°C,most commonly known as the 'Danger Zone'
Time	Microorganisms need sufficient time to grow; when exposed to the 'Danger Zone'
Oxygen	Microorganisms require oxygen in free or combined state; to favor their growth
Moisture	Microorganisms require moisture to grow and is measured in the form of 'Water Activity (Aw)'

FATOM: Conditions favoring growth of microorganisms



Danger zone temperature

Categorization of food on the basis of risk

High Risk Food (HRF)

HRFs are identified as vehicle for food poisoning and Food born disease outbreak. RTE foods support rapid growth of food poisoning bacteria because intended use of RTE is without further heating to destroy bacteria. Usually such foods are high protein and high moisture content which favours the growth of pathogens. Highly perishable food such as raw meat, fish & poultry requires refrigerated storage.

Cooked fish, shell fish, cook-chill meal etc., must be kept separate from raw foods. Since Raw foods are often contaminated with large no of bacteria including pathogens so it shall be kept separate from RTE foods even if frozen.

Low Risk foods

Normally kept in ambient temp as they cannot promote multiplication of bacteria (dry products). This category of foods is rarely implicated for food poisoning. Foods with high sugar content, acid or acidified foods, fried or dried foods with low Aw (less than 0.85), baked foods, canned foods, powdered foods, etc. are examples but once the powder is reconstituted, the same becomes High Risk Foods.

What are the risk factors associated with foods and FBDs?

Understanding these risks is necessary to control them as we know it is the risk that is to be prevented, eliminated or reduced to acceptable level through the hygiene and prerequisite programs and hazard control.

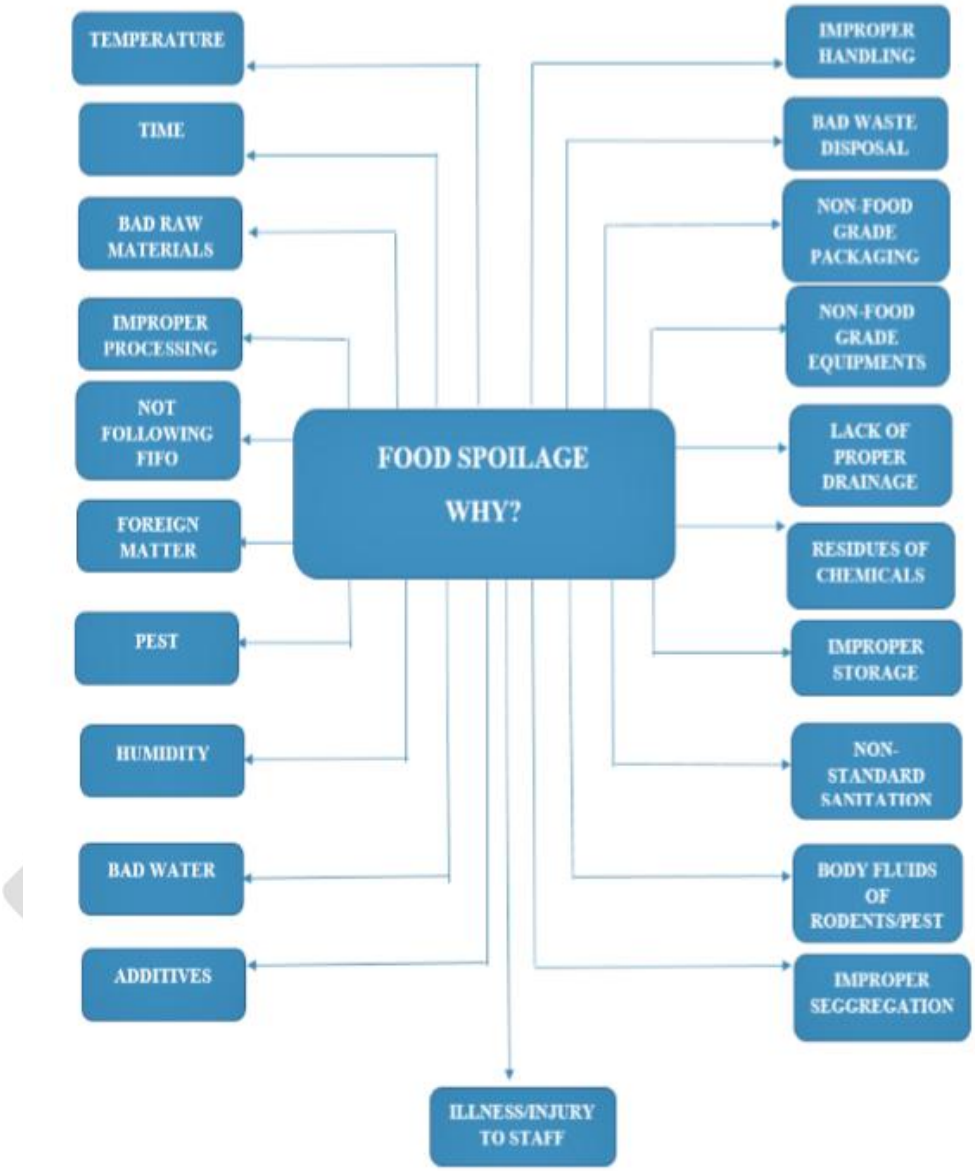
Unsafe food refers to food that contain harmful bacteria, viruses, parasites, or chemicals making it unfit for human consumption. Also, physical contaminations like glass particles, stones, and other extraneous matter in food causes food to be unsafe.

Food spoilage, as a part of Unsafe food, means that the original nutritional value, texture, flavour of the food are damaged; the food become harmful to consumers and unsuitable to eat.

A3 Food spoilage

Food spoilage means that the original nutritional value, texture, flavour of the food are damaged, the food become harmful to people and unsuitable to eat.

Major reasons for food spoilage are-



Reasons of Food Spoilage

Various causes of Unsafe Food

Foreign matter: Human hair, stapler, metal particles, fabric, plastic, alkali etc. are big threats to food safety. Anything that is not considered as food or food substance is considered as foreign matter.

Pest: Food infested with pest causes harm to human health. Contamination may be caused by body fluids like urine, fecal matter of rodents, reptiles, pests, nocturnal animals and birds present in the storage yard, marketing yard, transportation etc.

Non- food grade equipment: Non-corrosive, food grade material to be used for processing equipment's; to prevent metal contamination, chemical contamination.

Improper handling: Unclean hands, wrong selection of equipment causing cross contamination, and packing in unsuitable material.

Improper processing: Wrong process methods can lead to major changes in end product. Right temperature, right time, proper additives and understanding process steps is essential to ensure food safety.

Residues of chemicals: Chemicals from crop contaminants, residues from equipment or utensil sanitation operations. It is important to ensure thorough washing is done before equipment is taken into production.

Non-standard sanitation: Sanitation must be based on strict guidelines of either historical data or validation. If chemicals are used in less or more quantity or in an unverified process or method, sanitation will fail to achieve proper results giving way for food to become unsafe.

Poor quality raw materials: Quality of raw materials to be checked based on frequent sampling, before selection.

Poor quality animal (Fish): to be checked by veterinarian.

Additive: Additives of any nature like essence, flavors etc. can spoil food if not used in the right quantity. Unauthorized additive also must not be used.

Water: Water is involved in food process in various stages from washing to soaking then involved in either directly food production as an ingredient or in some in-direct manner as steam. It is also important for washing and sanitation operations. Potable water should conform to the specifications of IS 10500:2012.

Improper storage: Right combination of duration, temperature, ventilation and segregation defines a good storage. Any deviation in one of these could result in food becoming unsafe.

Illness/Injury to staff: Food safety is much dependent on the food handler's personal behavior and health status. A person with cough, cold, open wound, itching and any illness which is of an irritable nature tends to make him handle things without washing his hands after touching the body.

The most common danger to food safety is from cough and cold and open wounds for food handlers.

Improper segregation: Where certain ingredients/raw material contain/ or are allergens, the appropriate segregation of such materials, equipment, tools and final product is important to ensure consumer safety.

Humidity: Humidity is a major cause for enabling microbial growth, and rancidity. Food zones must have lesser than 65% humidity to ensure food safety.

Temperature: Temperatures of processing, holding, storing, transporting, are all important factor in food being safe.

Time: No raw material, or product should be held beyond designated shelf life.

Non-food grade packing: Intermediate and final product should be packed only in acceptable packing material to ensure food safety.

Improper waste disposal: Waste if not disposed in a hygienic manner, can breed pest and microorganisms which are a threat to food safety.

Section B- Implementation of Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP)

1. ESTABLISHMENT: DESIGN AND FACILITIES

Sl No.	Operational Flow	Sub Sec No.	Heading
1.	Design and Facilities	1.1	Location and Surroundings
		1.2	Layout and building design
		1.2.1	Construction, Design and Layout
		1.2.2	Internal Structure and Design
		1.3	Equipment and Containers design and Installation
		1.4	Facilities and Utilities
		1.4.1	Provision of Water Supply
		1.4.2	Air Quality and Ventilation
		1.4.3	Electricity &Lighting
		1.4.4	Personal Hygiene Facilities
		1.4.5	Compresses air and other gases
		1.4.6	Cleaning Facilities for food contact surfaces
		1.4.8	Storage Facility
		1.4.9	Laboratory and technical staff
		1.4.10	Other Facilities

1.0 DESIGN AND FACILITIES

1.1 LOCATION AND SURROUNDINGS

Introduction

Fish processing involves facilities along with other processes which includes receiving, washing & chilled storage,pre-processing, pre-dusting, battering, breading, freezing cooking, curing, freezing, or making fish products. Fish processing uses large quantities of water and generates wastewater which includes significant amounts of organic matter such as fat, blood, manure, hair, feathers, and bones. This wastewater can also contain disease-causing organisms, bacteria, parasite eggs, oil, grease, salt, nitrogen and ammonia compounds, phosphorus, and chlorine. Air pollution generated by fish processing can include particulate matter, volatile organic compounds, and hazardous air pollutants. Other by-products of processing include odours, noise, and solid waste for treatment or disposal.

Statutory Requirements-

"No Objection Certificate" to be obtained from Municipality or Panchayat or applicable local bodies before grant of license.
"No Objection Certificate" from the pollution control board of the State has to be obtained.
License/Registration under FSS Act' 2006 as per the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

Selection of Location & Surrounding Area –

Fish and Fish Processing Industry shall be located away from:

- environmentally polluted areas and industrial activities which produce disagreeable obnoxious odour, fumes, excessive soot, dust, smoke, chemical or biological emissions and pollutants, and which pose a serious threat of contaminating food. In case there are hazards from other environment polluting industries located nearby, appropriate measures shall be taken to protect the manufacturing area from any possible contamination;
- areas subject to flooding, otherwise measures should be taken to locate the premises at elevated level in a sanitary place;
- areas prone to infestations of pests;
- areas where wastes, either solid or liquid, cannot be removed effectively;
- without any direct access to any residential area, in case cannot be achieved, sufficient measured shall be demonstrated to show its not posing threat to food safety.

External boundary wall to prevent un-authorized entry of pets/ animals, etc.

Fish and Fish Product Processing Units

- It shall permit adequate maintenance, cleaning and/or disinfection, prevent any potential contamination, and provide adequate working space to allow good manufacturing and hygienic practices for all the operations.
- It should have adequate drainage and easy provision for cleaning. All drains and gutters shall be properly and permanently installed. Drain or Storm water shall be prohibited to enter the premises.
- Access should be controlled, and site boundaries shall be clearly identified.
- Access to animals other than intended for slaughter shall be restricted.
- The external area of the site shall be maintained in good order to avoid any potential contamination like pest harbourage and infestation.
- Roadways and areas serving the establishment which are within its boundaries or in its immediate vicinity shall have all weather surfaces suitable for wheeled surface to allow ready transport of animals.
- There should be adequate facilities for the ETP and location of ETP shall be at such a distance as to avoid the possibility of contamination.
- The facility shall be used for the purpose that it is meant for.
- The location should be preferably near to fish landing site, or accessible by road very easily.
- There shall be continuous provision of sufficient electrical power supply with proper back up to maintain the cold chain and to operate freezers and cold stores.

1.2 LAYOUT AND BUILDING DESIGN

1.2.1 Construction, Design and Layout

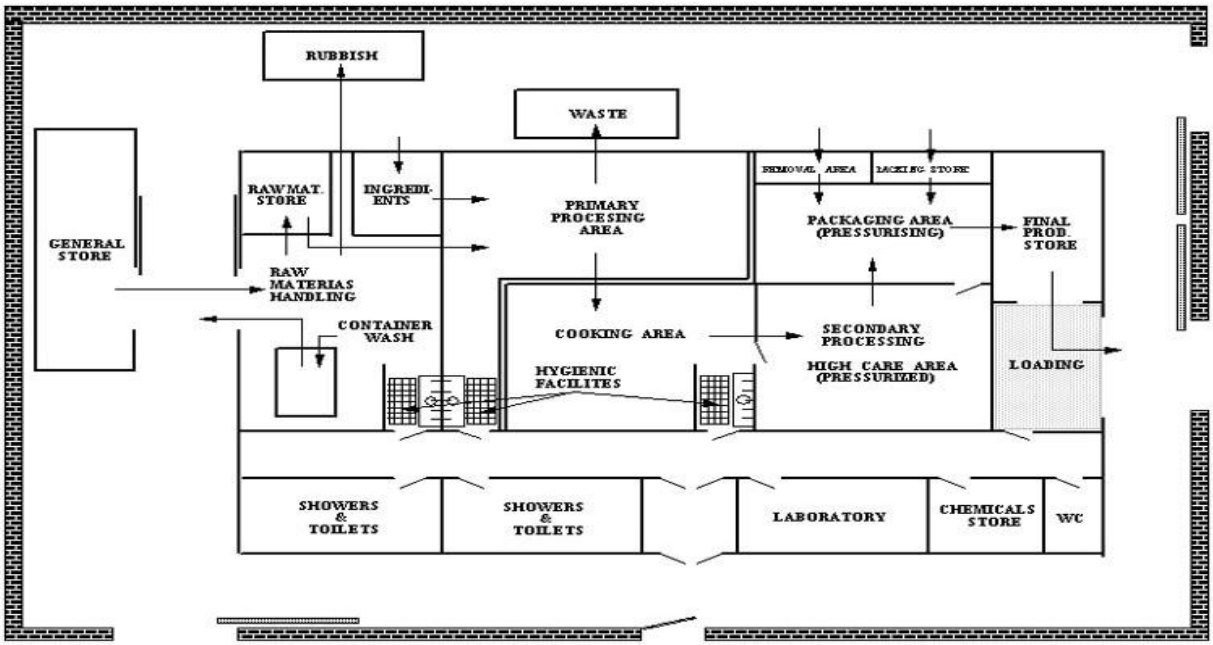
Premises' refers to all the elements of building and building surroundings.

The correct plant layout is crucial to produce safe products. A well laid out plant helps to reduce the risk of product contamination caused by pest, microorganism, people and material movement and helps in satisfactory performance of all operations

1.2.1.1 General Requirements

- The establishment shall be such so that there is sufficient protection from the environment and shall be of sufficient size for the work to be carried out under hygienic conditions.
- The design and layout shall be such as to preclude contamination and protect against accumulation of dirt, contact with toxic materials, shedding of particles into fish products and formation of condensation or undesirable mould on surfaces.
- Layout of different sections shall be such as to facilitate smooth and orderly flow of work and to prevent possible cross contamination of finished product from raw materials.
- The layout shall also ensure sufficient space in different sections for machinery, equipment, personnel etc. without congestion. Also, flow of drain should be opposite to the flow of the production.
- Non–operative areas(residential areas, machine room, toxic chemical storage areas, dry storage of food grade chemicals and packaging materials, offal and waste storage areas) inside the establishment shall be properly separated from operative areas (fish products handling areas) to avoid possible cross-contamination.
- The processing areas should have separation between clean and dirty sections and should be organised.
- Adequate working space for satisfactory performance of all operations.

- There shall be a raised platform for receiving the material and the sides and roof of the platform shall be sufficiently protected from extraneous contamination.
    - Separate and adequate facilities should be provided to prevent contamination:
    - Hazardous substances;
    - Cleaning chemicals
    - Dry storage of materials, packaging etc.



E.g.- Plant Layout

Roads in outside area

1.2.2 Internal Structure & Design:

1.2.2.1 Floors

- Shall be hard, waterproof, non-absorbent, impervious to minimize build-up of fish slime, scales, guts etc.), washable, cleanable and Sanitizable, non-slippery (likeepoxy, polyurethane concrete, tiling etc.) and made of nontoxic materials;
- without crevices and should be easy to clean and
- Slope should be sufficient so that liquids drain to trapped outlets.

Floor Design

Coving between floor & wall

Wall and pillar guards used to avoid daily wear and tear of the surfaces

1.2.2.2 Walls

- Should be waterproof, impervious, washable, cleanable & subitizable and nontoxic materials and should be light coloured,
- Should be smooth and without crevices and should be easy to clean to avoid accumulation/ absorption of dust, blood/ particles and microbial/fungal growth.
- The walls/floor junctions, corners and structural supports should be sloped/curve so that adequate cleaning can be done easily.

1.2.2.3 Ceilings and overhead fixtures

- Should be so designed, constructed and finished as to prevent any accumulation of dirt and minimize condensation, mould development and flaking, accumulation of dust and should be easy to clean;

Overhead Fixtures

1.2.2.4 Windowsand other openings

- õ Should be so constructed as to avoid accumulation of dirt
- õ Screens should be easily movable for cleaning and kept in good repair.
- õ Windows covered with wire mesh to prevent entry of dirt, dust, insect, pests, and birds.

1.2.2.5 Doors

- õ Should have smooth, non-absorbent surfaces and
- õ Where appropriate, be self-closing and close fitting;
- õ Air curtains/filters may be placed, wherever necessary
- õ Easy to clean & Sanitize
- õ In case of coated doors – No paint flaking

Ceiling

Window with mesh screen

Doors

1.2.2.6 Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes, should be so situated and constructed as to facilitate easy cleaning, sanitation and maintenance to avoid contamination.

Stairs

Wall and ceilings with crevices and mold growth

1.2.2.8 Vehicular areas

- Properly drained and concrete paved areas should be provided at places where vehicles are loaded or unloaded.

1.2.2.9 Wood Usage

- The use of wood not to be allowed in the establishment. Implements with wooden handles shall not be permitted inside the establishment.

***Note:** The construction of any chilling room, freezing room or freezer store shall satisfy the requirements mentioned above.

1.3 EQUIPMENT AND CONTAINERS

Equipment, Utensils and Machinery that come in direct contact with fish and fish products shall be hygienically designed, constructed, located and, if necessary, installed to ensure that they can be adequately cleaned, sanitized and maintained to avoid contamination.

Equipment's and containers in contact with exposed fish and fish products should:

- have smooth impervious surface,
- be resistant to corrosion.
- made of material which is non-toxic,
- does not transmit odour or taste,
- is free from pits and crevices
- be non-absorbent,
- be of Food grade material
- capable of withstanding repeated exposure to normal cleaning and disinfection,
- be easily cleaned, disinfected and maintained.
- Permanently mounted equipment shall either be installed sufficiently away from wall and above the floor.

No vessel, container or other equipment, the use of which likely to cause metallic contamination injurious to health shall be employed in the preparation, packing or storage of fish and fish products. It is recommended that all essential equipment should be made up of stainless steel.

Suitably designed Food contact equipment

Note -

1. All equipment shall be kept clean, repaired and maintained in sound condition all the time.
2. All measuring instruments / equipment like temperature gauges, pH meter, weighing balances, etc. shall be calibrated periodically for correct measurement.
3. Equipment and utensils should be designed to minimise sharp inside corners and projections and tiny crevices or gaps to avoid traps and crushing of the product.
4. Chutes and conveyors should be designed to prevent physical damage caused by long drops or crushing.

Working table: Shall be made of non-corrosive material that is easily cleanable, sanitizable, durable, light coloured, smooth and provided with pipes for waste collection. While designing avoid areas that can accumulate dirt and difficult to approach for cleaning.

Sanitary equipment: Placing and location of all sanitary equipment should permit easy access and thorough cleaning.

Containers for inedible material and waste should be leak proof, constructed of non-corrosive metal which is easy to clean or disposable and where appropriate, able to be closed securely.

Equipment Identification: Equipment and utensils used for inedible material or waste should be so identified and should not be used for edible products. Also, containers holding hazardous substances shall be closed when not in use, stored separately and lockable to prevent malicious or accidental contamination of food.

Refrigerated system: Chill rooms of adequate size with mechanical refrigeration system to maintain temperature at the required level (Chillers- 0°C to 4°C and Freezer- -18 °C or below) or adequate number of insulated boxes shall be provided to store raw material.

The equipment's shall be fitted with necessary gauges to indicate the temperature, pressure etc. The recording devices shall be calibrated at specific intervals.

SS EQUIPMENTS

SS EQUIPMENTS

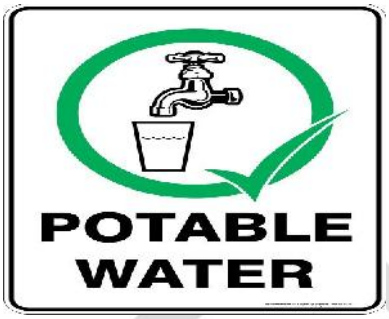
1.4 FACILITIES AND UTILITIES

The facilities and utilities are essential services that play a vital role to industry. Quality facilities and utilities provided like

- ✓ Provision of Water Supply
- ✓ Air Quality and Ventilation,
- ✓ Electricity and Lighting
- ✓ Personal Hygiene Facilities
- ✓ Compressed Air and Other Gases
- ✓ Cleaning facilities for food contact surfaces
- ✓ Storage Facilities
- ✓ Laboratory & technical Staff
- ✓ Other Facility

1.4.1 Water Supply

- An adequate supply of ***potable water*** with appropriate facilities for its storage and distribution shall be available.
- Potable water quality shall be as specified in the latest edition of BIS standard on drinking water (IS 10500). Potable water shall be tested bi-annually to confirm that it meets the requirements of this standard.



Adequate supply and / or water storage facilities

- Adequate supply of potable water with appropriate facilities for its storage and distribution should be available wherever necessary to ensure the safety and suitability of food.
- Own supply of fresh water or other water sources and use chlorine, the residual content of chlorine should not exceed that of potable water.
- Surface of Water tanks shall be easily cleanable & Sanitizable
- Storage tanks and water pipes should be protected against contamination. They shall be adequately designed, made of material that is on toxic, corrosion resistant material, and periodically cleaned and maintained.
- The records of the same shall be maintained. The tanks shall be covered to prevent access by pests and other extraneous matter.
- Where water filters are used, they shall be regularly monitored or effectively maintained.
- Water including ice or steam (including culinary steam) used as a product ingredient or in contact with fish and fish products or used for equipment and plant cleaning shall be potable and should not constitute a threat to the safety or suitability of the product.
- Provide sufficient supply of hot water wherever necessary in the establishment.
- Non-potable water can be used for cleaning of those equipment which does not come in contact with food and food contact surfaces. It can also be used for firefighting, refrigeration equipment, lavatory etc.
- Non-potable water pipes shall be clearly distinguished from those in use for potable water and shall not connect with, or reflux into, potable water systems.
- Colour coding is recommended for different type of water lines.

Separate pipelines for potable and non-potable water

1.4.2 Air Quality and Ventilation

- Ventilation should be provided to prevent excessive heat, steam condensation, dust and to remove contaminated air.
- The direction of the air flow should never be from a dirty area to clean area.
- Ventilation openings should be provided with an insect screen (easily removable and cleanable) or other protective enclosure of non-corrosive material.
- Air handling unit should have facilities to filter the flushing-in air through filters which reduce dust, humidity and bacterial load to recommended levels.


Exhaust fans

- This system should be subject to routine maintenance, cleaning and disinfection.
- System shall be accessible for cleaning, filter changing and maintenance. so that they do not become a source of contamination.

Best Practice:An air quality monitoring program should be implemented to ascertain effective interval for changing filters.

1.4.3 Electricity and Lighting

- In case of electricity breakdown, minimum electricity power backup shall be available to maintain the temperature of storage area where fish and fish products are stored.
- Adequate natural or artificial lighting should be provided throughout the slaughter house.
- Resulting color of the light shall not be misleading.
- Light bulbs and fixtures should be covered to prevent contamination of fish and fish products in case of breakage.

Processing Areas	Recommended Light Intensity (Lux)
All Inspection areas	540 Lux
Work rooms	220 Lux
Other areas	110 Lux

Recommended light intensity


Adequate Intensity of light and covered fixtures

Electrical panel and board should be covered

1.4.4 Personnel Hygiene Facilities

- Personnel hygiene facilities shall be available to ensure that an appropriate degree of personal hygiene can be maintained to avoid any cross contamination.
- Such facilities shall be suitably located & designated so that the employee must pass them when returning to the processing area.
- Facility shall have following facilities- hand washing, toilets, changing facility, rest and refreshment room and first aid facility.

1.4.4.1 Hand washing facilities

- Hand washing facility should be providedwith potable water at adequate temperature, fitted with dispensers for liquid soap and other hand cleansing agents (sanitizer) and suitable hygienic means for drying hands.
- Taps of non-hand operable type are preferable like foot/elbow/sensor/knee /automatic type etc.


Hand washing and drying facility

- Non- Perfumed liquid soap should be used.
- Where hand driers were installed should be in working condition at all time during working hours.
- Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near to each washing facility. Generally, and preferably, hand driers are considered better than paper towels based on cost efficiency and effectiveness.
- Dustbins to throw used paper towels should be foot-operated.
- Posters directing personnel how to wash their hands effectively near hand wash stations.
- Hand sanitizer should be provided and should be used after drying of hands. This is the next step of disinfecting hands after cleaning.

1.4.4.2 Provision of toilets:

- Sufficient number of latrines, urinals, for each gender shall be provided. Generally, 1:25 is followed for facility: employee ratio
- Toilets should be well lit and ventilated and should not open directly on to food handling areas.
- Adequate supply of water should be provided in toilets and urinals.
- Potable water should be used at the toilet wash basin stations

Gender Specific Toilets

Changing Facility with Lockers

Refreshment Room

1.4.4.3 Changing rooms/lockers:

- Suitable and sufficient facilities (for e.g. lockers, gum boots stand, apron stand etc.) for persons working in the fish processing units should be provided for changing their clothes, keeping their personal belongings and Street footwear.
- Adequate facility for lockers shall be provided. Separate lockers should be provided for home personal clothes and company uniforms.
- Lockers shall be made of such material that can be cleaned and sanitized effectively.
- Foot dip to be present at the entry level of the processing unit (Recommended Chlorine concentration – 100-200 ppm depending on the hygiene requirement of the establishment).

Changing Room

Provision of Lockers

1.4.4.4 Rest and refreshment room

- Rest & Refreshment Rooms shall be separate from other areas.
- These areas shall not open directly to fish handling areas,
- Only personal belongings to be kept in lockers,

Note: A display board mentioning' **Dos' and 'Don'ts'** for workers should be posted in a prominent place inside the premises, in English or local language, for all to understand.

Do's and Don'ts

1.4.5 Compressed air and other gases

- Compressed air, carbon dioxide, nitrogen and other gas systems wherever required used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.
- Quality of air, CO_2, nitrogen and other gas shall be monitored and maintained.
- The pipelines of gases exposed to production area and product must be made of such material that can be cleaned and shall not pose risk of contamination

1.4.6 Cleaning Facilities for fish contact surfaces

- Adequate facilities made of corrosion resistant materials with adequate supply of potable water shall be available for cleanliness of food contact surfaces namely floor, wall, plastic crates, equipment, table tops etc.
- Utensil and equipment cleaning and sanitizing facilities should be separated from food processing, storage, distribution and handling areas to prevent contamination.

1.4.7 Storage Facility

- Adequate facilities for the storage shall be provided.
- Storage facility shall provideprotection from dust, condensation, waste, pest access and harbourage and other sources of contamination.
- It shall be dry, well ventilated and enable monitoring and control of temperaturesin storage areas where required.
- It should be easy to maintain and clean.
- All materials and products shall be stored off the floor and with sufficient space away from the walls to allow inspection and pest control activities to be carried out.

Separate storage for:

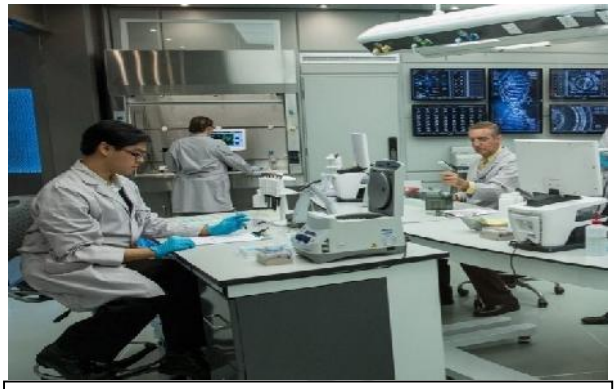
- Raw material & Semi processed material
- Packaging material
- Returned/rejected material / Recalled material
- Final product
- Allergens
- Hazardous chemical
- Cleaning & disinfection chemical
- Waste material (both bio degradable & non-biodegradable)
- Engineering tools

Recommended Temp control (wherever required):

- Freezer: -18°C or below
- Chillers: 0 - 4°C

1.4.8 Laboratory & Technical Staff:

- Adequate infrastructure including a laboratory facility and trained and competent testing personnel should be available for carrying out testing.
- Should not open directly to the fish processing area.



Quality Control lab

1.4.9 Other Facility

Work Shop: for routine repairing and maintenance of the plant.
Generator Room: stand by generator for providing power during the breakdown,
Boiler and Steam generator: Water used for steam generation should be of potable type.
Refrigeration Plant: Suitable capacity of refrigeration system shall be provided to achieve adequate temperatures wherever required.

2. FISH AND FISH PRODUCTS – PROCESSING INCLUDING PRE-PROCESSING

Sl No.	Operational Flow	Sub Sec No.	Heading
2.	Processing including Pre Processing	2.1	Receiving of Incoming Material
		2.2	Storage – Raw Material and Packaging Materials
		2.3	Fish and Fish Products – Processing including Pre-Processing
		2.4	Allergen Management
		2.5	Packaging of Fish and Fish Products and Warehousing
		2.6	Rework and Control of Non-Conforming Products
		2.7	Transportation and Distribution of Fish and Fish Products

2. FISH AND FISH PRODUCTS – PROCESSING INCLUDING PRE-PROCESSING

2.1 RECEIVING OF INCOMING MATERIAL

- There should be written specifications/quality standards for all incoming materials – fish and shellfish, ingredients and packaging materials.
  - ❖ Aqua Inputs used in aquaculture farms should be on CAA approved list and Aqua Feed from BIS.
  - ❖ For e.g. In case of Shrimps: to be procured from farmers registered under:
    - ➢ Marine Products Export Development Authority (MPEDA),
    - ➢ Coastal Aquaculture Authority (CAA) or
    - ➢ State Fisheries Department.
- There should be written specifications/quality standards for all incoming materials –ingredients and packaging materials.
- Suppliers of raw materials and ingredients should be evaluated regularly and must be FSSAI registered/ Licensed.

Receiving of Incoming material

- Materials on receipt shall be inspected and those complying with the specifications should be accepted into the processing facility and non-conforming materials should be rejected and proper records should be maintained thereof.
- Immediately on receipt, Fish/Shell Fish shall be washed or cleaned to remove soil or other contaminants using potable water.
- Recommended that temperature of fish at the time of delivery should be in the range of 0°C to +4.0°C in case of chilled and -18°C or below in case of frozen.
- All packaged raw materials shall be checked for 'expiry date'/'best before'/'use by date'.
- The incoming vehicles that bring the raw material should be checked for cleanliness and hygiene i.e. the trucks are clean, with no pests or dirt, with no strong odour and does not contain materials other than the raw material.
- To prevent cross contamination, the raw material receiving station shall be separate with adequate space to receive and store raw material in chilled conditions.

2.2 Storage – Raw Materials & Packaging Materials

- Fish/ Shellfish should be stored such that damage from over stacking or overfilling of boxes will be prevented and should be kept in shallow layers surrounded by sufficient finely divided ice or with a mixture of ice and water before processing.
- The temperature of the fish should be maintained between 0°C and +4°C in case of chilled and -18°C or below in case of frozen.

Fish Storage

Packing Material Storage

- Ingredients and packaging materials should also be stored appropriately in terms of temperature and humidity and protected and segregated to prevent cross contamination.
- A fish processing establishment shall store raw material and packaging materials in appropriate dry and ventilated areas for effective protection from dust, condensation, drains, waste and other sources of contamination during storage.
- Packaging material storage room should be closed from all sides to restrict entry of flies, rodents, birds, insects/pests etc.
- Storage of raw material/ ingredient, /packaging material shall be done as per FIFO (First in First Out) / FEFO (First Expire First Out) stock rotation system, as applicable.
- The food materials/ ingredient/ packaging material shall be stored on racks/ pallets such that they are stored off the floor on pallets and off the walls to ensure easy and adequate cleaning and prevent harbouring of any insects, pests or rodents.
- The storage of raw, processed, semi processed, rejected, recalled or returned materials or products, shall be made separately and properly segregated. These areas shall be marked for identification and shall be secured.
- All raw materials/food additives and ingredients shall be stored separately from printed packaging materials, sanitary, hardware and cleaning materials/chemicals.

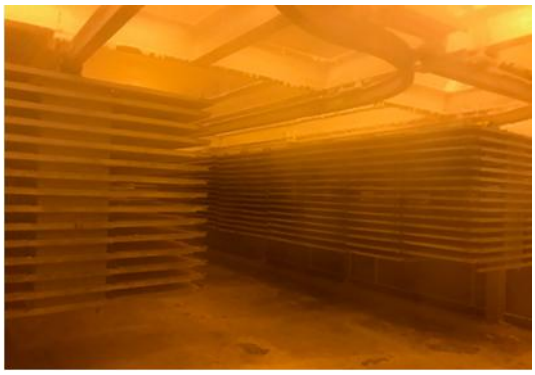
Packaging Material Storage

Raw Material Storage

Fish storage

2.3 Fish and Fish Products – Processing including Pre-Processing

- The flow diagram of processing operations and standard operating procedures shall be documented, implemented and should be displayed at appropriate locations in the production area.
- Standard operating procedures for process changeover i.e. from one kind of product to another or from one kind of fish to another shall also be maintained and implemented.
- Fish and shellfish should be handled and conveyed with care during pre-processing and processing operations to avoid physical damage such as puncture and mutilation as this can accelerate the rate of decomposition.
- Tables made of food grade steel with adequate water supply and provision for waste disposal should be used for handling, cleaning, cutting and processing of fish in pre-processing and processing units.
- The fish processing should be done in clean and hygienic environment with no cross
- contamination. The processes shall be specific for each product and could be blast freezing /chilling/ drying mechanically / salting and drying further / or any other local technology
- The processing establishment should ensure the product attains the specified core temperature during processing as prescribed by the competent authority and records to be maintained. For e.g., the core temperature of chilled products should be 0-4°C; core temperature of frozen fish products shall be -18°C or below.
- Samples should be taken during processing and tested for critical parameters and test results should be recorded and maintained.
- Ice used in cooling and holding raw product should not be mixed with ice used to store processed and packed products



Handling of Fish & Fish Products Handling of product during freezing

2.3.1 Specific requirements for Manufacturing of Processed Products

- All operation in connection with the preparation or packing of fish and fish products shall be carried out under hygienic conditions.
- Particular attention needs to be given to temperature control.
- The temperature of the processing and packaging rooms shall be controlled so as to maintain the temperature of the product in chilled or frozen condition as desired.
- Special care of food safety control measures related to cooking, handling and packing shall be taken for cookedfish and fish products.
- Cooked fish and fish products are those products that are subjected to heat treatment, wherein minimum thermal core temperature of 75°C is achieved.
- The cooking should be adequate to eliminate and reduce hazards to an acceptable level which might have introduced at raw food level.
- Products which are heated below 75°C but above 60°C there may be a microbiological safety risk, such type of products shall be treated as semi-cooked products. These products shall be re-heated above 75°C before consumption. Special instruction shall also be given on the product label stating re-heating of the product above 75°C before consumption.
- Products which are exposed to heating but below 60°Cshall be treated as raw processed products. Such type of products shall be cooked above 75°C before consumption. Special instruction shall also be given on the product label stating cooking of the product above 75 degree Celsius before consumption.

2.4 ALLERGENS

2.4.1 General

An allergen is a substance that causes an immediate allergic reaction in a susceptible person. Food allergens are almost always proteins although other food constituents, such as certain additives, are known to have allergenic (allergy-causing) properties.

Food allergy is a potentially serious immune response to eating or otherwise coming into contact with certain foods or food additives.

A food allergy occurs when the immune system:

- Identifies a particular food protein as dangerous and creates antibodies against it.
- The next time the individual eats that food, immune system tries to protect the body against the danger by releasing massive amount of chemicals including Histamine.
- Histamine is a powerful chemical that can cause a reaction in the respiratory system, gastrointestinal tract, skin or cardiovascular system.

- In the most extreme cases, food allergies can be fatal. Although any food can provoke an immune response in allergic individuals, a few foods are responsible for the majority of food allergies.

The following foods and ingredients are known to cause hypersensitivity amongst selective individuals & shall always be declared:

The big 8 Allergens declared in U.S. are followed in India currently by food industries in general which are listed as below:

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

The allergens marked in bold maybe more commonly encountered in Meat and Meat Products Industry.

Source: *http://www.foodallergens.info/Legal/CODEX.html*

2.4.2 Allergen Control Program (ACP)

PEOPLE

- Employee awareness through product and utensil identification
- Hand washing in between non-allergic and allergic materials
- Clothing- change of clothes wore while handling allergen materials.
- Rework control- Utmost care to be taken to handle allergen materials to avoid any accidental cross-contamination.
- Waste control- Allergen material wastes should not be allowed to pile up or spill which can result in environment cross contamination.

RAW MATERIALS & INGREDIENTS

- Knowledge of ingredients from suppliers to avoid any possible cross-contamination.
- Clear labelling and identification of all raw materials and ingredients
- Safe transport from supplier to receiving place
- Allergen items to store separately in food processing units.
- Avoid any spillage

PACKAGING

- Good and safe package integrity from supplier
- Correct labelling

CLEANING:

- Effective cleaning to avoid risk of cross contamination
- Cleaning ofequipment shall be done before using same equipment's for allergen and non-allergen material.
- Cleaning schedule to be developed keeping in mind all the chances of cross contamination
- Regular cleaning of spillages of allergen materials throughout processing

PRODUCTION:

- Minimize movement of materials
- Scheduling of production runs with appropriate cleaning between the runs
- Physical barriers between allergen and non-allergen materials
- Schedule allergen containing product last in production plan or necessary cleaning shall be done during shifting of production from non-allergen containing products from allergen containing products.
- Control and trace reworked products

Allergen Management

Major Allergens are –

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacean and products of these;
- Eggs and egg products;
- Fish and fish products;
- Soybeans and products of these;
- Milk and milk products (lactose included);
- Peanut, tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more."

Paste list of allergens at the relevant places in the processing areas for awareness among all the employees.

The allergens may include:

- All that are used intentionally
- Unintentionally (staff food, via contractors, transport, neighbours (air borne, etc.)

Allergen Control and Management

Supplier monitoring

- COAs should be obtained for all allergens from the approved suppliers.
- When reviewing specifications, the responsible person should look for formulations of the listed ingredients of the raw material.

Plant traffic flow

- Maintain all ingredient flow during the manufacturing from non-allergen using areas to allergen using areas. This will help prevent cross-contamination.

Raw material storage

- All raw materials that are allergens should be labelled with a tag that states "allergen." The label can be made Bold and with Bright colour for quick identification.
- Store all allergic foods or ingredients to a designated and separate area. For partially used allergic packets, the production staff should ensure the partially used packet should be stored separately and completely sealed and identified with label.
- Color-coding charts can also be placed throughout the production area, especially above all wall-mounted equipment and near storage areas for easy identification by plant personnel

Colour coding system for allergen specific utensils

- Dedicated scoops and utensils shall be used for specific allergens.
- Bright colours and words can be used for easy identification of different allergens.

Production scheduling and Cleaning

- Thorough cleaning should be there between allergic containing product manufacture and non-allergic containing product manufacture.
- Process should be there to ensure any allergen residues on the production line.
- Preferably products containing non-allergen ingredients should run before the product containing allergic ingredients.
- When production scheduling and cleaning operations are not performed between allergen containing production runs, allergen testing must be performed. For. E.g. ELIZA test kits are used to verify.

2.5 PACKAGING OF FISH AND FISH PRODUCTS AND WAREHOUSING

2.5.1 Fish and Fish Products Packaging

- The packaging design and materials shall provide protection for products in order to prevent contamination, damage and accommodate required labelling as laid down under the FSS Act & the Regulations there under.
- Only Food grade packaging materials as specified by FSSR regulation shall be used. Usually, food grade polythene film is used in all the different procedures of packing.
- Packing material should confirm FSSAI regulation i.e. Food Safety and Standards (Packaging and Labelling) Regulations, 2011 and regulation made there under. Packing should be covered and secured to prevent spoilage and contamination during transit and storage.
- Packaging section to be considered high care zone & access restricted & controlled via changing facility
- Clean protective clothing & footwear to be worn before entry
- Daily internal Calibration & recording of packaging equipment like weighing scales.
- Packaging Process steps to be performed without any delay to avoid contamination
- Non-toxic PM or gases to be used to not pose threat to the safety and suitability of processed product

Labelling –

- Product labelling must confirm the requirement laid down by Food Safety and Standards (Packaging and Labelling) Regulations, 2011 and and regulation made there under.
- Product Label minimum should contains below information as required by FSSAI.
    1. The Name of Food
    2. List of Ingredients
    3. Food Category number & Name
    4. Nutritional information
    5. Declaration regarding Veg or Non veg
    6. Declaration regarding Food Additives
    7. Name and complete address of the manufacturer with FSSAI Numbers
    8. Net quantity in terms of Weight, Number or litres
    9. Lot/Code/Batch identification
    10. Date of manufacture or packing
    11. Best Before and Use By Date
    12. Country of origin for imported food
    13. Instructions for use etc.


Fish Packaging and Labelling

2.5.1 Fish and Fish Products Storage including Warehousing

- It is recommended to follow best practices for warehousing. All packed goods should be stored 18" away from walls, preferably stocks to be kept on pallets.
- The warehouses should be kept clean, ventilated, lighted and under hygienic condition to avoid pest infestation, dirt, dust, smell.
- Where specified for a particular kind(s), temperature and humidity control systems should be introduced and must be carried out with calibrated recording equipment with appropriate maintenance of records. For e.g. for chilled condition it is0-4^{o}C and for frozen it is -18^{o}C or below
- All end products should be stored at right temperature in a clean, sound and hygienic environment.
- Severe fluctuations in storage temperature (more than 3 °C) should be avoided.
- Too long storage time (depending on fat content of species used and type of coating) should be avoided.

- Products should be properly protected from dehydration, dirt and other forms of contamination.
- In chilled storages, direct blowing of cold air to iced fish in crates should be avoided to prevent dehydration of fish. Extra ice may be placed on the top crate along with proper covering.
- In the case of frozen storage there shall be suitable defrosting system and suitable arrangements to remove melt water from the frost. It shall be ensured that during defrosting, variation in temperature to be minimized so as to ensure that product temperature may not rise above -18°C.

Storage of Final Product

Cold Storage

2.6 REWORK AND CONTROL OF NON-CONFORMING PRODUCTS

2.6.1 Rework management

- Rework shall be stored, handled and used in such a way that product safety, quality, traceability and regulatory compliance is maintained.
- Rework shall be clearly identified and/or labelled to allow traceability. Traceability records for rework shall be maintained (e.g product name, production date, shift, line of origin, shelf life etc.).
- When rework activities involve removing a product from filled or wrapped packages, controls shall be put in place to ensure the removal and segregation of packaging material and to avoid contamination of the product with extraneous matter.
- Stored rework materials shall be protected from exposure to microbiological. Chemical or extraneous matter contamination.
- If rework is incorporated into a product as an 'in process step', the acceptable quantity, the process step, method of addition, type and conditions of rework, including any necessary pre-processing stages, shall be defined

Rework Non-conforming product tag

2.6.2 Non-conformance handling

- A non-conformance could be identified through-
    - customer complaints,
    - internal audits,
    - external audits,
    - incoming material inspection
    - or simply during normal testing and inspection activities.
- All non- conformance incidents should be recorded and assessed.
- There should be a defined storage area and handling procedure for non-confirming raw material, packing material and finished goods.

2.7 TRANSPORTATION AND DISTRIBUTION OF FISH AND FISH PRODUCTS

All the transportation systems are expected to maintain the temperature of the fish and fish products within close limits to ensure its optimum safety and recommended shelf life. It is important that the fish and fish products is at the correct temperature before loading since the refrigeration systems used in most transport containers are not designed to extract heat from the product but to maintain the temperature of the product. In large containers used for long distance transportation, food temperature can be kept within recommended frozen temperature (at or below minus 18 degrees Celsius for frozen and at or below 4 degrees Celsius for chilled products). Transportation systems should be properly calibrated as well as licensed under FSS Act'2006.

Transport vehicle

- The dispatches of finished goods must follow FIFO or FEFO (First Expiry First Out) system.
- Vehicle inspection shall be in place.
- Conveyances and/or containers or tankers used for transporting Fish and Fish products shall be kept clean, hygienic and maintained in good repair condition. Where direct contact with Fish can occur such as during bulk transportation, the materials used in carrier construction should be suitable for food contact.
- Appropriate measures should be applied to minimize damage to products and to ensure packaging integrity.
- Facilities for recording temperature or data logger should be present.
- Ensure loading and unloading methods does not contaminate the product. The containers have to be clean and disinfected before loading.
- While loading in the refrigerated containers, the temperature in the container has to be brought to -12^{o}C (Precooling) so that there is no thawing of the frozen product cartons while they are loaded. However, in case of chilled products, pre-cooling temperature shall be at or below 4^{o}C.
- Avoid thawing of frozen fish and fish products cartons during loading
- After loading, the packaged fish and fish products shall be transported under hygienic conditions and at appropriate temperature that can be monitored at frequent intervals (Frozen at or below -18^{o}C and chilled/fresh product at or below 4^{o}C at all times).
- Effective cleaning and sanitation of containers between loads when used for transporting non-food items.
- Where conveyances and/or containers are used for transportation anything other than foodstuffs or for transporting different foods, there shall be effective cleaning between loads to avoid risk of contamination.
- The transport vehicle should be examined for possible cross-contamination of ready-to-eat fish and fish products by raw fish and fish products.

During Transportation

- ✓ Frozen product to be maintained at -18^{o}C or below (recommended to have max fluctuation +3^{o}C)
- ✓ Fresh fish, shellfish and their products – temperature close to 0^{o}C. It is recommended to use freezer bags, ice slurry, chilled seawater or refrigerated seawater, where appropriate.
- ✓ Fresh whole fish should be kept in shallow layers of melting ice and maintained at a temperature between 0-4 degree Celsius.

Transportation Vehicle

3.0 PERSONAL HYGIENE

Sr.No.	Topics
3.1	Health Status, Illness and Injury
3.2	Personal Cleanliness
3.3	Personal Behaviors
3.4	Work Wear and Gowning
3.5	Visitor control

3.0 PERSONAL HYGIENE

3.1 HEALTH STATUS, ILLNESS AND INJURY

- Fish handlers and employees of the establishment shall undergo a medical examination by a registered medical practitioner annually to ensure that they are free from any infectious and other communicable diseases. The establishment shall maintain relevant personal health records of personnel. Employees who come into direct or indirect contact with edible parts of fish in the course of their work shall:
    - where necessary, have a medical examination prior to employment
    - have medical examination routinely and when clinically or epidemiologically indicated
    - not work while clinically affected by, or suspected to be carrying, communicable agents likely to be transmitted through fish; andbe aware of and comply with reporting requirements to the slaughter house operator in respect of communicable agent.
    - People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through fish or while afflicted with infected wounds, skin infections, sores or with diarrhoea, shall not be allowed to enter any fish handling area. Any person so affected shall immediately report illness or symptoms of illness to the management of the establishment.

- All fish handlers shall be inoculated against the enteric group of diseases once a year and a certificate thereof shall be kept for inspection.
- In case of an epidemic, all fish handlers shall be inoculated or vaccinated.

PERFORMA FOR MEDICAL FITNESS CERTIFICATE FOR FOOD HANDLERS
(FOR THE YEAR .....)

(See Para No. 10.1.2, Part- II, Schedule - 4 of FSS Regulation, 2011)

It is certified that Shri/Smt./Miss.....
employed with M/s....., coming in direct contact with food items has been carefully examined* by me on date ..... Based on the medical examination conducted, he/she is found free from any infectious or communicable diseases and the person is fit to work in the above mentioned food establishment.

Name and Signature with Seal
of Registered Medical Practitioner /
Civil Surgeon

***Medical Examination to be conducted:**

1. Physical Examination
2. Eye Test
3. Skin Examination
4. Compliance with schedule of Vaccine to be inoculated against enteric group of diseases
5. Any test required to confirm any communicable or infectious disease which the person suspected to be suffering from on clinical examination.

Performa for Medical Fitness certificate for food handlers

In case of any injury/cut:

- Any person who is cut or injured should discontinue working immediately in any processing unit area (preparation, handling, packing or transportation);
- Should be suitably bandaged;
- All bandages should be completely protected by a water proof covering which is conspicuous in colour and is of such a nature that it cannot become accidentally detached.
- First aid facilities should be available.

Wound on hand

3.2 PERSONAL CLEANLINESS

- Fish and Fish Product handlers shall maintain a high degree of personal cleanliness with adequate, suitable and clean:
    - Protective clothing,
    - head cover,
    - face mask
    - gloves (if worn) and
    - gumboots
- Workers shall be provided with neat, clean and hygienic uniform/protective gears. The facility for cleaning and sanitation can be in house or outsourced.
- The personal protective clothing shall be worn in such an order to avoid any cross-contamination of dust/dirt, etc.; i.e. starting from head to foot. Head caps/headgears to be worn first and foot wears to be worn at the last.
- The facility for cleaning and sanitation can be inhouse or outsourced.
- To avoid loose hair contamination of food products, it is advisable to roll-on the sticky lint rollers on the dress. Other options being air tunnel for food handler passage before entering the processing hall.
- Fingernails shall be kept trimmed and clean without nail polish.

Protective clothing

Roll on lint rollers

Use of Gloves -

- If wearing gloves for handling of fish, ensure that they are approved type for particular activity
- Gloves to be washed and sanitized prior to use/ when contaminated followed by passing through potable water.

Hand washing Techniques:

Before entering the establishment/processing hall all persons should wash their hands in a dedicated sequence:

- Wet hands with potable water
- Apply liquid soap and make a lather for at least 30 seconds
- Apply, clean and rinse every part of hands including nails, between fingers, covering full hands, and on both the sides of the hands.
- Wash thoroughly with potable water
- dry hands with hand dryer / disposable tissue
- Sanitize hands

Notices requiring hand-washing should be displayed

Hand washing

- Hand washing with soap & water
- Elbow/foot/knee/automatic/sensor operated taps (to avoid direct touch), paper towel (for drying hands), foot operated dustbins (for throwing paper towels), sanitizer dispensers should be used.

Non-hand operative displayed hand washing stations

- Sanitize hands with chlorinated water (recommended 50ppm) and best practice is again wash hands in Chlorine water with lower ppm, followed by potable water.
- Training on hand washing techniques

Hand Dip and Foot Dip Facility

Hand washing should be done:

- At the beginning of fish or shellfish handling activities;
- Immediately after using the toilet;
- After handling animals or any contaminated material, tools, equipment or work surface, chemicals
- On coughing/sneezing, to avoid contamination of food items.
- In-between breaks & whenever they look dirty.

3.3 PERSONAL BEHAVIOUR

Persons working directly with fish and fish products shall maintain high standards of personal cleanliness at all times.

Tobacco and Smoking Not permitted inside food handling area

- They shall:
  - Do not smoke, spit, eat or drink, chew gum/ tobacco in areas or rooms;
  - Wash hands at least each time work is resumed and whenever contamination of their hands has occurred; e.g. after coughing / sneezing, visiting toilet, using telephone (use of mobile should be restricted wherever possible) etc.
  - avoid certain hand habits - e.g. scratching nose, running finger through hair, rubbing eyes, ears and mouth, scratching beard, scratching parts of bodies etc.- that are potentially hazardous when associated with handling

fish, and might lead to fish contamination through the transfer of bacteria from the employee to fish and fish products during its preparation.

- Not wore jewellery, watches, pins or other items as it pose threat to the safety and suitability of food. And keep nails short and clean.

(*Note- When unavoidable, hands should be effectively washed before resuming work after such actions.)

Protective Clothing

3.4 WORK WEAR AND GOWNING

- Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear protective work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears and fraying material.)
- Work wear shall not have buttons, outside pockets above waist level
- Work wear shall provide adequate coverage to ensure that hair, perspiration etc cannot contaminate the product.
- Hair, beards and moustaches shall be protected (i.e. completely enclosed) by restraints.
- Personal protective equipment, to be maintained in hygienic condition to prevent product contamination

Protective clothing

3.5 VISITORS

- Proper care shall be taken to ensure that food safety & hygiene is not getting compromised due to visitors in establishment.
- Generally, visitors shall be discouraged from going inside the production area or fish handling areas.
- Any visitor who visits Fish and Fish Products establishmentwhere fish is handled should wear clean protective clothing, footwear, mask, head cover and adhere to other personal hygiene and cleanliness provisions.
- All visitors should provide declaration in written of carrying no infectious disease.

Visitor handling

4.0 SUPPORT SERVICES

Sr.No.	Topics
4.1	Quality Control and Testing Facilities
4.2	Pest Control Systems
4.3	Waste Handling (Waste Disposal Management)
4.4	Training and Management
4.5	Audit, Documentation and Record Keeping
4.6	Product Information and Consumer Awareness
4.7	Traceability and Recall

4. SUPPORT SERVICES

4.1 QUALITY CONTROL & TESTING FACILITIES

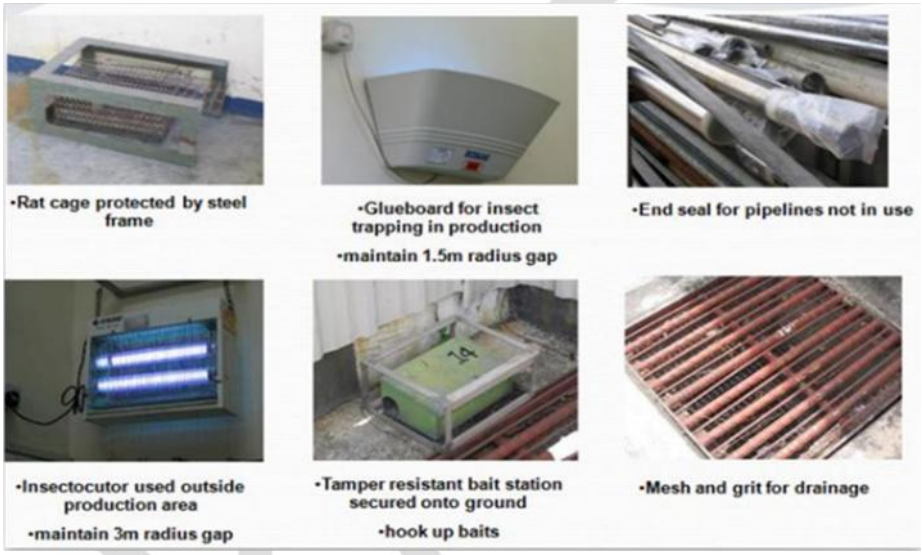
- The Fish & Fish products processing units shall have a quality control programme in place to include inspection and testing of incoming, in-process and finished products.
- Adequate infrastructure including the laboratory facility, trained and competent testing personnel (chemist/analyst and microbiologist) shall be available for carrying out testing.
- Recommended to have in- house microbiological laboratory with sterilization room, media preparation room, incubation room, laminar flow and washing rooms. If pathogen testing is conducted in-house, microbiology laboratory shall not open directly into process area.
- Microbiological examination needs to be carried out periodically for air, water, personal hygiene (hand swabs), food contact surface (knives, tables, equipment's etc.) etc, to ensure safety in finished products.
- Calibration of laboratory equipment's shall be done periodically.
- Each category or type of Fish product shall be tested as per FSS standards & regulations 2011 at least once in six months from NABL accredited or FSSAI notified laboratory. It is recommended to retain the control samples, till the end of shelf life.
- Records of testing shall be maintained.

4.2 PEST CONTROL SYSTEMS

- Buildings shall be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites.
- Holes, drains and other places where pests are likely to gain access shall be kept sealed.
- Bait stations to be installed outside and glue trap inside. Only approved baits to be used.
- Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals, birds and pets shall be excluded from the food premises.
- Establishment should have a nominated person to manage pest control activities, and/or with the help of an external appointed contractors with a valid and legal contract. Major pest activities for rodent, lizard, cockroaches, flies,

rats, mice and vermin, insects; to exclude from the establishments and processing areas.

- Shall have an effective pest monitoring programme and shall include the placing of detectors and/or trap in key locations to identify pest activity.
- A map of detectors and/or traps shall be maintained. Detectors and/traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.
- Treatment with permissible chemical, physical or biological agents, within the permissible limits, shall be carried out without posing a threat to the safety or suitability of food by trained operatives. Isolated storage with proper labels and identification.



Pesticide can be used but:

- Only if other precautionary methods cannot be used effectively and only approved pesticides should be used.
- Maintain record of MSDS or each pesticide used in the workplace.
- Handled and dispensed only by authorized and properly trained personnel.
- Prevent contamination to any equipment utensil.
- Store away from processing area, in closed cabinet outside the premises.
- All fish products should be removed before pesticides are applied.
- All equipment and utensils shall be thoroughly washed pprior to being used again.
- Labelled with a warning about their toxicity and use.

Pest control 4 D method

1D – Deny Entry- preventing Entry	2D-Deny Shelter- Elimination of Harborage of Pests	3D- Deny Food- Eliminate food sources to pests	4D- Destroy
Seal all holes, crevices at ceilings, walls and floors. Threshold clearances of doors <6mm, fix metal kicking plates. Double door/air curtains/strip curtains/ mesh screens, self-closing doors at appropriate locations. Missing/damaged gratings of drains installed/replaced.	Avoid False sealing in processing and storage area. Repair defects on walls, floors, ceilings, woodwork and other structure. Remove disused/ obsolete articles from food premises.	Store all foods and condiments in sealed/ covered containers. Floor free from food remnants. Prohibit preparing food and utensils cleaning at other places. Store refuse in dedicated closed container and discard periodically to prevent accumulation	Clean and disinfect pest infected places, clothing and equipment. Use insectocutor- place 4.5-6m away from food handling area. Use low wall mounted insectocutors. Clean insectocutor every week. Cover all foods during Pest control treatment. Use glue pads inside and rodent boxes outside the processing areas. Pest or chemical contaminated food be discarded.

4.3 CLEANING AND MAINTAINANCE

4.3.1 CLEANING AND SANITATION: The establishments and equipment shall be kept in an appropriate condition to facilitate all sanitation procedures and, prevent

Cleaning is required to remove all the physical contamination like – foreign matter, dust,dirt, etc.

Disinfection is required for destruction of microorganism (especially those which are pathogenic to human)

contamination.

- Cleaning and sanitizing programmes shall be established at facility to ensure that the food-processing equipment and environment are maintained in a hygienic condition to prevent contamination of food, such as from metal shards, flaking plaster, food debris and chemicals and records of the same shall be maintained.
- The programme should ensure that all parts of the establishment are appropriately clean, and shall also include the cleaning of cleaning equipment.

- The establishment should have written Sanitation SOPs that clearly describe procedures to prevent direct contamination or adulteration of product. These written procedures must:
    - contain all the procedures the establishment will conduct daily, before, during and after operation.
    - Identify the procedures to be conducted prior to operations and address, at a minimum, the cleaning of food contact surfaces of facilities, equipments and utensils.
    - Specify the frequency with which each procedure in the Sanitation SOP is to be conducted identify the establishment employee or position responsible for the implementation and maintenance of the procedures.
    - Be signed and dated by the individual with overall authority on-site or a higher-level official of the establishment.
    - This signature signifies that the establishment willimplement the Sanitation SOPs as written and will maintain the Sanitation SOPs in accordance with the requirements of this part.
- Cleaning and disinfection chemicals shall be food grade wherever chances of it may come in direct or indirect contact through equipments or plant surfaces, handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions, and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.
- Cleaning and disinfecting process may involve the following steps and the cleaning schedule should be displayed

Cleaning of Conveyor

    - **Pre-cleaning, preparation of area and equipment for cleaning**: Major solids (like removal of extra fish and fish products from area, packaging material from water etc.) are physically removed from floors, equipment and food contact surfaces.
    - **Rinse:**All surfaces are rinsed with clean water.
    - **Cleaning with detergent (food Grade):** Equipments and food contact surfaces are scrubbed using brushes with a suitable detergent to remove food residues, dirt, grease and other objectionable matter.
    - **Rinsing:** with potable water, as appropriate to remove all soil and detergent residues.

Meaning of Adequate hot water supply: Often there are multiple hot water supplies in a food manufacturing facility used for cleaning, hand washing etc. But if there is only one hot water supply, the term "adequate" should mean that even at times where large amounts of hot water is used.(e.g. during cleaning operations) the water supply from any tap in the establishment should not be decreased

- **Disinfection:**Food contact surfaces are then disinfected with 100mg/lt sodium hypochlorite sanitizer solution for 10 minutes to destroy most microorganisms on surface. Adequate contact time should be given for effective disinfection.
- **Post Rinse:** As appropriate, a final rinse with potable water to remove all disinfectant residues.
- **Storage:** Cleaned and disinfected equipment, container and utensils should be stored to prevent their contamination.

S.No.	Purpose	Recommended levels of available chlorine content
1.	Process water, glaze water and ice production. *	<5ppm
2.	Hand dip water	<20ppm
3.	Foot dip water	100-200ppm
4.	Water for sanitation of utensils, processing table, processing machinery etc.	100ppm
5.	Water for sanitation of floor and wall	100-200ppm
6.	Water for sanitation of drain	250-500ppm
*In case of process water and water for ice production higher level of chlorine to the tune of 10-15ppm is recommended for water disinfection, provided the chlorine level shall be reduced to recommended residue level before water/ice is used for food processing. *In case of hand dip; after passing through 20ppm; it is recommended to wash hands through 2 ppm chlorine solution followed by potable water, so as to reduce the chlorine residue level in the hands at an acceptable level.		

Chlorination Schedule

- A validation mechanism should be in place for all cleaning programme.
- The schedule of maintenance should be displayed at every appropriate place and the concerned supervisor should moderate such activities.
- Handlers or cleaning personnel, as appropriate, should be well trained in the use of special cleaning tools and chemicals, and in methods of dismantling equipment for cleaning and they should be knowledgeable in terms of the significance of contamination and the hazards involved.
- Designated area with lock & key provision should be allocated for cleaning equipments& chemical.The premises shall be cleaned thoroughly with disinfectants,
- prior to every production day and the equipment used shall be sterilized/sanitized before use.
- Preventive action shall be taken to avoid any paint flakes on walls and ceiling

Hand Dip and Foot Dip

- Planned and frequent microbial analyses of food contact areas must be carried out after cleaning and sanitizing to verify the adequacy of the sanitation regime and records of verification analyses have to be maintained.
- Raw and in-process products must be protected during cleaning and sanitation activities

4.3.2 Maintenance

- Preventive maintenance of equipment and machinery shall be carried out regularly as per the instructions of the manufacturer.
- A preventive maintenance programme must include all devices used to monitor and/or control food safety hazards and cover the maintenance procedure, frequency and identification of the person (and/ or external agency) responsible for maintenance activity.
- Internal & External calibration schedule for critical food safety equipment's should be maintained.
- Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination and post maintenance verification to be get verified.
- Lubricants, heat transfer fluids or any other similar material used shall be food grade where there is a risk of direct or indirect contact with the product.
- Equipment's breakdown and maintenance records should be maintained.
- Loose items control policy (Nut & bolts, Nails broken pieces or smaller parts of machines) should be followed to prevent any contamination with product or packaging material.
- Regular maintenance checks (which includes thermometers, thermostats, temperature gauges etc) should be made for fish tanks, equipments and transporting vehicles

4.4 Waste Disposal Management

- All fish waste and other waste materials (like dressing of shrimp/cleaning of fish by evisceration or splitting the belly, or filleting the fish) including solid, semi solid or liquid wastes shall be removed from time to time from the places where food is handled, or processed or packed and carried to the disposal area to prevent contamination of fish.
- Covered and non-hand operated waste bins shall be provided in sufficient numbers for collection and removal of all garbage, filth and refuse from the processing halls at a convenient time to a place away from the factory for disposal.
- Waste bins shall be thoroughly cleaned and disinfected immediately after use and when not in use.
- The drains should be cleared for easy flow of water while cleaning and sanitation as well as excess water spillage or washing facility as per requirement.
- Disposal of sewage and effluent in conformance with the requirements lid down under Environment Protection Act, 1986 and local rules wherever prevalent including those for plastics and other non- environmentally friendly materials.

- Adequate and efficient drainage and disposal system to be provided in the establishment.
- Waste stores and dust bins must be kept appropriately clean, free of pests and in closed conditions.

Keep no open drain inside the plant and Install covered drainage system inside the premises

- Waste disposal SOP should be defined & Hazardous waste disposal records to be maintained
- Its recommended as best practice to store bio degradable & non-degradable waste separately.

4.5 Training and Management

Awareness and responsibilities

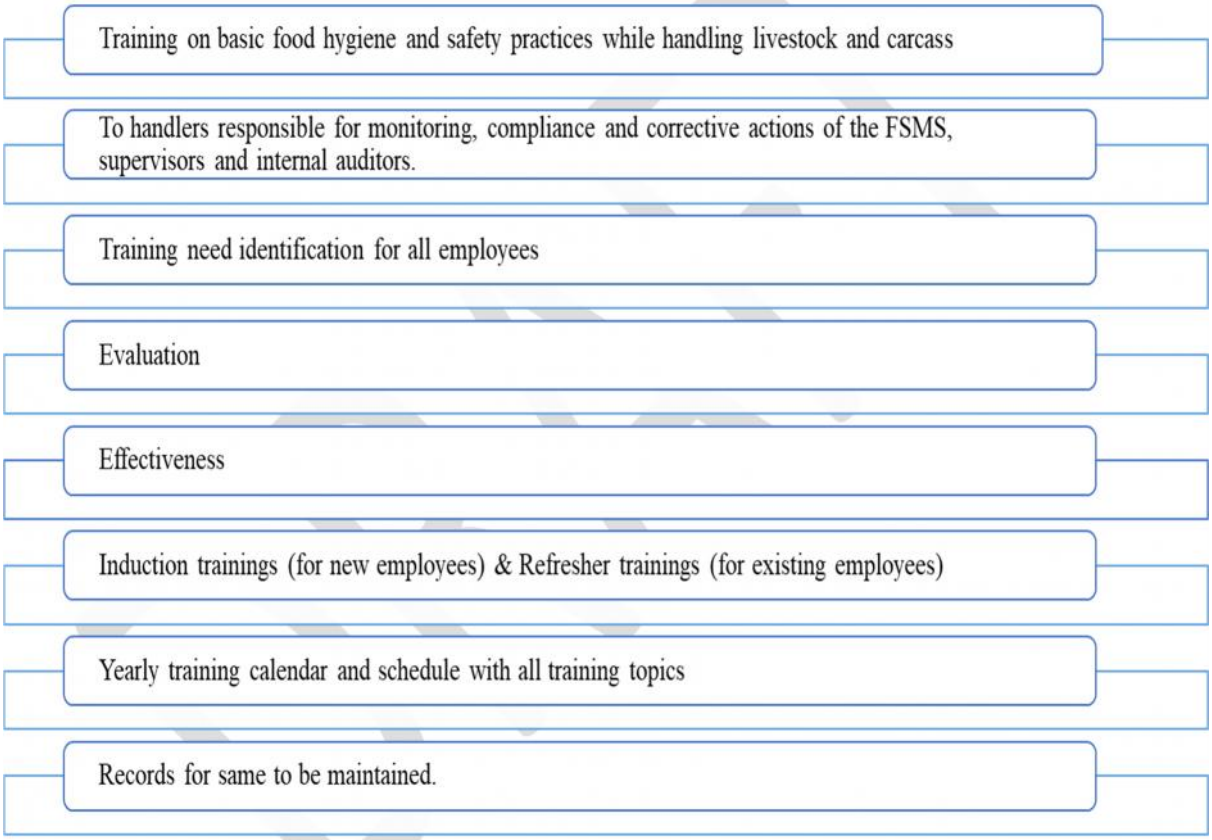
- All personnel should be aware of their role and responsibility in protecting fish and fish products from contamination or deterioration.
- Fish handlers shall have the necessary knowledge and skills to enable them to handle food hygienically.
- Those handling strong chemicals or potentially hazardous substances shall be trained in safe handling procedures and techniques.

Training programmes

- Every fish and fish product manufacturer shall have atleast one trained and certified food safety supervisor for every 25 food handlers or part thereof on all their premises.(FSSAI has provided an easy solution for training and certification through its new initiatives of Food Safety Training and Certification (FoSTAC) portal).
- Training in species identification and communication in product specification should be provided to fish handlers and appropriate personnel to ensure a safe source of incoming fish where written protocols exist.

Skills should be acquired by fish handlers and appropriate personnel in sensory evaluation techniques to ensure raw fish meet essential quality provisions of the appropriate standards from FSSAI

- Suitable trainings shall be given to all personnel handling food. Fish and shellfish hygiene training is of fundamental importance.
- All personnel should be aware of their role and responsibility in protecting fish or shellfish from contamination and deterioration. to enable them to have the required knowledge and skills in GHP and GMP for specific tasks along with personal hygiene requirements commensurate with their work activities, the nature of food, its handling, processing, preparation, packaging, storage, service and distribution.
- These training programmes shall be conducted by qualified, trained, authorized personnel.
- Records of training shall be kept.



Instruction and supervision

- Periodic assessments of the effectiveness of training, instructions programmes as well as routine supervision and checks should be made to ensure that food hygiene and food safety procedures are being implemented correctly and effectively by all personnel.
- Managers and supervisors of food processes should have the necessary knowledge and skills in food hygiene (GHP and GMP) principles and practices to be able to judge potential risks and take necessary action to remedy deficiencies.
- Handlers should have the necessary knowledge and skill to enable them to handle fish or shellfish hygienically.

- Handling of strong cleaning chemicals or other potentially hazardous chemicals should be with safe handling techniques or as per manufacturer's instructions

Refresher training

- Training programmes shall be routinely reviewed and updated wherever necessary.
- Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

Management & supervision

- The management shall lead establishment of Food safety management systems in their premises.
- The management shall ensure providing necessary trainings & resources to their employees to develop food safety culture at plant site.
- Shall appoint trained & competent managers and supervisors for management and supervision of food safety systems.
- The management shall provide and maintain documented standard operating procedure for FSMS systems compliance and its supervision at site through records /checklists on routine basis to control any possible hazards throughout supply chain.

4.6Audit, Documentation and Record Keeping

Self-evaluation and review

- Fish manufacturer shall conduct a self-evaluation process to review the effectiveness of the implemented food safety system at periodic intervals through internal and external audits or other mechanisms, but at least once in a year. Necessary corrective actions based on self-evaluation results shall be taken.
- Internal audit to be carried out by cross sectional departments.
- Fish manufacturer should also undertake a complete review of the systems including self- evaluation results, customer feedback, complaints, new technologies and regulatory updates at periodic intervals, but at least once in a year for continual improvement.

Documentation and record

- Appropriate documentation & records of receiving, processing, production and distributions shall be maintained in a legible manner, retained in good condition for a period of one year or the shelf-life of the product, whichever is more.
- Following records shall also be maintained by the Fish manufacturer:
  - incoming materials checks – raw materials, ingredients, packaging materials. Etc.
  - Inspection and testing
  - Operational controls such as temperature, pressure, time etc.
  - Product recall and traceability
  - Storage

- Cleaning and sanitation
- Pest control
- medical examination and health status
- Training
- Calibration
- Complaints and customer feedback
- Corrective and preventive actions
- Self-evaluation results

- Documentation, records and periodic audits/ inspection enhances the credibility and effectiveness of food safety control system.

4.7 Product Information & Consumer Awareness

Product Information and Labelling

- All packaged food products shall carry a label and requisite information as per provisions of FSS Act, 2006 and Regulations made there under. (Please refer http://www.fssai.gov.in/home/fsslegislation/fss_regulations.html)

- To ensure that adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the Fish & Fish Product safely and correctly and that the lot or batch can be easily traced and recalled.

General Requirements of Labelling

- Every pre-packaged food shall carry a label containing information as required here under unless otherwise provided, namely, —
- The particulars of declaration required under these Regulations to be specified on the label shall be in English or Hindi in Devnagri script: Provided that nothing herein contained shall prevent the use of any other language in addition to the language required under this regulation.

Pre-packaged food shall not be described or presented on any label or in any labelling manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect;

- Label in pre-packaged foods shall be applied in such a manner that they will not become separated from the container;
- Contents on the label shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use;
- Where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper and not obscured by it;
- License number shall be displayed on the principal display panel in the following format

fssai

LIC. No XXXXXXXXXXXXXX

- Labeling of Pre-packaged Foods
- The Name of Food:
- List of Ingredients:
- The list of ingredients shall contain an appropriate title, such as the term "Ingredients";
- The name of Ingredients used in the product shall be listed in descending order of their composition by weight or volume, as the case may be, at the time of its manufacture
- A specific name shall be used for ingredients in the list of Ingredients; Provided that for Ingredients falling in the respective classes, the following class titles may be used, namely :
- Nutritional information
- Declaration regarding Veg or Non-veg
- Declaration regarding Food Additives
- Name and complete address of the manufacturer
- Net quantity
- Date of manufacture or packing Best Before and Use by Date
- Instructions for use:
- Customer contact details
- Batch no./Lot no.

Consumer awareness and complaint handling

- Information shall be presented to consumers in such a way so as to enable them to understand its importance and make informed choices.

- Information may be provided by labelling or other means, such as company websites, education programmes and advertisements, and may include storage, preparation and serving instructions applicable to the product.
- Establishment shall have a system to handle product complaints with identified person or people responsible for receiving, evaluating, categorizing, investigating and addressing complaints.
- Complaints shall be accurately categorized according to safety concerns and other regulatory concerns, such as labelling and shall be investigated by appropriately-trained technical personnel.
- An effective complaint handling system should comprise the following:
    - Policy and complaints handling procedure
    - Clear identification of all possible complaint sources
    - Complaint capturing and categorizing based on the health and safety risk
    - Investigation and root cause analysis (RCA)
    - Corrective action
    - Complaint trending and analysis
    - Continual improvement

4.8 Product traceability and recall procedures

- Experience has demonstrated that a system for recall of product is a necessary component of a prerequisite programme because no process is fail-safe. Product tracing, which includes lot identification, is essential to an effective recall procedure.
- Establishment shall have a traceability system for assigning codes or lot numbers to incoming materials, packaging materials and finished products, etc. This will help to identify products backward & forward movement
    - Forward traceability- movement from raw material to stages in supply chain.
    - Backward traceability- movement from point of receiving of the supply chain to the source of raw materials.
- Establishment shall have a documented and effective product recall plan in place in accordance with the Food Safety & Standards Recall Regulations, 2017
- Product recall procedure should be internally tested and documented through mock recalls at least once in year by facility recall team.
- Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product.
- For traceability of the catchment area/ aquaculture farm records to be maintained, to ensure from where fish has been collected.
- Where there is a health hazard, products produced under similar conditions, and likely to present a similar hazard to public health, may be withdrawn. The need for public warnings should be considered.
- Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, or reprocessed in a manner to ensure their safety.
- Product recall procedure shall be as per FSSAI recall protocol mentioned in Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

SECTION C – IMPLEMENTATION OF HAZARD ANALYSIS AND CRITICALCONTROL POINTS

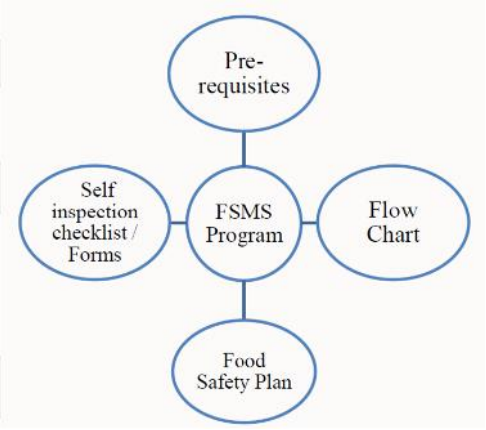
C 1: Introduction of FSMS

Internationally and even in India, there are many Food Safety Certifications which meets these requirements. These are Hazard Analysis and Critical Control Point (HACCP), ISO 22000, Food Safety System Certification (FSSC) 22000 and many more. These are voluntary certifications to strengthen the food safety system.
A Food Safety Management System (FSMS) is a network of interrelated elements that combine to ensure that food does not cause adverse human health effects. These elements include programs, plans, policies, procedures, practices, processes, goals, objectives, methods, controls, roles, responsibilities, relationships, documents, records, and resources. The purpose of FSMS is to ensure the manufacture, storage, distribution and sale of safe food.

However, under current Indian regulation defined by the FSS Act 2006, Food Safety Management System (FSMS) means the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business.

The Key elements of FSMS:

- ✓ Good Practices/ Pre-Requisites Programmes
- ✓ Hazard Analysis /HACCP
- ✓ Management Element / System
- ✓ Statutory and regulatory requirements
- ✓ Communication



FSMS PLAN

FSMS Plan

Every manufacturing / processing unit should submit a Food Safety Management System Plan. It has to be developed based on Schedule – 4 of Food Safety and Standards Regulation, 2011 in which general hygienic and sanitary practices to be followed by food business operators have been elaborated. Along with sanitation and maintenance of establishment premises, personal hygiene of workers as well as personal cleanliness is also to be ensured by the FBO's.

The Food Safety Plan shows:

Hazard	What problems could happen?
Control measures	What you do to stop problems
Critical Limits	What are the critical limits set for each control measure
Monitoring method	How do you make sure that what you are doing stops the problem
Corrective Action	What you do if something goes wrong
Records	What records you keep

C 2 HACCP IMPLEMENTATION INCLUDING CRITICAL CONTROL POINTS

Hazards Associated with Fish and Fish Products Manufacturing & HACCP Implementation for Important Control Measures

Implementing Hazard Analysis and Critical Control Point (HACCP) is crucial for any food manufacturing process. A HACCP plan covers the total supply chain, from inbound logistics, through storage, processing, sanitation and maintenance to the final use by the consumer. Across the operations, it must be ensured that procedures are available for internal logistics, processing specifications, working instructions, hygiene procedures and preventive maintenance plans. These procedures must cover start-ups, shutdown and unexpected stoppages during processing.

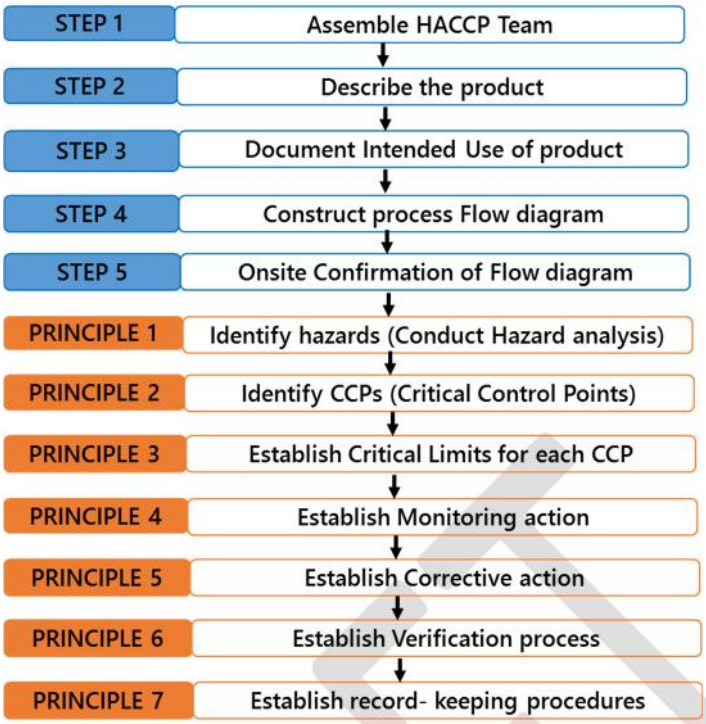
Brief Introduction of HACCP:

Hazard Analysis Critical Control Point (HACCP) is essential to carry out to identify the weakness of the production line and to suggest critical limits in compliance with legislation and therefore the preventive and corrective measures.

Though HACCP system was designed to aim zero defect products, yet it is not feasible to achieve 100% defect free products. However, it sets a goal to minimize the associated risks during production and subsequently reduce unacceptable unsafe products.

During implementation of HACCP, it is imperative to set controls at each point of the production line at which safety problems (physical, chemical and microbiological) are likely to occur.

A HACCP plan is required to be in place before initiating the HACCP system. A HACCP plan consists of 5 initial steps and 7 major HACCP principles.



Risk assessment is a critical step in a HACCP plan. Below is a template to determine what severity and probability a processing step is involved with and therefore what level of criticality is holds in the processing line.

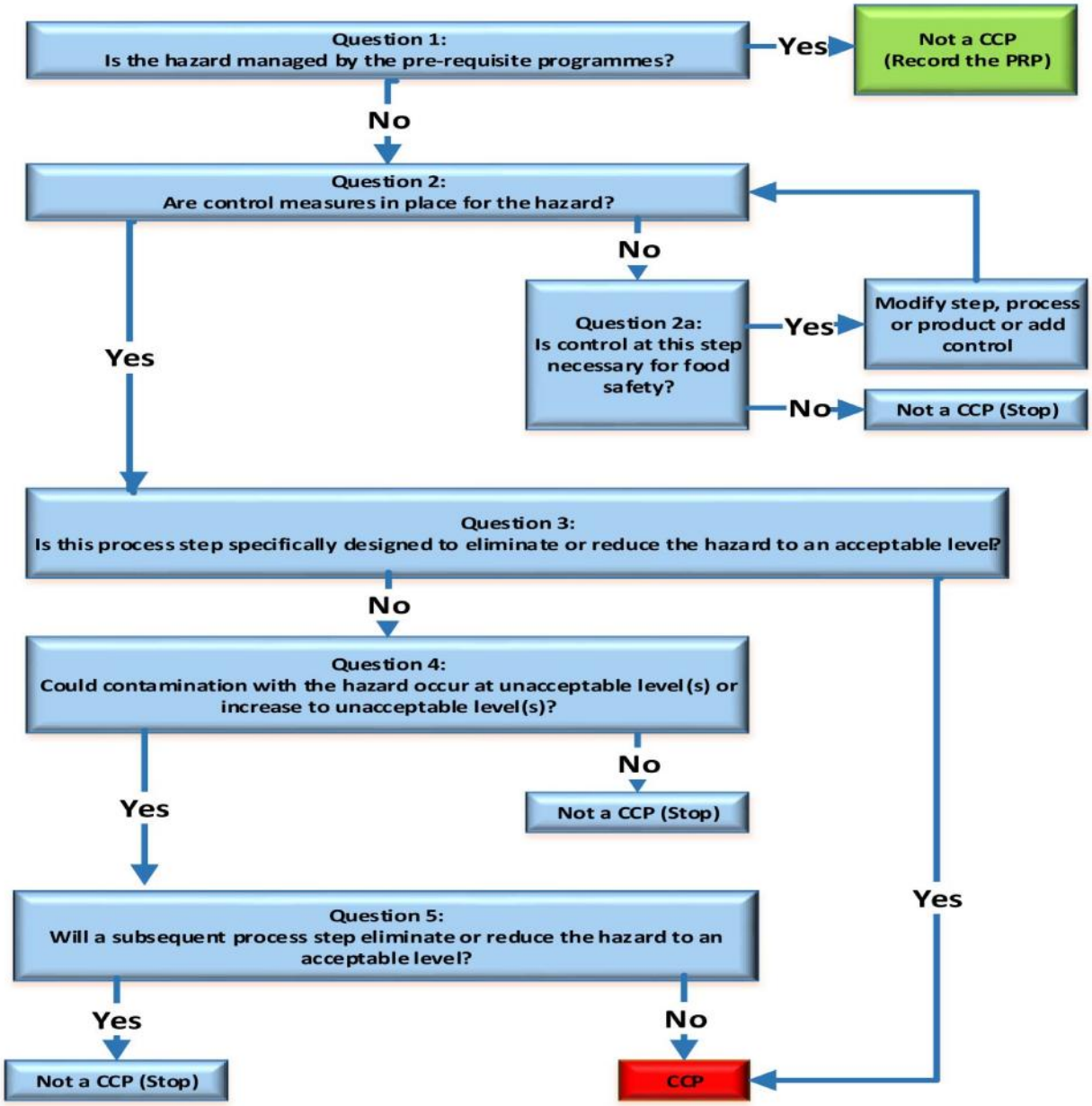
			Consequence/ Severity				
			How severe could the outcome be if the risk event occurs?				
			Severe	**Major**	**Significant**	**Minor**	**Insignificant**
Probability/ Likelihood	What's the chance of the risk occuring?	**Frequent**	Extreme	Extreme	Very High	High	Medium
		Likely	Extreme	Very High	High	Medium	Medium
		Occasional	Very High	High	Medium	Medium	Low
		Seldom	High	Medium	Medium	Low	Very Low
		Unlikely	Medium	Medium	Low	Very Low	Very Low

Introduction to Decision Tree

Hazard Analysis and Critical Control Point (HACCP) decision trees are tools that can be used to help you decide whether a hazard control point is a critical control point (CCP) or not. A CCP is a step at which control can be applied. However, it is not always possible to eliminate or prevent a food safety hazard, so this allows you to reduce it to an acceptable level

The purpose of a decision tree is to support the judgement of the team and help you to confirm whether the hazard needs more food safety controls. Decision trees are not mandatory elements of HACCP but they can be useful in helping you determine whether a particular step is a CCP.

It is vital that you determine the correct CCPs to ensure that food is managed effectively and safely. The number of CCPs in a process will depend on how complex the process is and how many hazards are present.


Question 1:
Is the hazard managed by the pre-requisite programmes?
Yes
Not a CCP
(Record the PRP)
No
Question 2:
Are control measures in place for the hazard?
No
Question 2a:
Is control at this step necessary for food safety?
Yes
Modify step, process or product or add control
No
Not a CCP (Stop)
Yes
Question 3:
Is this process step specifically designed to eliminate or reduce the hazard to an acceptable level?
No
Question 4:
Could contamination with the hazard occur at unacceptable level(s) or increase to unacceptable level(s)?
No
Not a CCP (Stop)
Yes
Question 5:
Will a subsequent process step eliminate or reduce the hazard to an acceptable level?
Yes
Not a CCP (Stop)
No
CCP
Yes

POSSIBLE HAZARDS IN FISH PRODUCTS MANUFACTURING

BIOLOGICAL HAZARDS

Biological hazards include pathogenic parasites, bacteria and viruses. These hazards can come from raw materials or from food processing steps. Fish caught from off shore waters are free from almost all pathogens, except *Vibrio parahaemolyticus* and *Vibrio vulnificus*, because these organisms are part of the normal bacterial flora of marine and brackish water environments.

Parasites-

The parasites known to cause disease in humans and transmitted by fish or crustaceans and mostly include helminths or parasitic worms. These are commonly referred to as nematodes, cestodes and trematodes. Fish can also be parasitized by protozoans, but there are no records of fish protozoan disease being transmitted to human beings. Parasites have complex life cycles involving one or more intermediate hosts and are generally passed to human beings through the consumption of raw, minimally processed or inadequately cooked products that contain the parasite infectious stage, causing foodborne disease. Freezing at –20 °C or below for seven days or –35 °C for about 20 hours for fish intended for raw consumption will kill parasites. Processes such as brining or pickling may reduce the parasite hazard if the products are kept in the brine for a sufficient time but may not eliminate it. Candling, trimming belly flaps and physically removing the parasite cysts will also reduce the hazards but may not eliminate them.

Parasitic Worms-

Nematodes

Many species of nematodes are known to occur worldwide and some species of marine fish act as secondary hosts. Among the nematodes of most concern are Anisakis spp., Capillaria spp., Gnathostoma spp. and Pseudoteranova spp., which can be found in the liver, belly cavity and flesh of marine fish. An example of a nematode causing disease in human beings is Anisakis simplex; the infective stage of the parasite is killed by heating (60 °C for one minute) and by freezing (–20 °C for 24 hours) of the fish core.

Cestodes

Cestodes are tapeworms and the species of most concern associated with the consumption of fish is Dibothriocephalus latus. This parasite occurs worldwide and both fresh and marine fish are intermediate hosts. Similar to other parasitic infections, the foodborne disease occurs through the consumption of raw or under-processed fish. Similar freezing and cooking temperatures as applied to nematodes will kill the infective stages of this parasite.

Trematodes

Fish-borne trematode (flatworm) infections are major public health problems that occur endemically in about 20 countries around the world. The most important species with respect to the numbers of people infected belong to the genera Clonorchis and Ophisthorchis (liver flukes), Paragonimus (lung flukes), and to a lesser extent Heterophyes and Echinochasmus (intestinal flukes). The most important definitive hosts of these trematodes are human beings or other mammals. Freshwater fish are the second intermediate host in the life cycles of Clonorchis and Ophistorchis, and freshwater crustaceans in the case of Paragonimius. Foodborne infections occur through the consumption of raw, undercooked or otherwise underprocessed products containing the infective stages of these parasites. Freezing fish at –20 °C for seven days or at –35 °C for 24 hours will kill the infective stages of these parasites.

Protozoan Parasites -These are single celled animals

Entamoebahistolytica- Can cause severe disease as classical amoebic dysentery which may be fatal if the parasite invades extra-intestinal tissues, such as liver, lungs or brain.

Giardia lamblia- It is associated with diarrhoea, constipation and gastrointestinal pains, rarely invade the tissues.

***Cryptosporidium* spp**. -These are the 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 immune

compromised patients. "Cryptosporidiosis" is acquired after ingesting food or water contaminated with infective cryptosporidium oocysts.

Bacterial hazards

The level of contamination in fish at the time of capture will depend on the environment and the bacteriological quality of the water in which fish are harvested

There are two broad groups of bacteria of public health importance that may contaminate products at the time of capture: (i) those that are normally or incidentally present in the aquatic environment, referred to as indigenous microflora: and (ii) those introduced through environmental contamination by domestic and/or industrial wastes. Examples of indigenous bacteria that may pose a health hazard are *Aeromonas hydrophyla, Clostridium botulinum, Vibrio parahaemolyticus, Vibrio cholerae, Vibrio vulnificus*, and Listeria monocytogenes. Non-indigenous bacteria of public health significance include members of the Enterobacteriaceae, such as Salmonellaspp., Shigellaspp. and *Escherichia coli*. Other species that cause foodborne illness

Viral Hazards

Molluscan shellfish harvested from inshore waters that are contaminated by human or animal faeces may harbour viruses that are pathogenic to human beings. Enteric viruses that have been implicated in seafood-associated illness are the hepatitis A virus, caliciviruses, astroviruses and the norovirus. The latter three are often referred to as small round structured viruses. All of the seafood-borne viruses causing illness are transmitted by the faecal–oral cycle and most viral gastro-enteritis outbreaks have been associated with eating contaminated shellfish, particularly raw oysters.

Occurrence of viral gastro-enteritis can be minimized by controlling sewage contamination of shellfish farming areas and pre-harvest monitoring of shellfish and growing waters as well as controlling other sources of contamination during processing. Depuration and relaying are alternative strategies, but longer periods are required for shellfish to purge themselves clean of viral contamination than of bacteria. Thermal processing (85–90 °C for 1.5 minutes) will destroy viruses in shellfish.

CHEMICAL HAZARDS

Fish may be harvested from coastal zones and inland habitats that are exposed to varying amounts of environmental contaminants. Of greatest concern are fish harvested from coastal and estuarine areas rather than fish harvested from the open seas. Chemicals, organ chloric compounds and heavy metals may accumulate in products that can cause public health problems. Veterinary drug residues can occur in aquaculture products when correct withdrawal times are not followed or when the sale and use of these compounds are not controlled. Fish can also be contaminated with chemicals such as diesel oil (when incorrectly handled) and detergents or disinfectants (when not properly rinsed out).

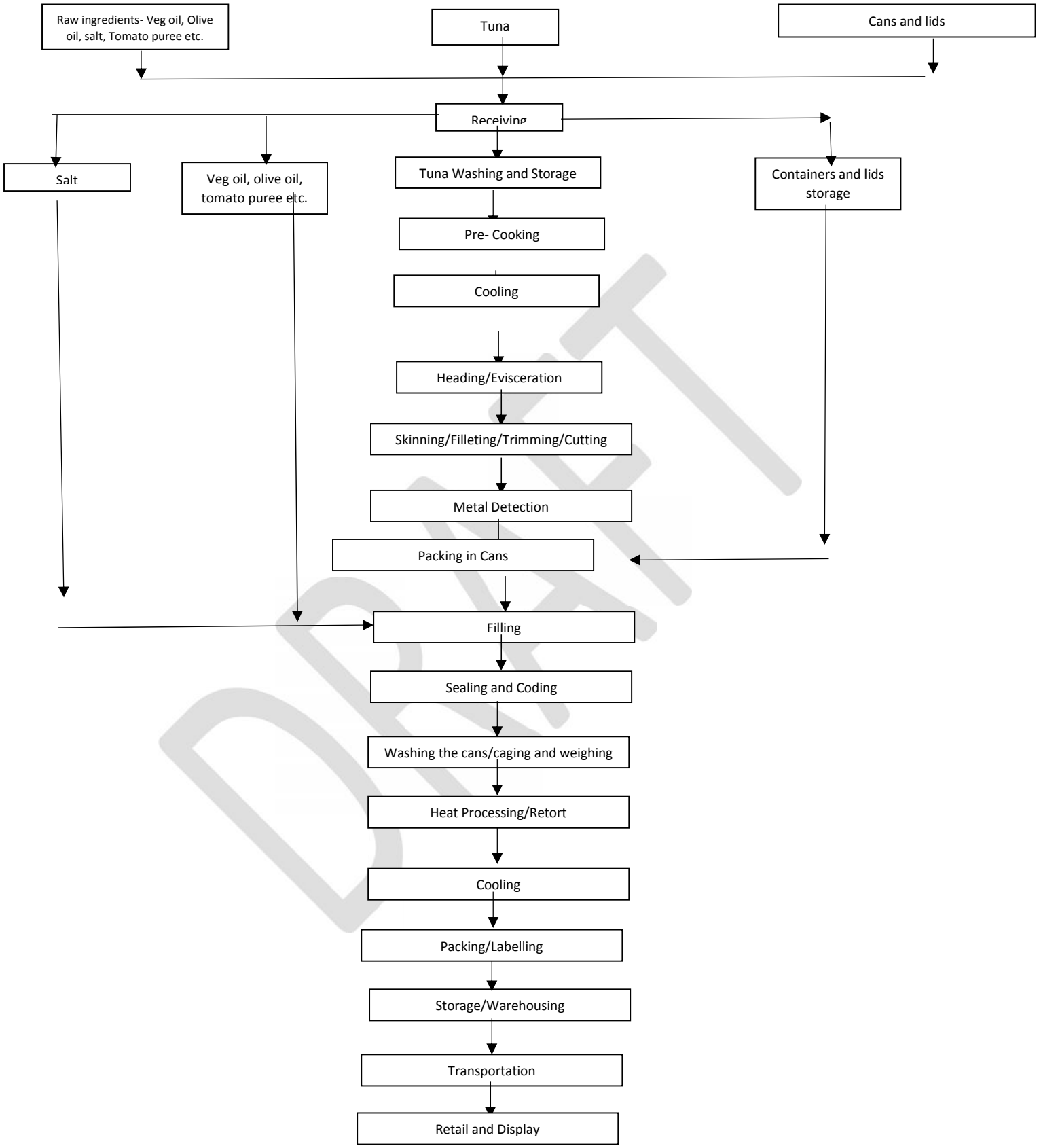
PHYSICAL HAZARDS

These can include materials such as metal or glass fragments, shell and bones.

However, many hazards were linked in the process which can be removed or reduced to acceptable level by an adequate food safety control and measures.

Process flow chart, Hazard Analysis

1.Canned Tuna (Oil/Brine/Sauce)- An example


Raw ingredients- Veg oil, Olive oil, salt, Tomato puree etc.
Tuna
Cans and lids
Receiving
Salt
Veg oil, olive oil, tomato puree etc.
Tuna Washing and Storage
Containers and lids storage
Pre- Cooking
Cooling
Heading/Evisceration
Skinning/Filleting/Trimming/Cutting
Metal Detection
Packing in Cans
Filling
Sealing and Coding
Washing the cans/caging and weighing
Heat Processing/Retort
Cooling
Packing/Labelling
Storage/Warehousing
Transportation
Retail and Display

1 a Table -Hazard Analysis Example – Canned Tuna

Note: This is only a reference model for Risk Assessment & CCP determination example. These may vary from manufacturing plant to plant depending on risk assessment and process control

Sl No.	Process Step	Hazard Type	Potential hazard	Likelihood	Severity	Risk	Preventive Measure	Q1	Q2	Q2A	Q3	Q4	Q5	CCP Y/N	Remark
1. 1.a.	Receiving of Tuna	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage
		Chemical	Histamine	M	H	MH	Time-Temperature control; Proper handling &icing during harvest, transportation & storage of Tuna	N	Y	-	Y	-	-	Y CCP-1	Tuna subjected to time-temperature abuse can develop scombrotoxin (Histamine).
		Physical	None	M	L	ML	Taken care by PRPs	Y	-	-	-	-	-	N	Visual Inspection to detect presence of foreign material
1.b.	Receiving of other raw material	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Presence of foreign material	M	L	ML	Taken care by PRPs a	Y	-	-	-	-	-	N	Visual Inspection to detect presence of foreign material
1.c.	Receiving and storage of cans and lids	Biological	Contamination of cans due to poor storage conditions	L	M	LM	Taken care by PRP's	Y	-	-	-	-	-	N	Maintain good air quality and humidity of the storage room
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Low quality or damaged cans	L	M	LM	Taken care by PRP's	Y	-	-	-	-	-		Purchase specifications and

			and lids Damaged cans and lids due to poor storage conditions											N	visual inspection of all lots of empty cans and lids. Cans must be stacked properly
2.	Washing	Biological	Microbial Pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
3.	Storage	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage
		Chemical	Histamine	M	H	MH	Taken care by PRPs	Y	-	-	-	-	-	N	Controlled by PRP's
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
4.	Pre-cooking	Biological	Microbial pathogens	M	L	ML	Controlled during retorting	Y	-	-	-	-	-	N	Completely eliminated or reduced to safe level during retorting
		Chemical	None	-	-	-	NA	-	-	-	-	-	-	-	_
		Physical	Metal Fragments	M	L	ML	Controlled in the following steps	N	Y	-	N	Y	Y	N	Controlled during the metal detection step.
5.	Cooling	Biological	Microbial pathogens	L	M	LM	Controlled in the following steps	Y	-	-	-	-	-	N	Eliminated in the retorting process
		Chemical	None	-	-	-	NA	-	-	-	-	-	-	-	_
		Physical	None	-	-	-	NA	-	-	-	-	-	-	-	

6.	Heading/Evisceration	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage
		Chemical	None												
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
7.	Skinning/Filleting/Trimming/ cutting	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage
		Chemical	None	-	-	-	NA	-	-	-	-	-	-	-	_
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
8.	Metal Detection	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Metal fragments	M	H	MH	Reject or reprocess the pouch containing metal pieces	N	Y	-	Y	-	-	Y; CCP-2	Metal fragments entering into the product from the processing machinery are detected at this step. Product containing metal fragments are rejected or reprocessed.
9.	Packing in Cans	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage

		Chemical	Metal poisoning	M	L	ML	Taken care by PRP's								All cans used should be made up of food grade material.
		Physical	Impurities present in the can	M	L	ML	All cans are cleaned and inspected before packing; Defective cans are discarded	-	-	-	-	-	-	-	Taken care by operational controls
10.	Weighing	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
11.	Filling of Oil/Brine/ Sauce	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
12.	Sealing and coding	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
13.	Washing of cans and weighing	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Only potable water is used
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
14.	Heat Processing /Retorting	Biological		M	H	MH	Proper cooking; Control of retorting time and temperature	N	Y	-	Y	-	-	Y; CCP-3	Adequate retorting is essential to eliminate the microbial pathogens

		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
15.	Cooling	Biological	Pathogen recontamination	M	L	ML	Controlled by sanitation programmes	Y	-	-	-	-	-	N	Recontamination can be prevented by adopting proper sanitation controls
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
16.	Packing/Labelling	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
17.	Storage/ Warehousing	Biological	Microbial Load	M	H	MH	Temperature to be maintained	N	Y	-	Y	-	-	N	Finished Product Storage done makes hazard unlikely to occur.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
18.	Transportation	Biological	Microbial pathogens	M	L	ML	Cleaning of vehicles Temperature to be maintained	Y	-	-	-	-	-	N	Controlled by sanitation programmes
		Chemical	None													
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
19.	Retail & Display	Biological	Microbial pathogens	M	L	ML	Adherence to GHP	Y	-	-	-	-	-	N	SOP for finished product storage during retail and display makes hazard unlikely to occur

		Chemical	None													
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-	-

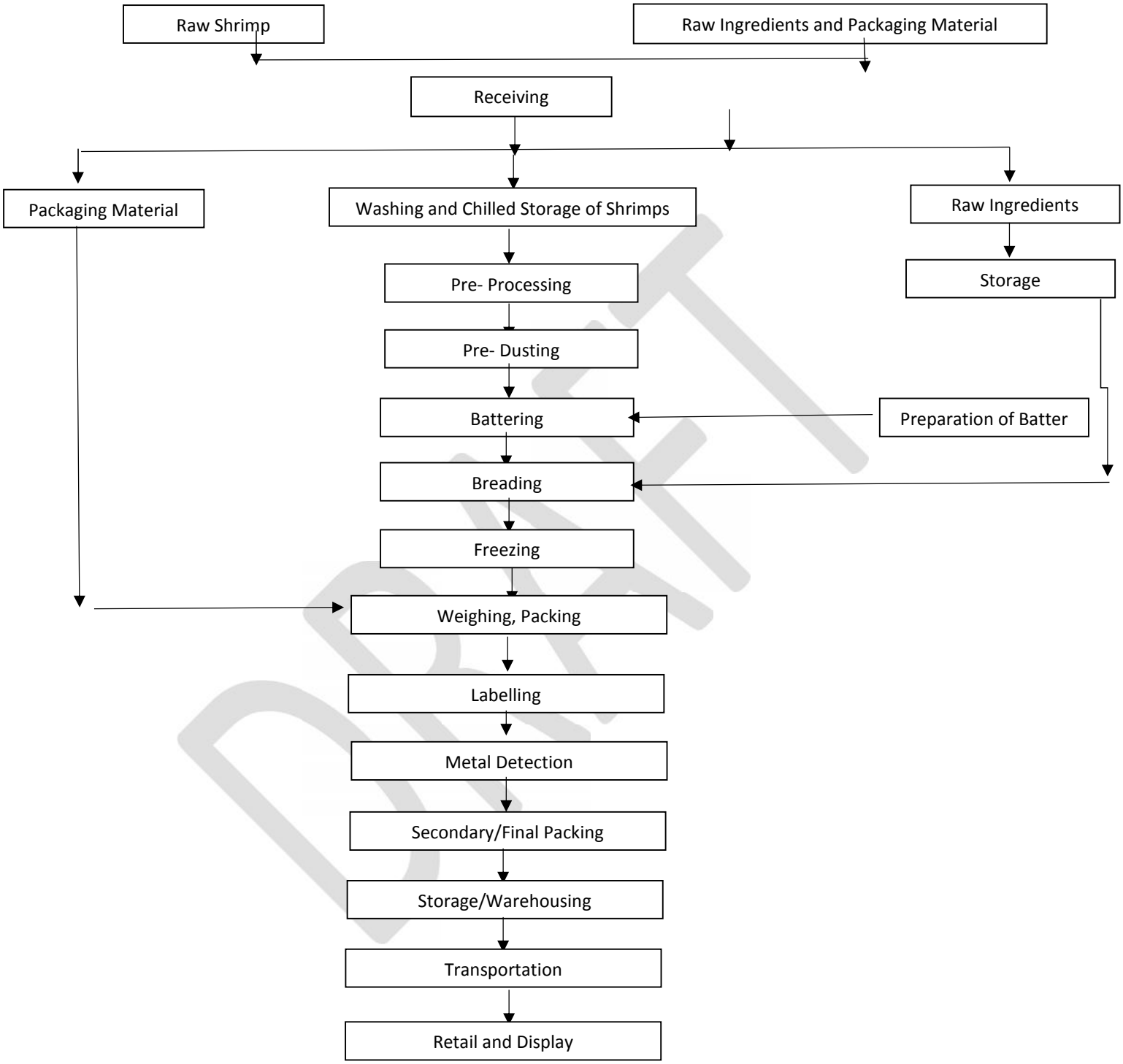
1.b. Table – HACCP Plan

Note: This is only a reference model for Risk Assessment & CCP determination example. These may vary from manufacturing plant to plant depending on risk assessment and process control

Sl.No.	CCP			Critical limit	Monitoring	Corrective Action		Verification	HACCP Record
						Immediate	Long term		
1.	CCP No. 1	**Process Step-** Receiving	**Hazard Addressed-** Histamine	**Critical Limit (CL)-** Fish surrounded by ice. Receiving temperature of fish should be ≤4°C. (Documentation of Validation of Critical limit to be made available)	**What -** Amount of ice and temperature of fish **How –** Visual check **When-** Every lot received **Where** - Receiving area **Who –** Receiving Supervisor	If icing is not adequate check the temperature of fish; If temperature ≥4°C reject the lot. Check the histamine content of suspected lot; reject if it exceeds 50ppm	Proper Training of Suppliers or if needed change the supplier.	**What:** Fish Temperature and Histamine concentration **How:** Probe type thermometer. **When:** Once in a day **Where:** Receiving Area **Who:** QC/QA Supervisor/Manager	1. Hazard Analysis records for justification for CCP's 2.CL Validation Records 3.Fish Temperature Monitoring Record. 4. Histamine Report 5. Correction and Corrective Action Records 6. Daily verification Records. 7. Raw Material Receiving log; 8.Supplier guarantee/declaration form 9.Audit Records 10. Calibration Records of probe.

2.	CCP No. 2	**Process Step-** Metal Detection	**Hazard Addressed-** Physical (Metal Particles)	**Critical Limits-** Metal detector should able to detect test stripes of 1.5 mm Ferrous, 2.5 mm SS & 2.0 mm Nonferrous (Documentation of Validation of Critical Limit to be made available)	**What:** Metal Detector sensitivity **How:** by passing all three test stripes from the metal detector **When:** before start of each shift and every hour **Where:** Metal Detector Point **Who:** Production Supervisor/Manager	Supervisor to hold previous production back to last "passed" calibration check. Re pass the product after proper calibration.	Periodic Maintenance of metal detector	**What:** Metal detector operation **How:**by passing test stripes **When:** At least two times per shift **Responsibility:** QC/QA Supervisor/Manager	1. Hazard Analysis Records 2. CL validation record. 3. Monitoring Records 4. Daily Verification Records. 5. Internal Audit Records 6. Correction Records 7. Corrective Action Records 8. Calibration Records of Probes
3.	CCP No. 3	**Process Step-** Heat Processing/ Retorting	**Hazard Addressed-** Microbial Pathogens	**Critical Limit (CL)-** Retorting Time: 30 minutes Temperature: 120°C. (Documentation of Validation of Critical limit to be made available)	**What -** Retorting Time & Temperature **How –** Monitoring of gauges/display **When-** Every lot **Where -** Retort **Who –** Operator	Reprocess the lot if a process deviation occurs	Proper Maintenance of Retort.	**What:** Product Temperature **How:** With probe type thermometer **When:** Once in a day **Where:** Retort Area **Who:** QC/QA Supervisor/Manager	1. Hazard Analysis records for justification for CCP's 2.CL Validation Records 3.Retorting Time and Temperature Monitoring Record. 4. Correction and Corrective Action Records 5. Daily verification Records. 6.Audit Records 7. Calibration Records of monitoring equipment's 8. Process Control log 9. Microbiological analysis record

2.IQF Breaded Shrimp- (An example)



2 a Table -Hazard Analysis Example – IQF Breaded Shrimp

Note: This is only a reference model for Risk Assessment & CCP determination example. These may vary from manufacturing plant to plant depending on risk assessment and process control

Sl No.	Process Step	Hazard Type	Potential hazard	Likelihood	Severity	Risk	Preventive Measure	Q1	Q2	Q2A	Q3	Q4	Q5	CCP Y/N	Reason for decision
1.	Receiving Of Shrimp	Biological	Microbial pathogens	M	L	ML	Controlled in further processing steps	Y	-	-	-	-	-	N	Reduced to acceptable level in the subsequent freezing step.
		Chemical	Sulphite Pesticide Antibiotic in case of Aquaculture	M	L	ML	Adherence to raw material specifications Supplier's guarantee that sulphiting agents are not used and the raw product is free from pesticide residues. Supplier's gurantee taking into account withdrawal period	Y						N	Supplier's declaration Adherence to specifications.
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
1.b.	Receiving of other raw material	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Presence of foreign material	M	L	ML	Taken care by PRPs a	Y	-	-	-	-	-	N	Visual Inspection to detect presence of foreign material
1.c.	Receiving and storage of Packaging material	Biological	Contamination due to poor storage conditions	L	M	LM	Taken care by PRP's	Y	-	-	-	-	-	N	Maintain good air quality, cleanliness and humidity of the storage room
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Low quality packaging material	L	M	LM	Taken care by PRP's	Y	-	-	-	-	-	N	Purchase specifications and visual inspection of all lots of packaging material. Packaging material used must be

															food grade.
2.	Washing	Biological	Microbial Pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage Use only potable water for washing	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage. Testing of potable water done against IS10500 standard requirements.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
3.	Storage	Biological	Microbial pathogens	M	L	ML	Time – Temperature control	Y	-	-	-	-	-	N	Adherence to PRP's control microbial multiplication.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
4.	Pre-processing	Biological	Microbial pathogens	M	L	ML	Taken care by GHP	Y	-	-	-	-	-	N	Adherence to GHP prevents microbial contamination
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Metal Fragments	M	L	ML	Controlled in the following steps	N	Y	-	N	Y	Y	N	Controlled during the metal detection step.
5	Pre-dusting	Biological	Microbial pathogens	M	L	ML	Controlled by GHP	Y	-	-	-	-	-	N	Adherence to GHP
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Metal fragments	M	L	ML	Final Product is passed through metal detector	Y	-	-	-	-	-	N	There are chances of metal contamination from the conveyor belts and equipment. Metal detection step eliminate the hazard.
6.	Battering	Biological	Microbial Pathogens	M	L	ML	Taken care by PRPs and GHP	Y						N	Adherence to GHP controls bacterial multiplication.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Metal	M	L	ML	Final Product is passed through	Y	-	-	-	-	-	N	

			fragments				metal detector								There are chances of metal contamination from the conveyor belts and equipment. Metal detection step eliminate the hazard.
7.	Breading	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs	Y	-	-	-	-	-	N	Adherence to GHP controls bacterial multiplication
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Metal fragments	M	L	ML	Final Product is passed through metal detector	Y	-	-	-	-	-	N	There are chances of metal contamination from the conveyor belts and equipment. Metal detection step eliminate the hazard.
8.	Freezing	Biological	Microbial pathogens	M	H	MH	Proper and adequate freezing	N	Y	-	Y	-	N	Y CCP - 1	Improper freezing may lead to pathogen growth and multiplication
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
9.	Weighing/ Packing	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
10.	Labelling	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
11.	Metal Detection	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-

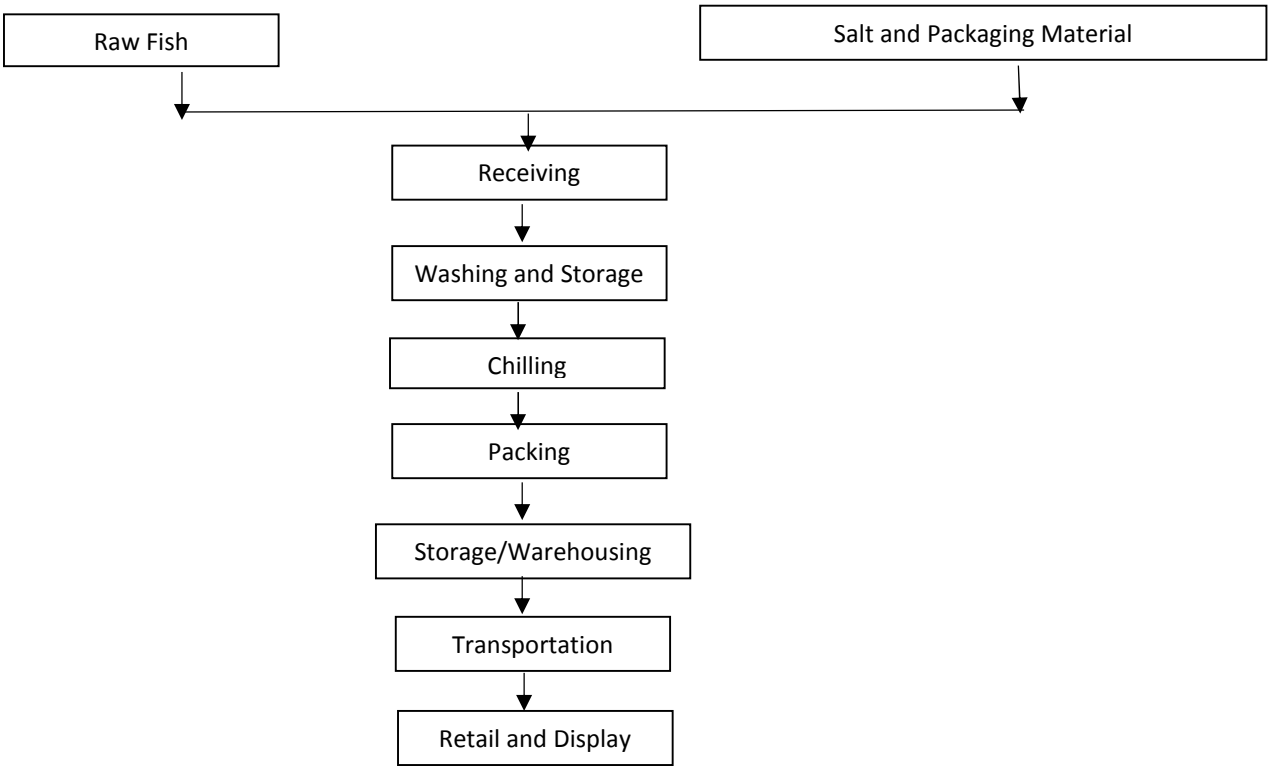
		Physical	Metal fragments	M	H	MH	Reject or reprocess the pouch containing metal pieces	N	Y	-	Y	-	-	Y; CCP-2	Metal fragments entering into the product from the processing machinery are detected at this step. Product containing metal fragments are rejected or reprocessed.
12.	Secondary /Final Packing	None	-	-	-	-	-	-	-	-	-	-	-	-	None
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
13.	Storage/ Warehousing	Biological	Microbial pathogens	M	L	ML	Temperature to be maintained	N	Y	-	Y	-	-	N	Finished Product Storage done makes hazard unlikely to occur.
		Chemical		-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
14.	Transportation	Biological	Microbial pathogens	M	L	ML	Cleaning of vehicles Time-temperature control	Y	-	-	-	-	-	N	Controlled by sanitation programmes and PRP's
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
15.	Retail & Display	Biological	Microbial pathogens	M	L	ML	Adherence to GHP	Y	-	-	-	-	-	N	SOP for finished product storage during retail and display makes hazard unlikely to occur
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-

2.b. Table – HACCP Plan-

Note: This is only a reference model for Risk Assessment & CCP determination example. These may vary from manufacturing plant to plant depending on risk assessment and process control

Sl.No.	CCP			Critical limit	Monitoring	Corrective Action		Verification	HACCP Record
						Immediate	Long Term		
1.	CCP No. 1	**Process Step-** Freezing	**Hazard Addressed** Microbial Pathogens	**Critical limit (CL)-** Freezing Time – 10 – 20minutes Temperature- -25°C Core temperature at or below -18°C (Documentation of Validation of Critical Limit to be made available)	**What -** Freezing Time & Temperature Frozen Product Temperature **How –** Monitoring of gauges/display Thermometer Probes **When-** Every half an hour **Where -** Freezer hall **Who –** Operator	Reprocess the lot if a process deviation occurs. Ensure the core temperature is ≥ -18°C	Proper maintenance of freezer	**What -**Product core temperature **How –** Using probe type thermometer **When-** Once in a shift **Who –** QA/QC Supervisor/Manager	1.Hazard Analysis records with justification for CCPs. 2. CL Validation Records 3.Freezing time and temperature monitoring records 4. Fish temperature monitoring record 5. Correction Record 6. Corrective Action Records 7. Daily Verification Records 8. Audit Records 9. Calibration Records of Probes 10. Microbiological Analysis Record. 11. Online QC Record
2	CCP No. 2	**Process Step-** Metal Detection	**Hazard Addressed-** Physical (Metal Particles)	**Critical Limits-** Metal detector should able to detect test stripes of 1.5 mm Ferrous, 2.5 mm SS & 2.0 mm Nonferrous (Documentation of Validation of Critical Limit to be made available)	**What:** Metal Detector sensitivity **How:** by passing all three test stripes from the metal detector **When:** before start of each shift and every hour **Where:** Metal Detector Point **Who:** Production Supervisor/Manager	Supervisor to hold previous production back to last "passed" calibration check. Re pass the product after proper calibration.	Periodic Maintenance of metal detector	**What:** Metal detector operation **How:**by passing test stripes **When:** At least two times per shift **Responsibility:** QC/QA Supervisor/Manager	1. Hazard Analysis Records 2. CL validation record. 3. Monitoring Records 4. Daily Verification Records. 5. Internal Audit Records 6. Correction Records 7. Corrective Action Records 8. Calibration Records of Probes

3.Chilled Fish- (An example)



3.a. Table -Hazard Analysis Example – Chilled Fish

Note: This is only a reference model for Risk Assessment & CCP determination example. These may vary from manufacturing plant to plant depending on risk assessment and process controls

Sl No.	Process Step	Hazard Type	Potential hazard	Likelihood	Severity	Risk	Preventive Measure	Q1	Q2	Q2A	Q3	Q4	Q5	CCP Y/N	Reason for decision
1.	Receiving	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs	Y		-	-	-	-	N	Not intended for raw consumption. To be fully cooked by the consumer.
		Chemical	Histamine (only for scombroid fishes)	M	H	MH	Time-Temperature control; Proper handling &icing during harvest, transportation & storage	N	Y	-	Y	-	-	Y CCP-1	Scombroid fishes (e.g. Tuna, Seer fish, Mackerel) subjected to time-temperature abuse can develop scombrotoxin (Histamine).
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
1.b.	Receiving of raw ingredient i.e. salt	Biological	None	-	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Presence of foreign material	M	L	ML	Taken care by PRPs a	Y	-	-	-	-	-	N	Visual Inspection to detect presence of foreign material
1.c.	Receiving and storage of Packaging material	Biological	Contamination due to poor storage conditions	L	M	LM	Taken care by PRP's	Y	-	-	-	-	-	N	Maintain good air quality, cleanliness and humidity of the storage room
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	Low quality packaging material	L	M	LM	Taken care by PRP's	Y	-	-	-	-	-	N	Purchase specifications and visual inspection of all lots of packaging

															material. Packaging material used must be food grade.
2	Washing	Biological	Microbial pathogens	M	L	ML	Controlled by PRP Use of potable water for washing	Y	-	-	-	-	-	N	Product should be cooked by the consumer Potable water to be tested against IS10500 standard requirements.
		Chemical	None	-	-	-	NA	-	-	-	-	-	-	-	_
		Physical	None	-	-	-	NA	-	-	-	-	-	-	–	_
3	Storage	Biological	Microbial pathogens	M	L	ML	Taken care by PRPs and eliminated during retorting stage	Y	-	-	-	-	-	N	Microbial pathogens are reduced or eliminated in the subsequent pre-cooking and retorting stage
		Chemical	Histamine	M	H	MH	Taken care by PRPs	Y	-	-	-	-	-	N	Controlled by PRP's
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
5.	Chilling	Biological	Microbial pathogens	M	H	MH	Proper and adequate Chilling	N	Y	-	Y	-	-	Y CCP-2	Improper chilling may lead to pathogen growth and multiplication; Product should be cooked by the consumer
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
6.	Packing	Biological	Microbial Pathogens	M	L	ML	Controlled by PRP. Food handlers are the source of hazard	Y	-	-	-	-	-	N	Microbial contamination can be prevented by adopting proper sanitation controls.

															Product should be cooked by the consumer
		Chemical	None	-	-	-	-	-	-	-	-	-	-	N	
		Physical	None	-	-	-	-	-	-	-	-	-	-	N	
7.	Storage/ Warehousing	Biological	Microbial Pathogens	M	L	ML	Temperature to be maintained	N	Y	-	Y	-	-	N	Finished Product Storage done makes hazard unlikely to occur. Product should be cooked by the consumer.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
8.	Transportation	Biological	Microbial pathogens	M	L	ML	Cleaning of vehicles Time-temperature control	Y	-	-	-	-	-	N	Controlled by sanitation programmes and PRP's
		None	None	-	-	-	-	-	-	-	-	-	N	None	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-
9.	Retail & Display	Biological	Microbial Pathogens	M	L	ML	Controlled by sanitation programmes	Y	-	-	-	-	-	N	SOP for finished product storage during retail and display makes hazard unlikely to occur Microbial contamination can be prevented by adopting proper sanitation controls. Product should be cooked by the consumer

		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-	-	-	-	-	-	-	-

3.b. Table – HACCP Plan Example

Note: This is only a reference model for Risk Assessment & CCP determination example. These may vary from manufacturing plant to plant depending on risk assessment and process controls

Sl.No.	CCP			Critical limit	Monitoring	Corrective Action		Verification	HACCP Record
						Immediate	Long term		
1.	CCP No. 1	**Process Step-** Receiving	**Hazard Addressed-** Histamine	**Critical Limit (CL)-** Fish surrounded by ice. Receiving temperature of fish should be ≤4°C. (Documentation of Validation of Critical limit to be made available)	**What -** Amount of ice and temperature of fish **How –** Visual check **When-** Every lot received **Where** - Receiving area **Who –** Receiving Supervisor	If icing is not adequate check the temperature of fish; If temperature ≥4°C reject the lot. Check the histamine content of suspected lot; reject if it exceeds 50ppm	Proper Training of Suppliers or if needed change the supplier.	**What:** Fish Temperature **How:** Probe type thermometer. **When:** Once in a day **Where:** Receiving Area **Who:** QC/QA Supervisor/Manager	1. Hazard Analysis records for justification for CCP's 2.CL Validation Records 3.Fish Temperature Monitoring Record. 4. Histamine Report 5. Correction 6. Corrective Action Records 7. Daily verification Records. 8. Raw Material Receiving log; 9.Supplier guarantee/declaration form 10.Audit Records 11. Calibration Records of probe.
2.	CCP No. 2	**Process Step-** Chilling	**Hazard Addressed-** Microbial Pathogens	**Critical Limit (CL)-** Temperature of fish should be ≤4°C. (Documentation of Validation of Critical limit to be made available)	**What -** Amount of ice and temperature of fish **How –** Visual check **When-** Every lot taken for production **Where** - Chilling area **Who –**Production Supervisor	If icing is not adequate check the temperature of fish; If temperature ≥4°C hold the lot.	Proper Training of Production in charge	**What:** Fish Temperature **How:** Probe type thermometer. **When:** Once in a day **Where:**Production Area **Who:** QC/QA Supervisor/Manager	1. Hazard Analysis records for justification for CCP's 2.CL Validation Records 3.Fish Temperature Monitoring Record. 4. Correction and Corrective Action Records 5. Daily verification Records. 6.Supplier guarantee/declaration form 7.Audit Records

									8. Calibration Records of probe.