

HACCP, Standards and Regulations

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Introduction

Hazard Analysis and Critical Control Point (HACCP) evolved as a quality assurance approach in late 1950's has been embraced as a food safety management tool throughout the world. Compared to traditional end product testing-based food safety programmes, HACCP is a dynamic, preventive system of food control with a prior anticipated risk-response approach.

HACCP is a preventive system to control significant identified hazards. It also functions by designing food safety into a product and controlling the process by which the product is produced. However, it should be noted that HACCP does not rely on end product testing or lot acceptance criteria. HACCP is a core component in all national and international food safety standards such as IS 15000, ISO 22000:2005, USFDA Seafood HACCP regulation (CFR 123, Title 21), Dutch HACCP, BRC Global Standard for Food, SQF 2000, IFS, etc.

HACCP is a system that identifies, evaluates, and controls hazards that are significant for food safety. As described by Codex Alimentarius Commission, General Principles of Food Hygiene (CXC-1 1969) and its HACCP Annex in 2020, HACCP can be implemented by 12 logical steps that include five preliminary steps and seven principles.

Step 1.	Assemble HACCP team	Preliminary Steps
Step 2.	Describe product	
Step 3.	Identify intended use	
Step 4.	Construct flow diagram	
Step 5.	On-site confirmation of flow diagram	
Step 6.	List all potential hazards	HACCP Principle I
Step 7.	Determine Critical Control Points (CCP)	HACCP Principle II
Step 8.	Establish validated critical limits for each CCP	HACCP Principle III
Step 9.	Establish a monitoring system for each CCP	HACCP Principle IV
Step 10.	Establish corrective actions	HACCP Principle V
Step 11.	Validation of the HACCP Plan and Verification	HACCP Principle VI
Step 12.	Establish Documentation and Record Keeping	HACCP Principle VII

Step 1: Assemble an HACCP team

HACCP team is a group of people who are assembled and given the responsibility of implementing HACCP system. People are chosen based upon their knowledge and experience in various aspects of food safety such as biological and chemical hazards, specific food production process, regulatory requirements, logistics and management. A member of the HACCP team serves as the leader and ensures that all requirements for institutionalizing HACCP system are addressed.

Example: For implementing HACCP in fish processing the HACCP team should comprise of persons having educational qualifications in fisheries science/fish processing/aquaculture, microbiology, biochemistry, engineering and management.

Step 2: Describe the product

Important characteristics of the product must be described in order to identify and evaluate hazards in subsequent steps. The product characteristics should include product nomenclature, composition, physical and chemical characteristics (a_w , pH, preservatives, allergenic potential), packaging, shelf life, storage conditions (temperature, humidity), labeling instructions for handling, storage and instructions prior to use by the consumer, distribution control, actual use and sale target.

Example: “Ready to Eat Fish Curry”

Product Description	
1. Product name(s):	Ready to Eat Rohu Curry
2. Important product characteristics	Retort Pouched
3. How it is to be used:	Ready to Eat
4. Packaging:	3 ply laminated (Polyester/Al/cast PP)
5. Shelf life:	3 years
6. Where it will be sold:	India, Nepal, Bangladesh, Sri Lanka
7. Labeling instructions: (i.e additives used)	Approved colour (E 160c), flavor enhancer (E621)
8. Special distribution control:	To be transported in shock-proof cartons

Step 3: Identify the intended use of the product

The normal or common use of the product must be identified. This step is especially designed taking into care vulnerability of target consumer against biological and chemical hazards. As YOPI (young, old, pregnant and immuno-compromised) populations are at higher risk, prior knowledge on the target consumer helps in stringent design of HACCP plan. Further, this step must take into account actual use of the product i.e. household use, institutional use or industrial use for further processing.

Example: Ready to Eat Fish curry is to be consumed by general public for house-hold consumption

Step 4: Construct process flow diagram for the product

The logical step-by-step process in the manufacture of the product should be represented with a flow diagram. All the processing steps starting from receiving till shipment should be included either in a single flow diagram or with modular diagrams when production is carried out in different sections.

Step 5: Verification of process flow diagram

The flow diagram constructed should be verified on-site by actually observing each step of the process starting from receiving of raw material to shipment of finished product. Based on this the process flow should be modified or amended. Successful development of HACCP plan depends on accuracy of flow diagram.

Step 6: List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards

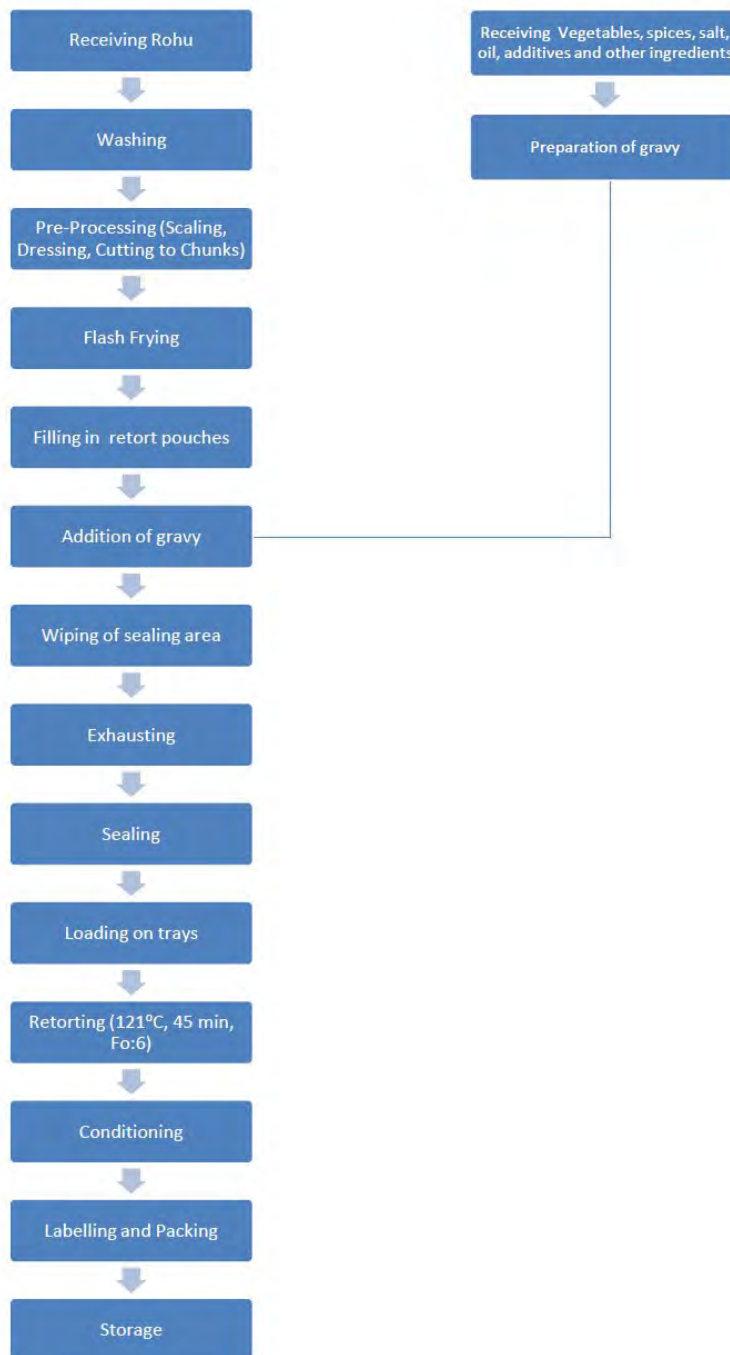
Three categories of hazards are identified viz. physical, chemical and biological by an elaborate two-step process *hazard identification* and *hazard evaluation*.

Hazard Identification:

Hazard is defined as *a biological, chemical, or physical agent in, or condition of food with the potential to cause an adverse health effect* (Codex Alimentarius, 1997). As per NACMCF (1997), hazard is also defined as *a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control*. At this step all potential hazards coming from

ingredients, raw materials, packaging materials and environment used for the preparation of the product are identified based upon the following information:

- Nature of the product and the product characteristics (pH, composition, a_w , and additives)
- Safety record of the product
- Normal microbial characteristics of the product and changes during storage and handling
- Raw materials, ingredients, and packaging materials used
- Activities, operations, equipment and personnel involved at each of the steps listed in the process
- Environmental conditions at the time the product is produced and stored
- intended use of the product



Hazard Evaluation:

Only significant hazards are identified based upon severity and likelihood of occurrence. Severity should be assessed based on the consequences of exposure to the hazard, whereas, the likelihood of occurrence is based on the epidemiological records, scientific evidence and susceptibility of the target consumers.

Identification of control measures:

The control measure for each significant hazard is identified and HACCP team determines in which step of the process flow such measure can be implemented. If there is no step where the control measure for the identified hazard can be exercised then process is modified or alternate hazard control measure is suggested.

Hazard	Control Measure
<i>Salmonella</i>	Thermal processing (Heating, cooking, pasteurization, retorting)
Pesticides	Testing for presence of residues; source control
Metal pieces	Detection and removal of metal pieces by using strong magnet and online metal detector

Step 7: Determination of Critical Control Point (CCPs)

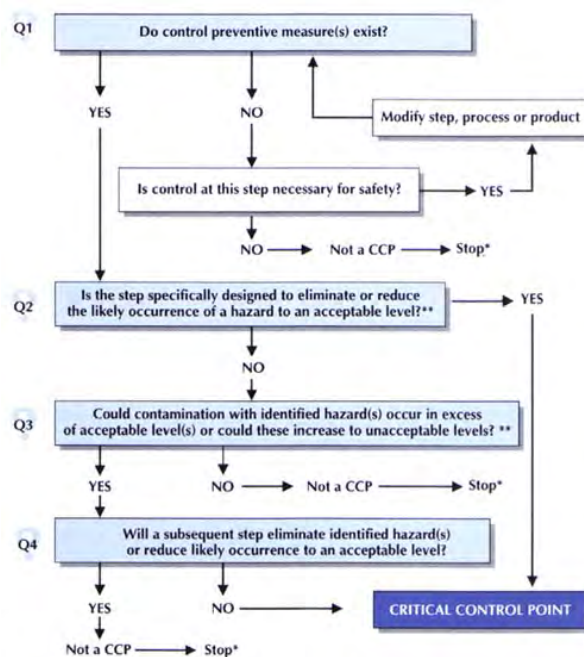
The HACCP team determines the step at which there will be control of the hazards that present unacceptable risks. This step is called as critical control point. Various definitions of CCP are as follows:

- A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Codex Alimentarius, 1997; NACMCF, 1997)
- The processing factors whose loss of control would result in an unacceptable food safety risk (ASQ, 1998)

CCPs are determined by using a decision tree (a sequence of questions to assist in determining whether a control point is a CCP or not) developed by Codex Alimentarius or NACMCF. Example: Retorting is a CCP for bacterial pathogens and receiving as a CCP for pesticide residues

Step 8: Establish validated critical limits for each CCP

The HACCP team must establish critical limits for accepting or rejecting a raw material, ingredient or a semi-finished or finished product that is obtained at a process step designated as CCP. Critical limit is defined as *a criterion that separates acceptability from unacceptability* (Codex Alimentarius, 1997). It is also defined as *a maximum or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce the occurrence of a food safety hazard to an acceptable level* (NACMCF, 1997). The



identified control measures can be validated as per Codex Alimentarius Commission CAC/GL-69-2008 and based upon those critical limits are determined.

Example: Validated time and temperature cooking regime; cooking at 72°C core temperature for 1 minute for 6D reduction of *Listeria monocytogenes*

Step 9: Establish monitoring procedures for each CCP

At each CCP the HACCP team establishes monitoring procedures to determine whether the prior specified critical limits are respected or not. Monitoring reveals loss of control at CCP so that appropriate action can be taken. Visual inspection and chemical testing methods are generally employed. Microbiological tests are time consuming and rarely used. Monitoring (continuous or periodic) must be reliable and calibrated equipment should only be used. All monitoring records must be maintained.

Step 10. Establish corrective action procedures for each CCP

The HACCP team must establish procedures to be followed if and when any deviation is observed during monitoring of a CCP. A product that is obtained at a process step where the CCPs are not respected is a nonconforming product and is unsafe for consumption. Corrective action procedures are established to prevent unsafe product from reaching the consumer. Corrective action procedures must include the following points:

- Identification of the cause of deviation
- Action to be taken to prevent recurrence of the deviation
- Time of occurrence of deviation
- Quantum of non-conforming products generated
- Action to be taken to prevent distribution of the product
- Rectification of the anomaly

CCP	Hazard	Monitoring Procedure
Retorting	Bacterial Pathogens	Monitoring time and temperature
Receiving raw material	Pesticides	Examination of certificate of analysis Examination of supplier guarantee/declaration
Metal detection	Metal pieces	Monitoring of product by metal detector

Step 11: Validation of the HACCP Plan and Verification Procedures

HACCP team must establish verification procedures for each identified CCP and as well as for entire HACCP plan. The term verification is defined in a number of ways; some of them are as follows:

- *Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 9000:2000).*
- *The application of methods, procedures, tests, and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (Codex Alimentarius, 1997).*
- *Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan (NACMCF, 1997).*
- *The act of determining whether products and services conform to specific requirements (QP, 2002).*

CCP	Hazard	Verification Procedure
Retorting	Bacterial Pathogens	Review of retorting records, microbiological testing of end-product Review of Calibration records of temperature and pressure sensors of retort
Receiving raw material	Pesticides	Review of certificate of analysis, review of pesticide usage record; periodic sampling of water and fish for pesticide analysis; Pesticide level in end product

Initial HACCP plan (prior to implementation) is verified by validating the critical limits, monitoring procedure and corrective action procedure. Ongoing HACCP programmes are verified by periodic review of monitoring and corrective action records, periodic sampling and analysis, product testing, system audit and periodic independent review of entire HACCP plan.

CCP	Hazard	Records
Retorting	Bacterial Pathogens	Retorting monitoring records Calibration records of temperature and pressure sensors of retort

Step 12: Establish record-keeping and documentation procedures

HACCP team must identify the records that need to be maintained as per the monitoring, corrective action and verification procedures. The following documents related to HACCP plan must be maintained by the organization:

- Composition of HACCP team
- Description of food product and intended use
- Verified process flow diagram
- Summary of hazard evaluation and list of significant hazards
- Summary of CCP determination and justification
- HACCP Plan form indicating CCP, corresponding hazards, critical limit, monitoring procedure (what, how, frequency and personnel responsible), corrective action procedure, verification procedure and records maintained
- CCP validation records
- Records of monitoring, corrective action and verification

Receiving raw material	Pesticides	Monitoring records of receipt of certificate of analysis; Farm visit and sampling records; pesticide usage record;
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Standards and Regulations for Fish and Fish Products**National Standards**

In India, standards related to fish and fish products are formulated by Bureau of Indian Standards (BIS) and Food Safety and Standards Authority of India (FSSAI). The standards of BIS are voluntary in nature and mostly used for certification purposes, whereas the standards by FSSAI are regulatory and mandatory for domestic trade and imported fish and fish products.

The BIS standards for fish and fish products are as follows:

1	IS 2168 : 1971 Reaffirmed In : 2016–Specification for pomfret canned in oil (First Revision)
2	IS 2236 : 1968 Reaffirmed In : 2016–Specification for prawns/shrimp canned in brine (First Revision)
3	IS 2237 : 1997 Reaffirmed In : 2018–Prawns (Shrimps) - Frozen - Specification (Third Revision)
4	IS 3336 : 1965 Reaffirmed In : 2016–Specification for shark liver oil for veterinary use
5	IS 3892 : 1975 Reaffirmed In : 2016–Specification for frozen lobster tails (First Revision)
6	IS 4303 (Part 1) : 1975 Reaffirmed In : 2018–Code of hygienic conditions for fish industry: Part 1 pre-processing stage (First Revision)
7	IS 4303 (Part 2) : 1975 Reaffirmed In : 2018–Code of hygienic conditions for fish industry: Part 2 canning stage (First Revision)
8	IS 4304 : 1976 Reaffirmed In : 2016–Specification for tuna canned in oil (First Revision)
9	IS 4780 : 1978 Reaffirmed In : 2016–Specification for pomfret, fresh (first revision)

10	IS 4793 : 1997 Reaffirmed In : 2016–Whole pomfret - Frozen - Specification (Second Revision)
11	IS 5734 : 1970 Reaffirmed In : 2016–Specification for sardine oil
12	IS 6122 : 1997 Reaffirmed In : 2018–Seer fish (<i>Scomberomorus</i> Sp.) - Frozen - Specification (First Revision)
13	IS 6123 : 1971 Reaffirmed In : 2016–Seer fish (<i>Scomberomorus</i> Spp.), fresh
14	IS 7143 : 1973 Reaffirmed In : 2016–Specification for crab meat canned in brine
15	IS 7313 : 1974 Reaffirmed In : 2016–Glossary of important fish species of india
16	IS 7582 : 1975 Reaffirmed In : 2016–Specification for crab meat, solid packed
17	IS 8076 : 2000 Reaffirmed In : 2016–Frozen cuttle fish and squid - Specification (First Revision)
18	IS 9808 : 1981 Reaffirmed In : 2016–Specification for fish protein concentrate
19	IS 10059 : 1981 Reaffirmed In : 2016–Specification for edible fish powder
20	IS 10449 : 1983 Reaffirmed In : 2016–Code for transport of live fish seeds for inland pisciculture purposes
21	IS 10450 : 1983 Reaffirmed In : 2016–Code for transport of fresh water aquarium fish
22	IS 10760 : 1983 Reaffirmed In : 2016–Specification for mussels canned in oil
23	IS 10762 : 1983 Reaffirmed In : 2016–Specification for mussels canned in oil
24	IS 10763 : 1983 Reaffirmed In : 2016–Specification for frozen minced fish meat
25	IS 11427 : 2001 Reaffirmed In : 2018–Fish and fishery products - Sampling (First Revision)
26	IS 14514 : 1998 Reaffirmed In : 2018–Clam meat - Frozen - Specification
27	IS 14515 : 1998 Reaffirmed In : 2018–Fish pickles - Specification
28	IS 14516 : 1998 Reaffirmed In : 2018–Cured fish and fishery products - Processing and storage - Code of practice
29	IS 14520 : 2018–Fish industry - Operational cleanliness and layout of market - Guidelines (First Revision)
30	IS 14890 : 2001 Reaffirmed In : 2018–Sardines - Fresh, frozen and canned - Specification
31	IS 14891 : 2001 Reaffirmed In : 2018–Mackerel - Fresh, frozen and canned - Specification
32	IS 14892 : 2000 Reaffirmed In : 2018–Threadfin - Fresh and frozen - Specification
33	IS 14949 : 2001 Reaffirmed In : 2018–Accelerated freeze dried prawns (Shrimps) - Specification
34	IS 14950 : 2001 Reaffirmed In : 2018–Fish - Dried and Dry - Salted - Specification
35	IS 16150 (Part 1) : 2014 Reaffirmed In : 2019–Fish feed - Specification: Part 1 carp feed
36	IS 16150 (Part 2) : 2014 Reaffirmed In : 2019–Fish feed - Specification: Part 2 catfish feed
37	IS 16150 (Part 3) : 2014 Reaffirmed In : 2019–Fish feed - Specification: Part 3 marine shrimp feed
38	IS 16150 (Part 4) : 2014 Reaffirmed In : 2019–Fish feed - Specification: Part 4 freshwater prawn (<i>Macrobrachium rosenbergii</i>) feed
39	IS 16292 : 2014/ISO 12877 : 2011 Reaffirmed In : 2019–Traceability of finfish products - Specification on the information to be recorded in farmed finfish distribution chains

40	IS 16293 : 2014/ISO 12875: 2011 Reaffirmed In : 2019–Traceability of finfish products - Specification on the information to be recorded in captured finfish distribution chains
41	IS 17186 : 2019/ISO 16741 : 2015–Traceability of crustacean products - Specifications on the information to be recorded in farmed crustacean distribution chains
42	IS 17187 : 2019/ISO 18537 : 2015–Traceability of crustacean products - Specifications on the information to be recorded in captured crustacean distribution chains
43	IS 17188 : 2019/ISO 18538 : 2015–Traceability of molluscan products - Specifications on the information to be recorded in farmed molluscan distribution chains
44	IS 17189 : 2019/ISO 18539:2015–Traceability of Crustacean Products -Specifications on the Information to be Recorded in Captured Crustacean Distribution Chains
45	IS 17281 : 2019–Requirements for Good Aquaculture Practices-India GAqP Shrimp Hatchery and Grow Out Farms
46	IS 17282 : 2019–Requirements for Good Aquaculture Practices-India GAqP Striped Catfish (<i>Pangasianodon hypophthalmus</i>)
47	IS 17283 : 2019–Requirements for Good Aquaculture Practices -India GAqP CARPS
48	IS 17284 : 2019–Requirements for Good Aquaculture Practices-India GAqP for Freshwater Prawn Culture
49	IS 17285 : 2019–Good Aquaculture Practices for Cage Culture in Fresh Water

The regulatory standards of FSSAI related to fish and fish products are given in the following regulations:

1. Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011
2. Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011
3. Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011
4. Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011
5. Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011
6. Food Safety and Standards (Import) Regulation, 2017
7. Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017
8. Food Safety and Standards (Advertising and Claims) Regulation, 2018
9. Food Safety and Standards (Packaging) Regulation, 2018
10. Food Safety and Standards (Labelling and Display) Regulations, 2020

International Standards

The major international standards related to fish and fish products are formulated by the following agencies:

- Codex Alimentarius Commission
 - Codex Standards, Code of Practices and Guidelines
- European Union
 - Hygiene Regulations; Microbiological criteria; Official control; Maximum levels for certain contaminants in foodstuffs; Pharmacologically active substances; Food Additives

- USA
 - United States Department of Agriculture (USDA)
 - USFWS
 - NOAA (National Oceanic and Atmospheric Administration)
 - United States Food and Drug Administration (USFDA)
 - Seafood HACCP Regulation (21 CFR 123)
 - Food Safety and Modernization Act (FSMA)
- China
 - National Food Safety System Standards
 - Food Safety Law (2015)
 - Law on Farm Product Quality and Safety (2006)
- Japan
 - Ministry of Health, Labour and Welfare
 - Food Sanitation Act
 - Food Safety Basic Act
 - Agricultural Chemicals Regulation Law
- Australia & New Zealand
 - Australia New Zealand Food Standards Code
- Canada
 - Health Canada
- South Africa
 - The Department of Agriculture, Forestry and Fisheries (DAFF)
 - The National Department of Health
 - The Department of Trade and Industry
- Russia and Customs Union
 - Hygienic requirements for safety and nutrition value of food products. Sanitary and epidemiological rules and regulations, sanpin 2.3.2.1078-01