

## **PRE-REQUISITE PROGRAMMES**

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HACCP IS NOT A STAND-ALONE SYSTEM. Effective HACCP system is built on a solid foundation of prerequisite programs. These are very much essential to the successful application and effective implementation of HACCP system. They provide basic environment and operating conditions that are necessary for the production of safe, wholesome food.

Before applying HACCP system in an organization it is necessary to ensure that the pre-requisite programmes are developed established and maintained effectively so as to provide a firm support to the HACCP system. Thus, a carefully developed and properly implemented pre-requisite programme can make HACCP implementation very simple. Thus the following points are to be considered essentially for a successful HACCP plan:

- Management commitment
- Plant design as per GMP
- Insect and pest control
- Hygiene and sanitation
- Trained personnel
- Site selection
- Plant layout
- Work-flow in processing
- Training at defined frequency

Most of these pre-requisite programmes are addressed by the Sanitation Standard Operating Procedures (SSOP) and Current Good Manufacturing Practices (cGMPs) listed in the Code of Federal Regulation (Current Good Manufacturing Practice in manufacturing, packing or holding human food, Code of Federal Regulation No.21 Part 110) and Standard Operating Procedures (SOPs). All food processors are expected to keep a written SSOP based on cGMP. The SSOP developed by the establishment should contain detailed procedures pertaining to daily sanitation procedures used before (pre-operational sanitation) and during (operational sanitation) operations so as to prevent direct product contamination or adulteration.

## **Standard Sanitation Operating Procedures**

Each processor should implement a written SSOP focusing on the following eight areas of sanitation.

### **Eight Key Areas of SSOP**

1. Safety of water
2. Condition and cleanliness of contact surfaces
3. Prevention of cross contamination
4. Maintenance of hand –washing/sanitization and toilet facilities
5. Protection from adulterant
6. Labelling, storage and use of toxic compounds
7. Pest management
8. Health of food handlers

#### **1. Safety of process water**

An adequate supply of potable water with appropriate facilities for its storage, treatment, distribution and temperature control and monitoring should be made available in the establishment. Water that directly comes into contact with food, or food-contact surfaces or water used for ice production should be derived from a safe and sanitary source. It is necessary to chlorinate the pre-treated water to a level as required for the particular food. Potable water should meet the guidelines for drinking water quality stipulated by EU Directive 98/83/EC or Indian National standard IS:4251

The processor should ensure that there are no cross-connections between potable water system and non-potable water system when the latter is used for purposes like refrigeration, steam generation, fire fighting etc. It is always necessary to keep a plumbing diagram of the factory showing potable and non-potable water system separately. The over-head tank should be kept closed so as to avoid external contamination. The tank should be cleaned and disinfected at least once in three months. Water potability should be ensured at least once in six months. However, the bacterial quality of water is to be checked every fortnight.

#### **2. Condition and cleanliness of Contact Surfaces including utensils, gloves and outer garments**

All food contact surfaces such as plant equipment and utensils, including equipments used for ice production and storage should be made of non-toxic materials. They should be so designed as to facilitate easy cleaning. They should be able to withstand the action of food, ingredients,

and chemicals, cleaning compounds and the environmental conditions (like extremes of temperature, humidity, salinity etc.) under which they operate. Each factory should have a regular cleaning schedule to clean and disinfect the food contact surfaces. The Sanitation Supervisor should ensure that the contact surfaces are cleaned well and that there are no chances for contamination from these contact surfaces. The efficiency of cleaning should be verified once in 3 months by drawing swab samples from the contact surfaces. Gloves and outer garments that can come into contact with food should be made of water-proof material and should always be kept clean.

**3. Prevention of Cross-contamination from insanitary objects to food, food- packaging material and other food contact surfaces including utensils, gloves and outer garments and from raw product to cooked product.**

Employee's hands, gloves, outer garments, utensils and food contact surfaces of equipment that come into contact with unclean objects (like waste, and other insanitary objects) should not come into contact with food before they are cleaned and sanitized.

Care should be taken to ensure that employee's hands, gloves, outer garments utensils and food contact surfaces of equipment that come into contact with raw products should not come in contact with cooked products.

There should be physical separation for cooked, ready-to- eat products and raw food during refrigerated storage.

**4. Maintenance of hand washing, hand sanitizing and toilet facilities**

Sufficient number of hand washing facilities should be provided with sanitizing preparations and single-use towels or hand dryers. It is the responsibility of the sanitation Officer/Hygiene Officer to ensure that everybody entering the processing hall wash and disinfect their hands. Level of chlorine in the hand-dip is to be monitored 2-3 times daily and proper records to this effect are maintained. Adequate toilet facilities, maintained in sanitary conditions, should be provided.

**5. Prevention of food, food packing material and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds and other chemical, physical and biological contaminants**

Necessary control should be taken to protect food, food contact surfaces and food packaging materials from adulteration with fuel, lubricants, pesticides, cleaning compounds, sanitizing agents, metal fragments or other chemical or physical contaminants. Care should be taken to

protect food and food contact surfaces from contaminants that may drip, drain or drawn into the food.

Whenever compressed gases are used (such as in Modified Atmospheric Packaging) they should be filtered or treated to ensure that these gases do not contaminate the food with unapproved food additives or other physical, chemical or microbiological contaminants.

### **6. Proper labelling, storage and use of toxic compounds**

Toxic products should be identified, held, stored and used under strict control of the on-line QC so as to avoid contamination of food, food- contact surface or food-packaging materials. All such products should be properly labelled and stored away from food processing area.

In a food-processing establishment only the following toxic materials should be permitted for use:

- ❖ Those required for cleaning and sanitizing
- ❖ Those required for testing purposes in the laboratory
- ❖ Those required for plant and equipment maintenance and operation and
- ❖ Those necessary for use in the operation of the plant.

There should be physical separation of dry and wet chemicals.

### **7. Control of employee health**

All employees should be subjected to periodic health check-up. If any person has or appears to have an illness, open lesion or any other source of microbial contamination that can contaminate the food, food-contact surface or food packaging materials, such persons should be excluded from doing work till he/she is fully recovered as evidenced by a medical examination. Employees reporting for duty after illness or long absence should be medically examined. The Medical Officer should certify that the individual is medically fit to work in a food industry. This certification is to be obtained at least once in a year.

### **8. Exclusion of pests**

Adequate measures should be taken to exclude pests from all areas of the food processing plant and to prevent contamination of food, food-contact surfaces and food packaging materials. Wherever baits are used for controlling rodents, a bait map showing the location of the trap should be kept. Whenever insecticides or rodenticides are used in a food processing area, it should be done only under expert supervision after taking adequate safety precautions to prevent contamination of food, food contact surfaces and food packaging materials. All food

processors should keep a written SSOP with procedures to be followed routinely to maintain a sanitary environment for producing a safe and unadulterated food product. A Hygiene Officer or Sanitation Supervisor should be employed to monitor the SSOP, document it and to take corrective action as and when necessary.

The eight areas described above should be monitored and documented by each food processor during processing at sufficient frequency. In a company working under the HACCP system, if the eight areas of SSOPs are not monitored regularly, it becomes a major non-compliance. For each SSOP a regular system of monitoring as per example given below is to be developed.

### Scheduled for Monitoring and Documentation

| What                            | how                | Frequency   | Who                                      | Records                     | Verification   |
|---------------------------------|--------------------|-------------|--|-----------------------------|--|
| Chlorine level in water         | Using test papers  | Twice daily | Hygiene Officer or sanitation supervisor | Daily Sanitation Check List | Weekly verification of records by QA Manager   |
| Cleanliness of contact surfaces | Visual Observation | Twice daily | Hygiene Officer or sanitation supervisor | Daily Sanitation Check List | 1. Weekly verification of records by QA Manager<br>2. Quarterly assessment of bacterial load on contact surface by swab-tests. |

### CURRENT GOOD MANUFACTURING PRACTICES (cGMP)

These are measures of general hygiene as well as measures that prevent food from being adulterated due to unhygienic handling under insanitary conditions.

Common cGMP activities include the following:

#### 1. Environmental hygiene

While constructing a food processing plant, care is to be taken to avoid areas leading to contamination of food.

#### 2. Selection of site for the Factory

Food processing factories should be selected in a locality where:

- ☞ Road frontage is available
- ☞ Good quality labour is available
- ☞ No chance for contamination from poultry
- ☞ No chance for contamination from butchery
- ☞ No chance for contamination from tannery
- ☞ No contamination from sewage disposal
- ☞ No contamination from municipal/hospital waste

### 3. **Building exterior**

Premises should be devoid of vegetation, which can provide shelter to pests. The area immediate to the building should be either tarred or concreted to avoid windblown dusts. All debris and garbage should be properly cleaned. Proper drainage is to be ensured. No branches of trees shall touch the building.

### 4. **Building interior**

Internal layout of the factory should have sanitary design features to facilitate cleaning.

- ❖ The building should be made of durable and easy to clean material.
- ❖ The surface of walls and floors should be made of impervious and nontoxic material.
- ❖ Walls should have a smooth surface and polished up to a minimum height of 5 ft. from floor to facilitate easy cleaning.
- ❖ Floors should have adequate drainage, preferably in the opposite direction of the process flow.
- ❖ Floor-wall joint and wall-wall joint should be rounded to avoid accumulation of dirt.
- ❖ Ceilings and overhead fixtures should be so constructed as to minimize the build-up of dirt and condensation.
- ❖ Windows should be easy to clean with slopping window to minimize the build-up of dirt. Where necessary, the windows should be fitted with removable and cleanable washable insect-proof screens.

## **5. Ground level water tanks**

If there are any ground level water tanks, they have to be protected from birds' excreta, falling leaves and rain water. It is ideal to fix ceramic tiles inside the water tank to avoid crevices and subsequent bacterial contamination.

## **6. Equipment**

All equipments should be designed and constructed so as to ensure proper cleaning and disinfection. Equipments and containers should be made of non-toxic materials. Only food grade plastic and food-grade steel are to be used for food contact surfaces.

Equipments used for cooking, cooling and freezing of food should attain the desired temperature as rapidly as possible. Such equipments should have temperature control and monitoring facilities.

Containers used for collecting, holding and storing of waste products and inedible or dangerous substances should be made of impervious materials and should be specifically identifiable. Containers for holding dangerous substances should be kept in locked room under strict vigil to prevent accidental contamination.

## **7. Drainage and waste disposal**

Adequate drainage and waste disposal facility should be provided. They should be constructed in such a way as to avoid the risk of contamination of food. Liquid waste from the unclean area shall not flow through the clean area. Wherever regulation exists, the food processing factories shall get a proper certification for effluent treatment. A proper system of waste collection and removal should be established.

## **8. Personal hygiene facilities**

The plant should have sufficient number of hand wash stations provided with potable hot or cold water, liquid soap and hand sanitizer. Water taps should be of foot operable type. Adequate numbers of toilets should be provided for male and female workers separately.

### **9. Ventilation**

Adequate means of natural or mechanical ventilation should be provided. Air intakes should preferably be on the roof or at least six feet above the ground, the incoming air should not take in dust, noxious odours or exhaust air from the plant. Ventilation system should be designed and constructed in such a way that air never flows from unclean areas to clean areas.

### **10. Lighting**

There should be adequate natural or artificial lighting. Sufficient light will improve the quality of work. It will also be useful to reveal any defect/filth/physical hazard present in the food product. Light fixtures should be properly protected so that broken glass pieces will not contaminate food in the event of accidental breakage. It is advisable not to fix any light bulb just above the processing table.

### **11. Traffic flow pattern**

Product flow inside the plant should be uni-directional without any chances of back flow so that raw material is received at one end and finished product is shipped from the opposite end. Movement of employees, equipment and tools from unclean areas to clean area should be controlled so as to prevent cross contamination. It is advised that even air flow from dirty areas to the cleaner area is to be avoided.

### **12 Storage**

Adequate storage facilities for food, food-ingredients, packing materials and non-food chemicals like cleaning materials, lubricants, refrigerants and fuels should be provided.

### **13. Training**

All food handlers who directly or indirectly come into contact with food should be trained either by outside agencies or by in-house staff. Food handlers should have adequate knowledge and skill to perform their role hygienically. Personnel handling toxic and hazardous chemicals should be properly trained in safe handling techniques. Staff Engaged in hazard analysis, CCP monitoring corrective action or verification should be trained in the HACCP system and they should be competent enough to perform their duties.

### **14. Calibration**

A Schedule for calibration of equipments should be established. All CCP monitoring equipments like thermometer, pH meter, moisture meter, electronic



clock, hygrometer etc. should be calibrated at regular frequencies usually once in a year. All weights, pressure gauges and temperature gauges of food processing equipment should also be calibrated and necessary documents generated.

#### **15. Transport vehicle cleaning**

All vehicles used for transporting raw materials, finished products, packaging material and water and ice (whenever sourced from outside) should be cleaned and sanitized prior to use. For perishable food articles like fishes, meat etc. use refrigerated trucks or reefer containers.

When the same conveyance is used for transporting different food or non-food articles, proper cleaning should be done between loads and the cleaning should be documented.

#### **16. Personnel hygiene and cleanliness**

All employees who directly come in contact with food, food-contact surfaces and food packaging material should adhere to strict hygiene practices when on duty so as to prevent contamination. These hygiene practices mainly include the following:

- a) Employees should wear proper outer garments suitable to the operation to prevent contamination of food, food-contact surfaces or food packaging materials
- b) Utmost importance should be given to personnel cleanliness. Habits like biting nails, chewing, Scratching body parts etc should be discouraged.
- c) Employees should be instructed to wash their hands thoroughly using sanitizers in a hand washing facility before commencement of work, after each absence from the workstation or whenever the hands become soiled or contaminated.
- d) All food handlers should be directed to remove all unsecured jewellery and other objects that can fall into the food, equipment or container. They should also be instructed to remove jewellery like rings, bangles, hair pins, toe rings or anklets.
- e) When gloves are used, they should be maintained clean and in sanitary condition. The gloves should be of an impermeable material and shall be replaced by fresh ones at the interval of 2 hrs.
- f) Appropriate clothing like hairnet, cap and beard covers should be used to avoid contamination with hair
- g) Employee should not be allowed to eat, drink, smoke or chew gum in production areas

From the above, it is clear that the success of HACCP system depends greatly on the effective implementation of pre-requisite programmes like SSOP and CGMP. The HACCP Team. Therefore should give due importance to these pre-requisite programmes while implementing the HACCP system.

### **Standard operational Procedures (SOPs)**

**Approach:** Standard operational procedures (SOPs) are written documents of the processor on the operating procedures to be followed in the unit. The processor should say what are the raw material to be used and the quality specification for the raw material.

**Raw Material Sampling:** In the case of non-branded items, quality is to be checked on each arrival. It is better to depend upon branded products and, in such cases, samples are drawn once in three months and tested for quality as per laid down specifications.

**Responsibility:** The Hygiene Officer/Sanitation Officer will be responsible to this and the records will be maintained.

**Approved Vendors/Suppliers:** Each Company shall effect purchase only through approved vendors/suppliers. All new suppliers are evaluated for their capability to supply products as per specification. The assessment of suppliers is done with on-site evaluation of their facilities, verification of track records and evaluation of samples. Records of assessment and a list of approved suppliers are maintained. Production Manager is usually responsible to approve the suppliers as well as to remove them from approved status in cases of poor performance. All suppliers are to be re-evaluated for their performance once in a year.

**Visiting Premises of Vendors:** SOP should specify whether any quality/safety guarantee is to be obtained from the Vendor. It should also spell out the company's schedule to inspect the premises of the Vendors. Proper documentation with recommendations/suggestions for improvement is also to be generated. In cases, where the results of inspection indicate chances for hazards from these premises, the Vendor's name is to be removed from the approved list.

**Receipt of Raw Material:** Raw material shall preferably be received in air-conditioned receiving areas provided with air curtasss and self-closing doors. All items are to be bought from well-reputed suppliers who maintain high standard of food, hygiene and requirement specification. Supplier's premises should also be inspected to know about the packaging and storage conditions. They have to be informed about standard and quality specifications of the product including the delivery temperature.

All materials received in are to be checked weighed and kept away from floor preferably on stainless steel platforms. The food shall be inspected for its freshness; temperature, colour, odor, contamination infestation, satisfactory packing, expiry date and labelling. The external packing material such as cartons, gunny bags etc. are to be removed before the food item is taken to the store.

The temperature at which raw material is to be received is to be specified. Mode of storage and precautions to be taken are to be spelled out. SOP should explain in detail the various process step involved in the productionof food product including the time temperature conditions at various stages, The names of any preservatives, additives, chelating materials, antioxidants and colouring materials added have to be declared.

SOP should specify the end product quality specifications of the products produced and should specify the quality of tests to be performed, the testing frequency and the parameters to be tested is better to depend upon competent accredited laboratories, the unit may have to insist the source form where the packaging materials are to be purchased and the quality specifications. The unit may have to insist food grade certificate in case, the material comes direct contact with the packaging material. The mode, type and duration of cleaning and disinfection of process machinery, contact surfaces, water tank etc. may have to be specified in the SOP. SOPs should be written in a concise, step-by-step easy to read and easy to understand format. The information presented should be unambiguous and not complicated.

Prerequisite programs deal with the “Good housekeeping” concerns of the establishment, whereas, HACCP manages speciefies process hazards. Prerequisite programmss are outside the HACCP plan, but still within the HACCP system.

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