



Chapter 12

Prerequisite Programs (GMP & SSOP) Implementation in Seafood Industry

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

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

Employee training and training records

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

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



Good Manufacturing Practices (GMP)

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

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

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

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

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



Subpart A - General Provisions

- §117.1 Applicability and status
- §117.3 Definitions
- §117.4 Qualifications of individuals who manufacture, process, pack or hold food
- §117.9 Records required for this Subpart

Subpart B - Current Good Manufacturing Practices

- §117.10 Personnel
- §117.20 Plant and grounds
- §117.35 Sanitary operations
- §117.37 Sanitary facilities and controls
- §117.40 Equipment and utensils
- §117.80(a) General processes and controls
- §117.80(b) Raw materials and other ingredients
- §117.80(c) Manufacturing operations
- §117.93 Warehousing and distribution
- §117.95 Holding and distribution of human food by-products for use as animal food
- §117.110 Defect action levels

Subpart F - Requirements applying to records that must be established and maintained

- §117.305 General requirements applying to records

Sanitation Control Procedures (SCPs)

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

The Seafood HACCP Regulation SCPs (21 CFR part 123.11) include one recommendation and three requirements. It is recommended that processors create a written sanitation standard operating procedure (SSOP) that describes how sanitation procedures will be performed. Written SSOPs would outline the goals, methods and activities that are needed to be performed in order to meet the SCP requirements. Well-designed, written SSOPs that are



properly implemented are an effective means to prevent insanitary conditions associated with the processing environment and employee practices that may contribute to food safety hazards.

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

Eight Key Sanitation Areas

- 1) *Safety of water*: Water (and ice) that contacts food or food-contact surfaces shall be of safe and of sanitary quality
- 2) *Condition and cleanliness of food contact surfaces*: Food contact surfaces shall be of a proper design and maintained in a clean and sanitary manner to prevent food contamination
- 3) *Prevention of cross contamination*: Employee hygiene, personnel practices and the design of the facility must prevent cross-contamination and allergen cross-contact
- 4) *Maintenance of hand washing, hand sanitizing and toilet facilities*: Sanitary facilities must be accessible, properly maintained, and adequately supplied. An adequate sewage disposal system must be in place
- 5) *Protection from adulterants*: Food, food contact surfaces, and food packaging material must be protected from microbiological, chemical and physical contaminants and allergen cross-contact
- 6) *Labeling, storage and use of toxic compounds*: Toxic cleaning compounds, sanitizing agents and pesticides must be properly labeled, used and stored in a manner that protects food, food contact surfaces and packaging material from contamination. Toxic compounds must be stored in a secured area with limited access separated from food processing and areas where food and packaging materials are stored
- 7) *Employee health*: Controls are necessary to ensure that employee health conditions do not cause food contamination.
- 8) *Exclusion of pests*: Processors must ensure that pests, such as rodents, birds, domestic animals and insects are not allowed in any area of a food processing and/or storage facility

These eight key areas of sanitation should be monitored at a frequency sufficient to ensure conformance. In addition to that the monitoring results and corrections made for any deficiencies must be recorded. The frequency or time for monitoring will vary according to Training Manual on 'Quality Assurance of Fish and Fishery Products, ICAR-CIFT, Cochin-29 (18-29 Sep., 2023)



various types of products and the schedule of operations. The SCP monitoring forms or records must include the name and location of the processor, the date and time the monitoring was performed, corrections made and the signature or initials of the person conducting the monitoring. The sanitation monitoring, corrections, and sanitation control recordkeeping may be performed as part of a firm's HACCP Plan controls, or separately.

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