Chapter 2

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

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

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

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

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

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

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

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

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

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

Genesis of Food Safety Standards and Regulations

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

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

Salient features of some Export regulations related to Seafood European Union

European Union is the biggest importer of fish and fishery products in the world. The food safety regulations set by EU is harmonised, gets periodically updated, transparent and based on principles of risk assessment. The key elements of EU requirements for import of seafood are (a) certification by a competent authority (b) compliance to hygiene and public health requirements in terms of structure of vessels, landing sites, processing establishments and on operational processes, freezing and storage (c) certified production area for bivalves (d) national control plan on heavy metals, contaminants, residues of pesticides and veterinary drugs (e) approval of establishments.

The legal acts of EU are managed through regulations, directives, decision, recommendations and opinions.

Regulation: A binding legislative act applied in entirety across EU

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

USA

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

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

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

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

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

The U.S. Food and Drug Administration (USFDA) is vested with the primary Federal responsibility for the safety of seafood products in the United States. It operates a mandatory safety program for all fish and fishery products under the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, the Public Health Service Act, and related regulations. The most important regulation enacted by USFDA was “Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products” published as final rule 21 CFR 123 on 18th December 1995 and came into force on 18th December 1997. It required processors to adopt the preventive system of food safety controls known as HACCP (Hazard Analysis and Critical Control Point). Seafood was the first food commodity in the U.S. to adopt HACCP in USA. For screening imports, USFDA uses a tool “Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)”, that targets higher risk products for examination and sampling and minimizes the delay in shipments of lower risk products.

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

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

(HARPC): Requires human and animal food facilities to

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

Sec. 106.Protection against intentional adulteration

Sec. 111. Sanitary Transportation of Food

Sec. 301. Foreign supplier verification program

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

Sec. 302. Voluntary qualified importer program

Allows for expedited review and entry; facility certification required

Sec. 303. Certification for high-risk food imports

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

Sec. 304. Prior notice of imported food shipments

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

• Effective July 3, 2011

Sec. 307. Accreditation of third-party auditors

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

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

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

Sec. 309. Smuggled Food

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

• Rules on anti-smuggling strategy is already framed

China

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

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

Russia

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

fishery products are as follows:

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

Japan

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

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

Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC) was established in 1961- 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to implement their Joint FAO/WHO Food Standards Programme. CAC has the mandate to formulate food standards, code of practice, guidelines and recommendations to protect health of consumers, ensure fair practices in food trade and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations. Codex operates through thee standing expert scientific bodies convened under the auspices of FAO and WHO to generate food data and provide risk-assessment type advice:

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

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

Available Codex Standard for Fish and Fishery Products

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

Code of Practice

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

Guidelines

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

Codex standard applicable to Fish and Fishery Products

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

Bureau of Indian Standards (BIS)

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

BIS Standards on Fish and Fishery Products

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

Food Safety and Standards Authority of India (FSSAI)

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

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

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

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

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

HACCP concept in seafood quality assurance

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

Hazard Analysis Critical Control Point (HACCP)

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

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

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

Pre-requisite programmes

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

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

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

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

Basic principles of HACCP

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

Principle 1: Conduct a hazard analysis.

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

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

Principle 2: Determine the Critical Control Points (CCPs)

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

Principle 3: Establish critical limits.

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

Principle 4: Establish a monitoring system

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

Principle 5: Establish a procedure for corrective action,

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

Principle 6: Establish procedures for verification

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

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

Developing a HACCP plan (FAO guidelines)

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

Step 1 - Establish a HACCP team

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

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

Task 2 - Describe the product

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

Task 3 - Identify the product's intended use

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

Task 4 - Draw up the commodity flow diagram

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

Task 5 - On site confirmation of flow diagram

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

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

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

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

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

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

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

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

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

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

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

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

Task 10 - Establish corrective action - (Principle 5)

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

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

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

Task 12 - Keep record - (Principle 7)

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

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

Steps involved in developing HACCP system

(Based on Codex 1997)

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

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

Definitions in HACCP

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

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

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

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

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

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

Deviation: Failure to meet a critical limit.

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

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

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

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

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

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

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

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