

GUIDANCE DOCUMENT

FOOD SAFETY MANAGEMENT SYSTEM

(FSMS)

FOOD INDUSTRY GUIDE TO IMPLEMENT GMP/GHP REQUIREMENTS



SPICES

Food Industry Guide to implement GMP/GHP requirements

SPICE PROCESSING

Based on Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011

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Disclaimer:

It is to be noted that this guidance document does not intend to replace any legal provision of Food Safety & Standard Act, 2006 & regulations thereunder. Further, wherever the provision of this document conflicts with Part IV of Schedule 4 of Food Safety & Standard (Licensing and Registration of Food Businesses) Regulation, 2011 or any other regulation under Food Safety & Standard Act, 2006 for that matter, the provision given in the Regulations shall prevail

PREFACE

India traditionally has been the powerhouse of Spices of the world being the largest producer, consumer and exporter of this product. India produces over 8.5 million tons of Spices annually and exports about one million tons valued at US Dollars 2.78 billion which is over 45 % of the global trade in Spices both in terms of volume and value, occupying Numero Uno positions in variety of spices like Chilli, ginger, cumin and turmeric. Though India's export credentials are impressive, it still forms only about 15% of the total production. These 15% of the produce goes through stringent quality standard as per the higher legislative standards required by most of the importing countries.

The balance of 85% or around 7 million tons of various 52 Spices produced for domestic consumption, are not as strictly monitored as is done for exports and therefore it is imperative that FSSAI sets up similar legislative standards so that Indian consumers are also protected from any kind of health hazards.

Spices have generally been regarded as low risk; however, the incidence of food-borne illness and food recalls associated with this sector has increased significantly in recent years. Further, Spices are natural products that, without antimicrobial treatment, can harbour large numbers of bacteria, including *Salmonella* and pathogenic *E. coli*. Moreover, Spices are often added to foods that will not undergo further processing and will be consumed as ready-to-eat products.

In an effort to help to reduce the risk associated with Spices and assist manufacturers that wish to adopt a Hazard Analysis Critical Control Point (HACCP) approach, FSSAI has developed the Guidance document on **Food Safety Management System (FSMS) for Spice Processing**. This guidance document should be read with the Food Safety and Standard Act 2006, Rules and Regulations; 2011 in force as amended from time to time.

The Manual has been developed keeping the requirements of Industrial sectors in mind and will be a dynamic one requiring changes on a regular basis depending on the situation.

The Manual has been prepared by a team of experts from FSSAI, the Spice Industry; All India Spices Exporters Forum and World Spice Organization; and we acknowledge their contributions in its creation.

Pawan Agarwal – CEO, FSSAI

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SCOPE

This guidance document was developed to provide the requirements to be ensured from the time of post harvesting, drying and storage of whole spices to grinding, blending, storage, packaging and transportation of spices. As per the Codex, dried, fragrant, aromatic or pungent, edible plant substances, in the whole, broken or ground form, e.g. spices and dried aromatic herbs, impart flavour, aroma or colour when added to food. The production, processing, and packing of spices and is very complex.

The document is divided into five main sections. The first section gives an overview of the spices processing industry in India. The second section contains guidance for implementation of good manufacturing practices and good hygiene practices as outlined in Part II of Schedule 4 of Food Safety & Standard (Licensing & Registration of Food Businesses) Regulation, 2011, which are required to be followed at each step in the supply chain, to ensure food safety.

The third section of this document is recommendatory in nature and provides the basic knowledge and criteria for implementation of Hazard Analysis and Critical Control Point (HACCP) system by the food businesses. This section includes the detailed manufacturing process with a process flow chart and relevance of main processing steps & two tables: Hazard Analysis and HACCP Plans. Tables of Hazard Analysis is expected to help the industry to identify the food safety risks related to each processing step, to identify the Critical Control Points (CCPs), recommended corrective actions and other related information. The sample HACCP Plans could be used as reference by the industry and modified or altered based on their operations.

The fourth section provides an inspection checklist for food business operator to audit their facility & operations. The FBOs can evaluate themselves based on the indicative scoring. The last section gives important templates and forms which will be required by FBOs to maintain the records. This includes mandatory forms as prescribed by FSSAI & few templates for maintaining records of processes critical for food safety.

A. OVERVIEW OF SPICES INDUSTRY IN INDIA

OVERVIEW OF SPICES INDUSTRY IN INDIA

India is the world's largest producer and exporter of spices of the 109 varieties listed by the International Organization for Standardization (ISO), as the country produces and exports about 75 varieties of spices. Indian spices are known over the world for their **aroma, texture and taste**.

India primarily exports pepper, chilli, turmeric, ginger, cardamom, coriander, cumin, fennel, fenugreek, celery, nutmeg and mace garlic, tamarind and vanilla. Processed spices such as spice oils and oleoresins, mint products, curry powder, spice powders, blends and seasonings are also exported. India's share in the world trade of spices stands at 45% in terms of volume and value.

Spices are considered the most valued product in the trade of commodities. The major exporting countries in global trade of spices are India and China and the major markets for consumption are USA and Europe.

In terms of the value of world trade, pepper, cardamom, ginger, turmeric, chilli, cinnamon nutmeg/mace, cloves, pimento and vanilla are the most important spice crops from tropical regions and cumin, coriander, sesame seeds, mustard, sage, bay, oregano thyme and mint are the spices crops from the non-tropical regions.

Spices produced in India are being used both as whole and processed. Further, the global demand for spices throws up several challenges, mainly for food sustainability, traceability and safety standards to the spice industry in the country. Food safety could be managed through modern processing technology & good hygienic and manufacturing practices.

B. PRE-REQUISITE PROGRAM

B. PRE-REQUISITE PROGRAMS

Introduction

Prerequisite programs are defined as a range of programs/procedures used to support the HACCP program. Prerequisite programs are essential to the overall management of food safety issues and provide the basic environmental and operating conditions for a manufacturing facility. Prerequisite programs should be developed, implemented, and documented before putting a HACCP plan in place.

I. Establishment-Design and Facilities

1. Location and Surroundings

Buildings and surrounding areas should be designed, constructed and maintained in a manner which prevents conditions that may result in the contamination of spices.

- The Food Establishment shall ideally be located away from environmental pollution and industrial activities that produce disagreeable or obnoxious odour, fumes, excessive soot, dust, smoke, chemical or biological emissions and pollutants, and which pose a threat of contaminating food areas that are prone to infestations of pests or where wastes, either solid or liquid, cannot be removed effectively.
- In case there are hazards of other environment polluting industry located nearby, appropriate measures should be taken to protect the processing/manufacturing area from any potential contamination.
- Consideration of production site location should include an evaluation of the area prone to floods and water logging.
- Adequate drainage facilities shall be provided for grounds, roofs and other areas to avoid stagnation of water.
- The manufacturing premise should not have direct access to any residential area.

2. Premises & Rooms

2.1 Construction, Design and Layout

Layout

The application of appropriate hygienic design standards to building and layout is essential to ensure that contaminants are not introduced into the product.

- As far as possible, the layout of the food establishment shall be such that food preparation/manufacturing processes are not amenable to cross contamination from other pre and post manufacturing operations like goods receiving, packaging etc.
- Premises and rooms should be designed to exclude moisture from the environment. In general, areas in which Spices are handled should not have drains, however, if drains are present, surrounding floor should be properly sloped for effective drainage and kept dry under normal conditions.
- It is desired that the premises & rooms should be designed with a means of dust control, since Spices are likely to generate particulate matter that can be carried out to other parts of the room by air currents.
- **Process Flow Separation:** It should be designed to facilitate hygienic operations according to the one-way flow direction, without backtracking from the arrival of the raw materials at the premises to the finished product, and should provide for appropriate temperatures condition for the process and the product.
- Premises and rooms used for Spices should be physically separated from wet processing areas and designed such that they can be cleaned routinely with minimum amount of water.
- The premises should have:
 - Separate a) Raw material receiving area and b) finished product dispatch area:
 - Designated areas for storing raw materials and ingredients, packaging materials, finished products, processing chemicals, and cleaning and sanitization chemicals.
 - Designated waste treatment & garbage disposal area
- Openings intended for transfer of materials shall be designed to minimize the entry of foreign matter and pests.

2.2 Internal Structure

Floors, Walls and Ceilings

- Floors, walls and ceilings should be made of impervious material and should be smooth and easy to clean with no flaking paint or plaster.
- Floors, Ceilings and walls must be maintained in a sound condition to minimize the accumulation of dirt, condensation and growth of undesirable moulds.
- The Floors of processing area shall have adequate and proper drainage and shall be easy to clean and where necessary, disinfect.
- Floors shall be sloped appropriately to facilitate drainage and the drainage shall flow in a direction opposite to the direction of manufacturing process flow.
- Ceiling surfaces as well as other overhead equipment, e.g. ventilation units, light fixtures, conveyors and pipes must be clean, in good repair, free of flaking paint, rust, holes, unsealed openings, or other conditions that could result in product contamination.

Windows and Doors

- Windows, doors and all other openings to outside environment shall be well screened with wire-mesh or insect-proof screen as applicable to protect the premise from fly and other insects /pests/animals. **The mesh or the screen should be of such type which can be easily removed for cleaning.**
- The doors shall be fitted with automatic closing springs.
- Doors shall also be made of smooth and non-absorbent surfaces so that they are easy to clean and wherever, necessary disinfect.
- Adequate control measures should be in place to prevent insects and rodents from entering the processing area from drains.

3. Equipment & Containers

3.1. General Equipment

3.1.1. Design, Construction and Installation

Equipment should be designed to facilitate cleaning and disinfection with little or no water and, when wet cleaning is required, to allow thorough drying before reuse of the equipment for

spices. Alternatively, the design should allow disassembling such parts that can be taken to a room designated for wet cleaning and disinfection, where applicable.

- The equipment designed should be as simple as possible, with a minimal numbers of parts which are easily accessible and/or removable for inspection and cleaning.
- Equipment should not have pits, cracks, corrosion, crevices, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets, or dead ends. Hollow areas of the equipment as well as cracks and crevices should be eliminated whenever possible or permanently sealed.
- Equipment should be installed so as to allow access for cleaning and to minimize transfer of dust particles to other pieces of equipment or to the environment.
- The risk of contamination from equipment should be assessed and controlled. Wherever possible, forklifts, utensils, and maintenance tools for the finished product and packaging areas should be different from those used in the “raw” material area.
- Equipment and containers that come in contact with food and used for handling, storage, processing and packaging shall be made of corrosion free materials which do not impart any toxicity to the food material.
- Equipment and containers for waste, by-products and inedible or dangerous substance, shall be specifically identifiable and suitably constructed.
- Containers used to hold cleaning chemicals and other dangerous substances shall be properly identified and stored separately to prevent malicious or accidental contamination of food.

3.1.2 Preventive Maintenance

- Preventive maintenance program documented and verified by a designated person shall be available which shall include all equipment within the facility and should prescribe the frequency at which the preventive maintenance should be carried out.
- All equipment should be inspected for hygiene and damage on a regular basis. A line start-up check is suggested and immediate corrective or preventive actions are taken in case of requirement.
- On completion of maintenance/repair cleaning of equipment, the supervisor must ensure that all tools and other materials have been removed and returned to their appropriate places as and when equipment is cleaned, prior to releasing the equipment for production.
- If outside contractors are required for preventive maintenance or equipment repair, there should be a formalized system for the management of food safety. The contractors shall be

requested to follow the instructions given to them and once all the work is completed, the area in question should be inspected and cleaned.

- Repairs to or servicing of equipment shall be done by trained employees or approved contractors or the equipment manufacturer. Calibration of instruments should be done by appropriately trained personnel.
- Leaks and excess lubrication shall be identified and eliminated. Lubricants, heat transfer fluids or any other similar material used shall be of food grade where there is risk of direct or indirect contact with the product.
- The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in process sanitation procedures, and pre-use inspection and approval by both Production and Quality Assurance QA.

3.2 The following are some examples of instrumentation that may be required to control factors significant to the process:

Metal Detectors

- Metal detection equipment should be designed, constructed, installed, calibrated and maintained in a manner to ensure effective removal of metals. This may include adjustment for product effect, selection of target metal and size, timing of the reject mechanism and suitability for environmental conditions.

Magnets

- Magnets should be used in such a manner so that it effectively removes ferrous metal prior to, or after, certain operations. The strength and type of magnets should be appropriate for use.
- Magnets should be monitored to ensure effective operation and surface exposure (e.g. adequately cleaned, metal particles removed).

Scales/Metering Devices

- Scales are designed and installed to withstand the environmental conditions or are adequately protected (e.g. away from drafts, rust, corrosion, etc.).
- Scales and meters are calibrated in accordance to the equipment manufacturer's manual to ensure accuracy and compliance to the legal meteorology rules & regulations at all times.

Other Instrumentation

Other specialized instrumentation necessary for the control of factors significant to food safety is in place and calibrated as necessary.

4. Facilities/Utilities

The facilities are essential services that play a vital role to industry. Quality facilities and utilities provided like water, light, hygiene facilities etc. are prerequisite for an effective food safety and are explained as follows:

4.1 Lighting

- Adequate natural or artificial lighting shall be provided throughout the factory to enable personnel to operate in a hygienic manner. Further, the light produced shall not distort colours and be shadow free at the inspection area.
- The intensity of light should be adequate to the nature of the operation. Recommended interior light intensities (in lux) for food processing plants is as under:

Functional Area	Lux
Product inspection	1180-1400
Processing areas	590-700
Packaging	750-860
Maintenance areas	750-860
Bulk ingredient storage	320-430
Ingredient warehouse	215-320
Finished product warehouse	215-323
Raw material receiving	215-320
Administrative offices	645-970
Cafeteria	430-540
Locker and rest rooms	320-540

- Lighting fixtures must wherever appropriate, be protected to ensure that food is not contaminated by breakages of electrical fittings. The fixtures should be designed to avoid accumulation of dirt & be easy to clean.



Fig: Protective covering on tube lights and bulbs

4.2 Air Quality & Ventilation

- Ventilation system natural and/or mechanical including air filters, exhaust fans, wherever required, shall be designed and constructed so that air does not flow from contaminated areas to clean areas.
- Filters (e.g. filters for intake air and compressed air) are cleaned or replaced at least as often as the manufacturer specifies, or more frequently if a problem is indicated, such as evidence of filter fouling or perforation.
- Air used as a processing technique (e.g. pneumatic conveying, air agitation, air blowers, air dryers, etc.) is appropriately sourced and treated (e.g. air intakes, filters and compressors) to reduce any source of contamination.
- The quality of air shall be ensured through regular monitoring and records shall be available.
- Ventilation fans in walls should be screened so that there is no insect ingress when fans are turned off. Turbo ventilators in roofs should be protected to prevent rain access and should not be located above any open processing or storage areas. If this is unavoidable, catch trays should be located below the vents.
- Maintain critical processing areas under positive air pressure to prevent dust, flying insect entry, and cross-contamination of unfiltered air. (Air curtains or strip curtains at all entry levels exposed to outside are recommended).

4.3 Water

- Only potable water shall be used for all process related activities including washing and cleaning of machines/equipment that come in contact with food, hand washing.
- An evaluation of the chemical, physical, microbiological, and radiological characteristics of the source water conforming to IS 10500 shall be done.

- Where water supplies are chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications
- Regular cleaning schedule and procedures for cleaning of water storage tanks shall be in place and records for compliance with the documented procedures shall be maintained.
- Storage tanks shall be kept under lock and key. All storage tanks shall be effectively covered to prevent the entry of pests and other contaminants.
- **Non-potable water** shall have a separate supply system that is labelled and not connected to the potable water system. Take measures to prevent non-potable water refluxing into the potable system
- The water pipes & all connectors shall be made of material that is non-toxic, corrosion resistant, free from cracks, impervious & should be sealed.

4.4 Cleaning

- Adequate facilities for cleaning, disinfecting of utensils and equipment shall be provided. The facilities must have an adequate supply of hot and cold water if required.

4.5 Personnel Facilities and Toilets

- Personnel facilities shall include those for proper washing and drying of hands before touching food materials including wash basins and a supply of hot and/or cold water as appropriate.
- Personal facilities shall also include separate lavatories, of appropriate hygienic design, for males and females separately and changing facilities for personnel. All such personnel facilities shall be suitably located so that they do not open directly into food processing, handling or storage areas.
- Number of toilets should be adequate depending on the number of employees (male/female) in the establishment and they should be made aware of the cleanliness requirement while handling food.
- Rest and refreshment rooms shall be separate from food process area and these areas shall not lead directly to food production and storage areas.
- A display board mentioning do's & don'ts for the workers shall be put up inside at a prominent place in the premise in English or in local language for everyone's understanding.

4.6 Storage

- Spices are susceptible to mould contamination and/or growth if storage conditions are not appropriate. Spices should be stored in an environment with humidity that does not result in product moisture that can support the growth of moulds. Storage areas shall be dry and well ventilated.
- Separate area shall be defined to keep non-conforming materials.
- A separate, secure (locked or otherwise access controlled) storage area shall be provided for cleaning materials, chemicals and other hazardous substances.

4.7 Food Testing Facilities

- A well equipped, laboratory for testing of food materials/food for physical, microbiological and chemical analysis in accordance with the specification/standards laid down under the rules and regulations should be in place inside the premise for regular/periodic testing and whenever required. If there is no in house laboratory facility, then regular testing shall be done through an accredited lab notified by FSSAI
- In case of any suspicion or possible contamination, food materials/food shall be tested before dispatch from the factory.
- In case of complaints received and if so required, the company shall voluntarily do the testing either in the in-house laboratory or a lab notified by FSSAI.

4.8 Drainage and waste disposal

- Adequate drainage and waste disposal systems and facilities shall be designed and constructed so that the risk of contaminating food or potable water supply is avoided.
- Waste disposal shall be done in accordance with specific requirement of Factory Act/State pollution control board.

4.9 Compressed air & other gases

- Compressed air, carbon dioxide, nitrogen & other gas systems wherever required used in manufacturing &/or packaging shall be constructed & maintained so as to prevent contamination.

- Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil & water.
- Requirements for filtration, humidity (RH %) and microbiology shall be specified. Filtration of the air should be as close to the point of use as is practicable.

II. Establishment–Control of Operations

Appropriate measures should be taken at each step in the food chain to minimize the potential for contamination of spices by microbial pathogens (including mycotoxin-producing moulds), chemical contaminants, excreta, rodent hair, insect fragments and other foreign materials.

1. Management of Raw Material/Packaging Material

1.1 Selection of Suppliers

Spices should be obtained from approved suppliers. There shall be a defined process for the selection, approval and monitoring of suppliers. The process shall include an assessment of the supplier's ability to meet quality and food safety expectations, requirements and specifications.

Because of the diversity of production practices for spices, it is important to understand the controls in place for production of the incoming material. When control measures used to produce spices are not known, verification activities such as inspection and testing should be increased.

1.2 Supplier monitoring

- Risk assessment shall be conducted for all the spice suppliers.
- There are chances of cross contamination among the Spices which are cultivated in lands close to each other. Such Spices and the suppliers shall be considered as having high risk.
- High risk rated supplier sites shall be audited at regular frequencies and ensured that they have enough systems in place to control the chances of cross contamination.
- When reviewing specifications, the responsible person should look for any allergic ingredient in the raw material.

1.3 Raw Material Receipt

- Spices should not be accepted by an establishment if it is known to contain contaminants, undesirable micro-organisms, extraneous matter, which cannot be reduced to an acceptable level by normal sorting and/or processing.
- Spices suspected of being contaminated with animal or human faecal material should be rejected for human consumption. Special precautions should be taken to reject spices showing signs of pest damage or mould growth because of the potential for them to contain mycotoxins such as aflatoxins.
- Raw materials should be inspected and cleaned/sorted prior to processing (foreign matter, odour and appearance, visible mould contamination). Laboratory tests, e.g. for moulds or pathogens such as *Salmonella*, should be conducted when necessary.
- **Spices in which Salmonella is detected** should not be used unless they are subjected to an effective microbial reduction treatment. (FSSAI standard for salmonella in spices : **Absent/25g**)
- Delivery vehicles (raw material/ packing materials) shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit.
- The inspection should cover the vehicle condition, whether it has **any holes and/or water damage, any condensation caused by the varying temperature zones the product may have gone through while being delivered, any damage to product packaging, any type of contamination to the packaging, checking that there are no non-food items on the truck, no dead/live insects, no allergen material etc.**
- The reception area should be protected from the weather, have sufficient lighting to allow for accurate inspection, and have good pest protection devices. During the inspection and unloading procedure, systems should be in place to prevent birds, insects and other pest gaining entrance to the facility.
- Based on the inspection results incoming materials need to be categorized as **Accepted, Rejected or Accepted under concession.**
- The manufacturer should ensure that Good Agricultural Practices are followed at the farm level by the Spice growers.
- Packing material which comes in direct contact with food shall be of food grade quality and the food grade certificate shall be available.

- Records of incoming materials as well as their source of procurement shall be maintained for inspection & traceability.

1.4 Storage

- Food storage shall be designed and constructed to enable food to be effectively protected from contamination during storage, permit adequate maintenance and effective cleaning.
- Segregation shall be provided for the **storage of raw, processed, rejected, recalled or returned materials** or products which will be **distinguishably marked and secured**. Raw materials and food shall be stored **in separate areas from printed packaging materials, stationary**, hardware and cleaning materials/chemicals.
- **The conditions of storage** in term of temperature and humidity **requisite for enhancing the shelf-life of the respective food materials/products** shall be **maintained**.
- **Storage** of raw materials, ingredients, work-in-progress and processed food products shall be subject to FIFO (First in, First out), FEFO (First Expire, First out) stock rotation system as applicable.
- Containers made of non-toxic materials shall be provided for storage of raw materials, work in progress and finished/ready to serve products.
- The food materials shall be stored reasonably well above the floor level on pallets and away from the wall so as to facilitate effective cleaning and prevent harboring of any pests, insects or rodents.
- In case wooden pallets are used, they should be identified with Numbers and fumigated/prophylactic treatments given as required. Maintain the records for the same. Tarpaulin sheets (Paper card board sheet) (or other suitable method) shall be kept on the pallet before keeping the material, to avoid direct contact with the wooden surface

2. Spices processing

Food processing operations flow diagram and **standard operating procedures** shall be documented, implemented and should be displayed at operations site. Also, standard operating procedures for process changeover from one kind of product to another shall be maintained and implemented.

2.1 Zoning of the Establishment:

Depending on the risk assessment of the activities at the establishment, separate the establishment into Low, Medium and High food safety risk zones.

2.2 Plant traffic flow:

Traffic patterns should be established with respect to movement of personnel and materials according to the one way flow direction, without backtracking, criss-crossing, and with partitioning for separation of operations **.e.g. the raw material area to the finished product area, in order to prevent cross-contamination.**

2.3 Allergen Control & Allergenic material storage

Allergens are a major concern today for all food manufacturers. Since very small amounts of an allergen are capable of causing reaction in sensitive individuals, the control of potential allergic ingredients and the possibility of cross-contamination is essential in all manufacturing facilities.

The ultimate goal of the **Allergen Control Program** is to protect consumers with food related allergies. - This is accomplished through, but not limited to: ingredient review, labeling, rework, segregation, scheduling, sanitation and training. - Procedure(s) outlining allergen ingredient review, labeling, rework, segregation, scheduling, sanitation and training should be documented.

All materials that are allergens (RM/SFG/FG) should be labeled with a tag that states "Allergen." and should separately be kept. **The label can be made Bold and with Bright colour for quick identification. The common allergens in spices are** cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these; soybeans and products of these; peanut, tree nuts and nut products; sesame; celery & mustard.

2.4 Hygiene control in Specific Process steps :

- a. **Mechanical Drying:** Raw material used for the preparation of spices may be dried mechanically (e.g forced air drying), provided that adequate measures are taken to prevent contamination of the raw material during the process. Drying time should be reduced as

much as possible by using optimal drying conditions to avoid fungal growth and toxin production.

To prevent the growth of microorganisms, especially mycotoxin producing mould, a **safe moisture level** should be achieved **as rapidly as possible** and **Mechanical drying methods** should be used **instead of natural drying (open) air drying**, where possible.

Moisture limits for some of the dried whole spices after drying are mentioned in the table below:

Name of the spice	Maximum Moisture limit, % w/w
Cassia whole	12.0
Cloves whole	12.0
Coriander whole	9.0
Cumin whole	10.0
Cumin black (Kalonji) whole	10.0
Fennel whole	12.0
Fenugreek whole	10.0
Ginger whole	12.0
Mace whole	10.0
Mustard whole	10.0
Nutmeg whole	10.0
Black pepper whole	13.0
Turmeric whole	12.0
Aniseed whole	12.0
Ajowan (Ajwain)	11.0
Celery whole	10.0
Caraway(Siahjira) whole	12.0
Cardamom whole	13.0
Large Cardamom whole	12.0
Chillies and Capsicums whole	11.0

- b. **Cleaning** : Spices should be cleaned properly (e.g culled and sorted) to remove physical hazards (such as presence of animal and plant debris, metal and other foreign material) through manual sorting or use of equipments such as destoner, gravity separator, sieve metal detectors etc.

- c. **Microbial Reduction Treatments:** When necessary to reduce risk, spices should be treated with a validated microbial reduction treatment prior to reaching the consumer in

order to inactivate pathogens such as *Salmonella*. Commonly used methods involve the application of steam, fumigation and Irradiation.

Factors that should be controlled when using:

1. **Fumigation Treatments:** Chemical concentration, exposure time, Vacuum and /or pressure, density of the product and gas permeability of the packaging material.
2. **Steam:** Exposure time and temperature.
3. **Irradiation:** Radiation dose and the size and shape of the package, as well as the penetrability of the packaging material to the type of radiation of radiation used.
4. Food processing daily process critical parameters like temperature/vacuum etc. records shall be maintained with appropriate coding for traceability.
5. Intermediate in-process samples should be taken and tested for critical parameters and test results records should be maintained.

2.5 Microbial cross- contamination

- Raw products that may present a potential hazard should be processed in separate rooms, or in areas physically separate from those where end-products are being prepared.
- Spices that have undergone a microbial reduction treatment should be processed and stored separately from untreated spices
- Equipment should not be used for both treated and untreated products without adequate cleaning and disinfection before use with treated products.

2.6 Physical and Chemical contamination

- Appropriate machines should be used to remove physical hazards such as **pebbles or heavier stones** to separate foreign matter from the product, **air tables or gravity separators** can be used for particles of same size and different density. **Sieves of different diameters** may also be used.
- Regardless of the type of separator used, the following parameters should be considered: **size of particles, density, weight and size, air speed, inclination of the sieve plate, vibration, etc.** for highest effectiveness of the procedure. **Metal detectors/Magnets**

should be used to detect and separate ferrous from non-ferrous/metallic matter. Spices should be arranged in a fine layer to facilitate the said operation.

3. Spices Packaging and Warehousing

3.1 Packaging & Labelling

1. Packaging Requirements

- Spices e.g. dried chili peppers, **should not be sprayed with water as it** may result in growth of moulds and microbial pathogens, if present.
- Bags with food grade liners should be used to protect the spices from Moisture, contamination, infestation of insects and rodents.
- It is recommended that new bags or containers be used for food contact packaging. If reusable containers are used, they should be properly cleaned and disinfected before use. **Particular attention paid to the potential for loose bags fibers that can become potential contaminants.**
- **Secondary containment bags/containers providing additional protection** can be reused but should not have been previously used to hold non-food materials such as chemicals or animal feed.
- Only packaging materials required for immediate use are kept in the packaging or filling area.

2. Labelling

Control of labelling is important to ensure that the correct label is applied to each product. Use of incorrect labels could mislead the consumer and could pose a potential health hazard to segments of the population with allergies.

The manufacturer should have procedures in place to ensure that the correct label is applied to the correct product. Typical controls are listed below.

- Product types are effectively separated during changeovers (e.g. appropriate breaks between products, visual inspection to ensure products are not mixed prior to labelling).
- Different product labels or pre-labelled packaging should be effectively separated, and the number of product label types should be kept to a minimum.

- During storage, care is to be taken to prevent mixing of individual labels or bundles of labels (e.g. labels are stored in separate boxes, no labels are loose and unused labels are returned to the correct boxes).
- Procedures should be in place to ensure the product being supplied or added to the labelling operation corresponds to the labels in use (e.g. on-line checks to ensure that products are correctly labelled).

Minimum Mandatory labeling of pre-packaged foods must have the following details

- Name
- Name of the product
- Net weight
- Name and address (manufacturer, packer, distributor, importer, exporter or vendor)
- Batch number
- Date manufacturing /packing
- Best before use date
- Veg /non-Veg Logo
- FSSAI registration number
- Ingredient declaration
- Nutritional value

Note: For details please refer FSS (Packaging & Labeling) Regulations, 2011 and amendment there under.

3.2 Warehousing

- The warehouses should be kept clean, ventilated and under hygienic condition to avoid pest infestation, dirt, dust, smells.
- Finished products shall be kept at appropriate height to avoid damages at bottom boxes.

Process Step	QC/QA Check Points
Receiving	<ul style="list-style-type: none"> ✓ Specifications of spice required; ✓ Establishing inspection procedures for receipt of correct specified product; ✓ To ensure testing equipment is calibrated to ensure accurate test results; ✓ Training of staff in inspection procedures & Training of workers; ✓ Rejection of damaged/mouldy materials; ✓ Correct sampling methods for inspection; ✓ Checks for foreign Material such as wood, glass and other non-metallic substances;

	<ul style="list-style-type: none"> ✓ Checks for Mycotoxins (Aflatoxins ; mg/kg : Max 0.03 ppm); Salmonella Sp.
Storage	<ul style="list-style-type: none"> ✓ Avoid contamination by sanitation chemicals & pests; ✓ Control of store room temperature; ✓ Stock rotation procedure supervision; ✓ Implementing cleaning schedules.
Drying	<ul style="list-style-type: none"> ✓ Adequate drying (Time & Temperature checks); ✓ Moisture content after drying; ✓ Avoid cross contamination; ✓ Training of personnel to operate equipment; ✓ Record maintenance of batches; ✓ Recording procedures.
Treatment	<ul style="list-style-type: none"> ✓ Adequate treatment exposure time; ✓ To ensure testing equipment is calibrated to ensure accurate test results; ✓ Chemical Residue ✓ Survival of pathogens like Coliforms, Salmonella etc due to inadequate treatment; ✓ Record maintenance of batches.
Cleaning & Grinding	<ul style="list-style-type: none"> ✓ Checks for foreign matter such as stones, dirt, wire, string, sticks, excreta, other animal contamination; ✓ Correct handling to minimize loses.
Blending	<ul style="list-style-type: none"> ✓ Avoid cross contamination; ✓ Allergen control; ✓ Record maintenance of batches; ✓ Correct handling to minimize loses
Metal Detection	<ul style="list-style-type: none"> ✓ Checks for presence of metal pieces in product; ✓ Training of personnel to operate equipment; ✓ Establishing recording procedures ✓ Record maintenance of batches
Bagging & Weighing	<ul style="list-style-type: none"> ✓ Correct handling to minimize loses ✓ Establishing recording procedures ✓ Checking for physical appearance of container/package ✓ Checking for vital points like shelf life and date of manufacture
Shipping/ Distribution	<ul style="list-style-type: none"> ✓ Inspection of container for seal & tamper-proof prior to stuffing ✓ Correct handling to minimize loses

4. Rework & Control of Non-Conforming Products

4.1 Rework

- Handling of Rework/Add-back –to be done in such a way to avoid cross contamination during processing, handling and storage.
- Rework shall be clearly identified and/or labelled to allow traceability.
- Traceability records for rework shall be maintained.
- All rework should be certified by QA department before reincorporating.
- There work classification or the reason for rework designation shall be recorded (e.g. product name, production date, shift, line of origin, shelf-life).
- Segregation requirements for rework shall be documented and met.

4.2 Control on Non – Conformance products

The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after non conformity is encountered. These actions include:

- a. Reviewing non conformities (including customer complaints),
- b. Reviewing trends in monitoring results that may indicate development towards loss of control,
- c. Determining the cause(s)of nonconformities,
- d. Evaluating the need for action to ensure that nonconformities do not recur,
- e. Determining and implementing the actions needed,
- f. Recording the results of corrective actions taken,
- g. Reviewing corrective actions taken to ensure that they are effective.
- h. Corrective actions shall be recorded.

5. Food Transportation and Distribution

- Vehicles of only FSSAI registered transporters shall be used for transportation.
- The dispatches of finished goods must follow FIFO or FEFO (First Expiry First Out) system.
- Conveyances and/or containers used for transporting shall be kept clean and maintained in good repair and condition to protect from contamination and shall be designed and constructed to permit adequate cleaning and/or disinfection. Where direct contact with food may occur, materials used in carrier construction should be suitable for food.
- All vehicles shall be properly covered with tarpaulin or closed container.
- Finished product boxes are kept at prescribed max. height to avoid damages.
- Care should be taken to prevent condensation when unloading spices from a refrigerated vehicle or while taking out of a cold storage.
- In warm, humid weather, the products should be allowed to reach ambient temperature before exposure to external conditions. Spices that have been spilled are vulnerable to contamination and should not be used as food.

6. Food Traceability and Recall

- A recall may be initiated after the initial investigation of reported incident at manufacturing unit or complaints/received from consumers or customers or any other sources.
- A system/written procedure shall be in place to enable the recall of any lot of product and provide detailed information to assist in the investigation of any identified produce contamination.

Note: In some instances, the establishment may initiate a voluntary recall of a product because of the use of a raw ingredient or packaging material which has been determined to be unsafe. By linking raw ingredient lot codes to the finished product code, your establishment will be able to identify which of your finished products need to be recalled

- Traceability system shall be in place to identify production lots in relation to batches of raw materials, packaging materials, processing, packaging and delivery. All records are to be maintained.

Suggested Reading: Product recall procedure shall be as per FSSAI recall protocol mentioned in Food Safety and Standards (Food Recall Procedure PART III Section 4) Regulations.

6. Quality Control

- The FBO shall have a quality control programme in place to include inspection and testing of incoming spices/food additives/in process and finished products.
- All incoming raw materials/packaging materials/Food additives/Ingredients test records or Certificate of Analysis (COA) shall be maintained. Adulteration tests defined under FSS regulations should be performed with each lot. Testing shall be done as per the approved method. The list of the type of adulteration in spices is annexed.
- In-process and finished product samples should be tested and records should be maintained. Finished goods shall be tested annually for contaminants as laid down in FSS regulations 2011 & amendment thereunder from FSSAI approved labs. It is recommended to retain the control samples in a separate area, till the end of shelf life. Further, it should be disposed off. Testing records shall be maintained. Refer to the approved laboratory list by FSSAI.
- **An In-house laboratory facility with trained and competent testing personnel should be available for food testing. If there is no in-house laboratory present, then all the regular testing shall be done through a laboratory notified by FSSAI.**
- If pathogen testing is conducted in-house, the microbiology laboratory shall not open directly into process area. The tested sample and remnant should be autoclaved before disposing off.
- Calibration of laboratory equipment shall be done periodically.

III. Establishment–Maintenance& Sanitation

1. Cleaning and Sanitation

1.1 Cleaning and sanitizing agents and tools

- Cleaning and sanitizing agents and chemicals shall be clearly identified, stored separately and used only in accordance with the manufacturer's instructions.

- Tools and equipment's like scrubbers, brushes, plastic brooms, vacuum cleaners etc. should be of hygienically designed and robust, so that they pose no threat to food safety of product. Further, they should be dedicated to specific areas.



Fig: Cleaning brushes



Fig: Cleaning mobs



Fig: Cleaning Tools with scrubber

1.2 Cleaning and sanitization program

- A cleaning and disinfection programme shall be drawn up and observed and the record thereof shall be properly maintained, which shall indicate **specific areas to be cleaned, cleaning frequency and cleaning procedure to be followed**, including equipment and materials to be used for cleaning. Equipments used in manufacturing will be cleaned and sterilized at set frequencies.

- **The cleaning and disinfection schedule** should describe whether to use **wet or dry cleaning**. The presence of water in the dry processing environment can result from improper use of water during cleaning so it should be ensured that drying is done thoroughly.
- Effectiveness of the sanitation program is monitored and verified (e.g. by a pre-operational inspection of premises and equipment or, where appropriate, by microbiological sampling) and where necessary, the program is adjusted accordingly.
- A vacuum cleaner can be used for cleaning up fine dust as brushing tends to push dust into the air for it to settle elsewhere.
- The sanitation program is adjusted as necessary to incorporate new cleaning procedures (new equipment, new chemicals, etc.).The sanitation program may be used to provide control over cross-contamination issues associated with the production of non-allergenic and allergenic products. Equipment is cleaned in a manner to prevent cross-contamination between allergen containing products and non-allergen containing products.
- Operations begin only after sanitation and drying requirements have been met.

1.2.2 Cleaning methods

Dry Cleaning is the preferred means of cleaning establishment handling spices.

- Dry cleaning involves the use of tools such as vacuum cleaners, brooms and brushes.
- Dry cleaning is especially important in older establishment in which, inspite of regular maintenance, there may be a potential for the presence of cracks or other harbourage sites that may be difficult to eliminate. Even if residues of Spices enter such a site, potential problems can be minimized, if the residues and the sites are dry and kept dry.
- Wet Cleaning may be appropriate in certain circumstances, e.g when salmonella has been detected in the environment.
- When water usage is necessary, minimal amounts should be used, and the use of high pressure hoses should be avoided.
- Wet Cleaning should be followed by disinfection to inactivate microorganisms. Disinfectants that will rapidly evaporate such as alcohol-based disinfectants, provides a means to spot-

disinfect equipment with a very minimal introduction of water. it should be followed by thorough drying.

- For dry cleaning, compressed air should not be used except in special situations (e.g to dislodge dust from inaccessible points).Moreover, if and when compressed air is used, it should be dried and filtered to exclude microorganisms and moisture prior to use.

1.2.3 Verification as to the effectiveness of cleaning should include;

- a) Visual inspection
- b) Analytical methods like:
 - Swabbing using conventional microbiological swab or rapid method based on ATP Bio luminescence Technology.
- c) Cleaning record shall be maintained for the same period as manufacturing records.



Fig: Storage of cleaning tools.

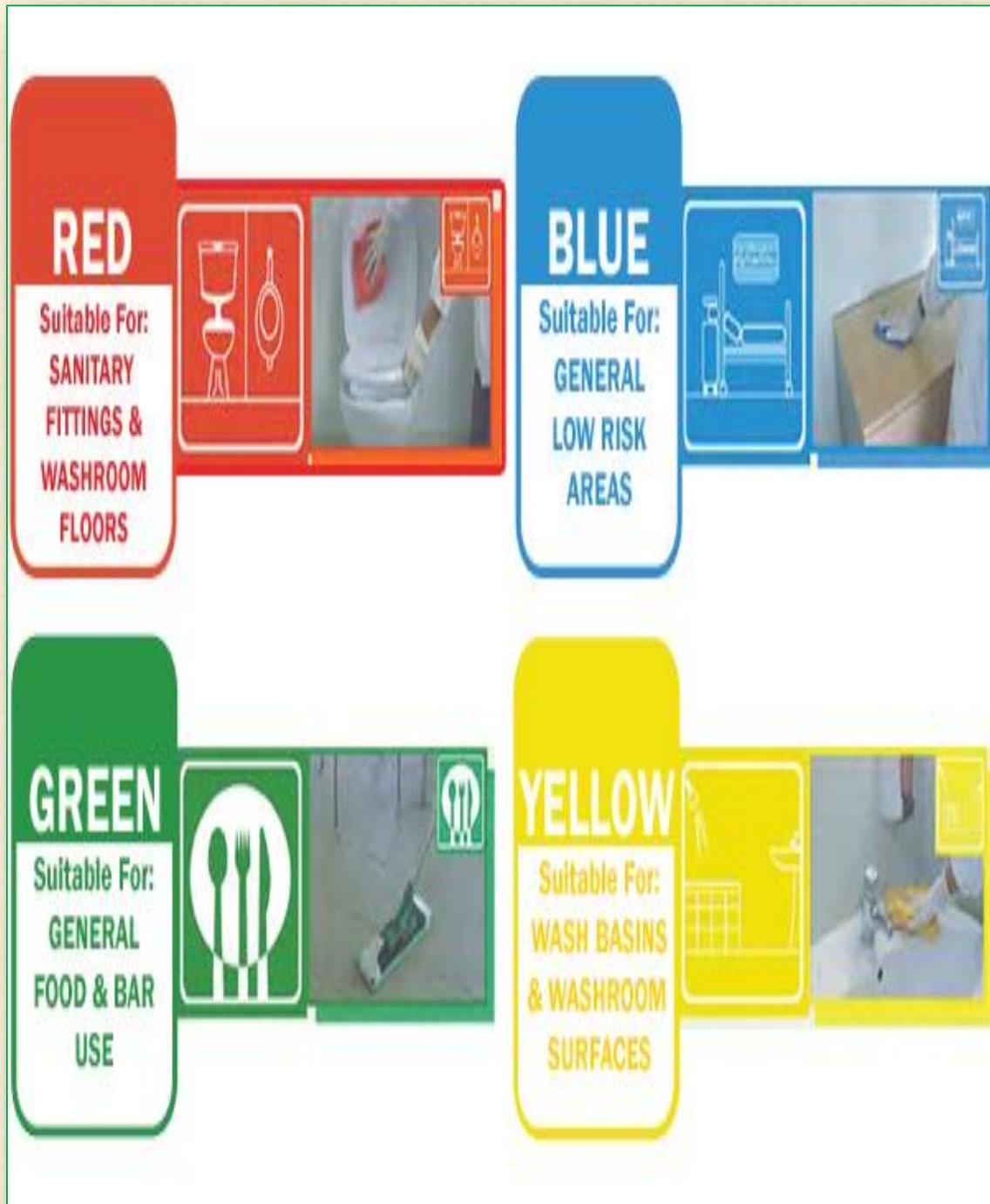


Fig: Colour coding system for cleaning different areas

2. Maintenance

- Preventive maintenance programs must include all devices used to monitor and/or control food safety hazards and cover the maintenance procedure, frequency and identification of the person (and/or external agency) responsible for maintenance activity. It shall be carried out regularly as per the instructions of the manufacturer.
- Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination and post maintenance verification to be get recorded. Internal & External calibration schedule for critical food safety equipment's should be maintained.
- Lubricants, heat transfer fluids or any other similar material used shall be food grade where there is a risk of direct or indirect contact with the product.
- It is recommended as best practice to maintain plant equipment's breakdown records.
- Loose items control policy (Nut & bolts, Nails broken pieces or smaller parts of machines) should be followed to prevent any contamination with product or packaging material.

3. Pest Control System

3.1 Pest control programs

- Pest management programs shall be documented and shall identify target pests and address plans, methods, schedules, control procedures and where necessary, training procedures.
- Establishment shall have a nominated person to manage pest control activities and/or deal with external appointed contractors. Records of pest management shall be maintained.
- Treatment with permissible chemicals, physical or biological agents, within appropriate limits, shall be carried out without posing a threat to the safety or suitability of food.
- Food materials shall be stored in pest-proof containers stacked above the ground and away from walls.

3.2 Preventing access

- Food Establishment, including equipment and building shall be kept in good repair to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places like external doors, windows ,ventilation openings where pests are likely to gain access shall be kept in sealed condition or fitted with mesh/grills/cladding or any other suitable means as required and animals, birds and pets shall not be allowed to enter into the food establishment areas/premise.
- Site external and internal environment, storage facilities, equipment and associated ancillary areas (including waste handling areas, drainage and overheads) shall be kept clean and free of product accumulations to prevent pest infestations.

3.3 Harborage and Infestations

- Storage practices shall be designed to minimize the availability of food and water to pests. Potential pest harborage (e.g. burrows, holes, crevices) shall be sealed.
- Material found to be infested shall be handled in such away to prevent contamination of other materials, products or the establishment.
- Where outside space is used for storage, stored items shall be protected from weather or pest damages (e.g. rodent damages, bird dropping)



Fig: Rodent Box Sample



Fig: Glue Traps

3.4 Monitoring and detection

- **Detectors and traps** shall be designed and located so as to prevent potential contamination of materials, products and facilities and should be placed in key locations to identify pest activity.
- **Glue traps** may be used in manufacturing areas and Rodent baits outside in premises shall be inspected daily so that captured pests may be removed. **Use of UV light traps** (Electronic fly killers) is used where applicable and shall be emptied regularly.
- External bait stations shall be positioned to keep pest away from building entrances. It is recommended that bait station be placed at regular intervals around the perimeter of the building.

3.5 Eradication

- Eradication measures shall be put in place immediately after evidence of infestation is reported.
- Pesticide use and application shall be restricted to trained operatives and shall be controlled to avoid product safety hazards. **Only fully trained qualified personnel** should be permitted to apply pesticide application.
- The use of insecticide within food factories shall be kept to minimum or avoided.
- Chemicals use for pest control shall be approved under Insecticide Act,1968.
- Records of pesticide use shall be maintained to show the type, quantity and concentration used; where, when and how applied, and the target pest. All chemicals used for pest control measures, shall be accurately labelled and stored securely away from raw materials

4. Waste Disposal Management

Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products or production areas.

4.1 Waste Collection

- The waste shall be collected in identifiable containers with lid and shall be removed from the processing areas either at the end of the operations or when the container is full.
- Waste storage facilities shall be:

- away from the processing area;
 - designed to prevent access to waste by pests;
- Waste containers shall be kept in designated area and constructed of impervious material which can be readily cleaned and sanitized (Foot operated bins are recommended)
- Facilities shall be designed to prevent access to waste or inedible material by pests and avoid contamination of food, potable water, equipment, buildings or roadways in the premises.

4.2 Waste Disposal

- Accumulation of waste shall not be allowed in food-handling or storage areas. Removal frequencies shall be managed to avoid accumulations, with a minimum daily removal
- The disposal of the waste shall be done in such a way that it should not cause any hazard to the environment. Records for the disposal shall be available.
- If the waste disposal is outsourced, it has to be done through approved contractors only and the records shall be maintained.
- Disposal of sewage & effluents (solid, liquid & gas) shall be done as per the Environment Protection Act, 1986 & local rules, wherever applicable.

4.3 Drainage System

- Drains shall be designed, constructed and located so that the risk of contamination of materials or products is avoided. Drainage direction shall not flow from a contaminated area to a clean area.
- In general, if drains are present, the surrounding floor should be **properly sloped for effective drainage** and kept dry under normal conditions.
- Drainage & sewage system should be equipped with appropriate traps and vents to effectively capture contaminants such as sewer gases, pests etc.

IV. Establishment-Personal Hygiene

Personal hygiene plays an integral part to safeguard the food produced from any sort of cross contamination. A good personal hygiene and behavior prevents the food from contamination and subsequently hazards in the product and hence illnesses to the consumers.

Personal hygiene can be taken care by main aspects like **health and hygiene of food handlers, duties of employers as equal to employees** in the area of personal hygiene by providing the **appropriate environment and facilities**.

1. Health Status and Illness Injury

- A person known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, shall not be allowed to enter into any food handling area.
- The Food business shall develop system, whereby, any person affected by illness (jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected lesions and discharges from ear, eye or nose etc.), **shall immediately report illness or symptoms of illness** to the management for possible exclusion from food handling area and medical examination of the food handler shall be carried out apart from the periodic check-ups, if clinically or epidemiologically indicated.
- **Medical examination of all food handlers/** employees of the establishment shall be **done once in a year to** ensure that they are free from any infectious, contagious and other communicable diseases. A record of these examinations signed by a registered medical practitioner shall be maintained for inspection purpose.
- **Inoculation of factory** staff including workers against the enteric group of diseases shall be done once a year and a record towards that shall be kept for inspection.
- In case of an epidemic, all factory staff including workers shall be **vaccinated irrespective of the early vaccination**.
- In food handling area, personal with open cuts, wounds or burns shall be required to cover them with suitable water proof dressing before starting operations. The dressings should preferably be **brightly coloured and metal detectable**.

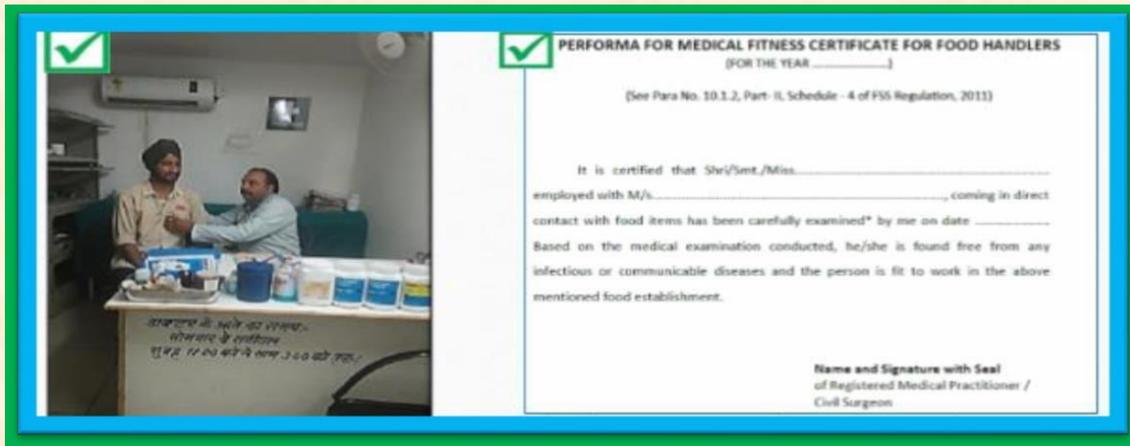


Fig: Medical Check-up and Medical certificate

a. Protective Clothing/Work wear:

- The Food business shall provide to all food handlers adequate and suitable clean protective clothing, head covering, face mask, gloves and foot wear and the food business shall ensure that the food handlers at work wear only clean protective clothes, head covering and footwear every day.
- Clothing mandated for food protection or hygiene purposes shall not be used for any other purpose.
- Work wear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product. Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints.
- Laundry facility shall be provided for washable garments in the establishment but where this facility is not available, outside contractors should be engaged.
- Shoes for use in processing areas shall be fully enclosed and made from non-absorbent materials.
- Boots or foot wears shall be cleaned inside and outside, kept in inverted position to maintain them dry and free of any foul odour or slime. Shoes worn outside food handling area shall not be allowed to enter food handling area.
- Other persons entering into the plant (customers /visitors/contractors/calibration agencies /maintenance persons etc.) shall be provided with hair nets, beard nets (if necessary) masks, aprons and shoe covers while entering in to the plant.



Fig: Different Personal hygiene wears.



Fig: Storage of Personal hygiene Clothing

4. Personal Cleanliness

- Food handlers shall maintain a high degree of personal cleanliness. They shall always wash their hands with soap and clean potable water, disinfect their hands and then dry with hand drier or clean cloth towel or disposable paper at the beginning of food handling activities immediately after handling raw food or any contaminated material, tools, equipment or work surface, where this could result in contamination of other food items or after using the toilet. Hand washing notices shall be posted at appropriate places.
- Food handlers engaged in food handling activities shall refrain from smoking, spitting, chewing, sneezing or coughing over any food whether protected or unprotected.
- They **should trim their nails** and **hair** periodically and **avoid certain hand habits** –e.g. scratching nose, running finger through hair, rubbing eyes, ears and mouth, scratching

beard, scratching part of bodies etc. that are potentially hazardous and might lead to food contamination through transfer of bacteria from employee to the product during processing.



Fig: Touch free (hands free) taps at wash basins to avoid cross contamination



Fig: Sequential Steps for washing hands

3. Personal Behaviour

- Any behaviour or unhygienic practices which could result in contamination of food shall be prohibited in food processing, distribution, storage and handling areas. This includes smoking, chewing or eating, sneezing or coughing over unprotected food, spitting etc.
- Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas as if they pose a threat to the safety and suitability of food.
- Should provide **separate lockers/place** provided for persons regularly working food processing areas to keep their personal belongings, tiffin etc. **Food contact tools** and equipment shall not be kept in personal locker.

4. Visitor Control

- Generally should be discouraged from going inside the food handling areas. Proper care has to be taken to ensure that food safety & hygiene is not getting compromised due to visitors in the floor area.
- **Food Business Operator should implement and display visit or control policy.**
- The Food Business shall ensure that visitors to its food manufacturing, processing or handling areas must wherever appropriate, wear protective clothing, footwear and adhere to the all the personal hygiene provisions required for personnel required in the food business.

V. Establishment–Product Information and Consumer Awareness

1. Product information & Labelling

- All incoming, in-process and finished products shall be suitably identified for product identification, stage of processing, inspection and test status etc. so as to avoid their inadvertent use. **Lot identification** shall be done to facilitate traceability, product recall, effective stock rotation etc.
- All packaged food products shall be labelled with requisite information as per provisions of Food Safety and Standards Act, 2006 and Regulations made there under so as to ensure that adequate and accessible information is available to next person in the food chain to

enable them to handle, transport store, process, prepare, display or use the food products safely and correctly and that the lot or batch can be easily traced and recalled if necessary.

2. Consumer awareness and Complaint handling

- Information shall be presented to consumers in such a way so as to enable them to understand its importance and make informed choices. Information may be provided by labelling or other means, such as company websites, education programmes and advertisements, and may include storage, preparation and serving instructions applicable to the product.
- The Food Business shall have a system to handle product complaints with identified person or people responsible for receiving, evaluating, categorizing, investigating and addressing complaints. Complaints shall be accurately categorized according to safety concerns and other regulatory concerns, such as labelling and shall be investigated by appropriately-trained technical personnel.
- Regular complaint data analysis can be utilized to reduce future customer complaints

V. Establishment–Training and Management

1. Awareness and Responsibilities

- The Food Business shall ensure that all food handlers are aware of their role and responsibility in protecting food from contamination or deterioration.
- Food handlers shall have necessary knowledge and skills which are relevant to food processing/manufacturing, packaging, storage and distribution.

2. Training Programmes

- The Food Business shall ensure that all the food handlers are instructed and trained in food hygiene and food safety aspects along with personal hygiene requirements commensurate with their work activities, the nature of food, its handling, processing, packaging, storage and distribution.
- FSSAI has provided an easy solution for training and certification through its new initiatives of **Food Safety Training and Certification (FoSTAC) portal**. FSSAI recommends that all

licensed food businesses must have at least one trained and certified Food Safety Supervisor under FoSTaC for every 25 food handlers in each premise.

- All food handlers (permanent or contractual) are to be assessed for existing competence/awareness/ skills/knowledge. All personnel responsible for monitoring, corrections and corrective actions of the food safety management system are trained.
- Training program should be developed with **training calendar**. Such training shall also include personnel who enter areas on a temporary basis (e.g maintenance workers, contractors).Systems should be in place for assessing effectiveness of training. **Records of training** shall be maintained.

3. Instruction and Supervision

- Routine supervision and checks to ensure that food hygiene and food safety procedures are being carried out effectively.

4. Refresher Training

- Training programmes shall be routinely reviewed and updated wherever necessary.

5. Management & Supervision

- FBO shall appoint a food safety team leader who, irrespective of other responsibilities, shall have the responsibility and authority.
- FBO shall appoint trained & competent managers and supervisors for management and supervision of food safety systems.
- The FBO management shall provide and maintain documented standard operating procedure for FSMS systems compliance and its supervision at site through records/checklists on routine basis to control any possible hazards throughout supply chain.

VII. Audit, Documentation and Record Keeping

1. Self-Evaluation and Review

- A periodic audit of the whole system according to the written SOP of the FBO shall be done to identify/gaps for further improvement in the GMP&GHP system.
- The FBO shall conduct a self-evaluation process to review the effectiveness of the implemented food safety system at periodic intervals through internal and external audits or other mechanisms, but at least once in a year.
- The FBO shall analyse the results of verification activities, including the results of internal and external audit and take necessary actions and to provide evidence that any corrections and corrective actions that have been taken are effective.

2. Documentation and Records

- A written food safety plan that includes a description of each of the hazards identified in the hazard analysis process, as well as the control measures that will be implemented to address each hazard, shall be prepared by food business operators.
- **Appropriate records of Spices processing/production, storage, distribution, food quality, laboratory test results, cleaning and sanitation, pest control and product recall shall be maintained.**
- Records shall be retained in good condition at least for a period of one year or the shelf life of the product, whichever is more.

C. HACCP IMPLEMENTATION INCLUDING CRITICAL CONTROL POINTS

C. HACCP IMPLEMENTATION INCLUDING CRITICAL CONTROL POINTS

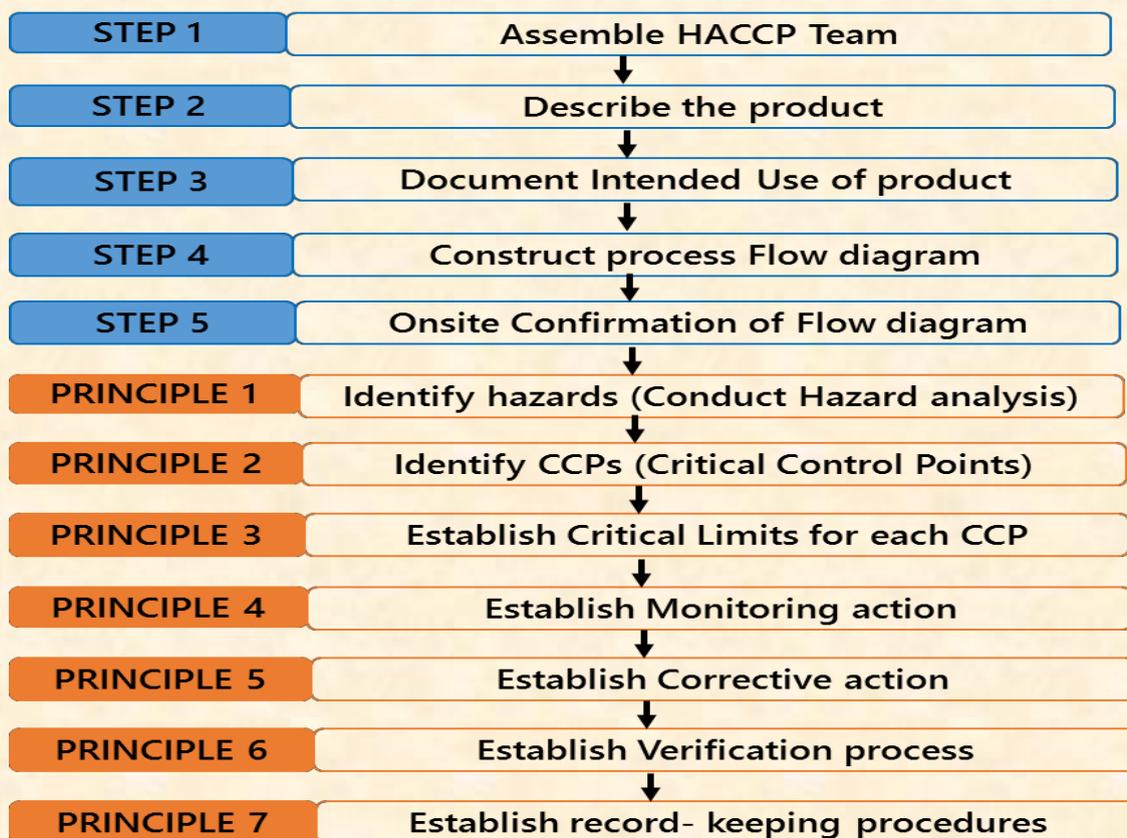
Implementing Hazard Analysis and Critical Control Point (HACCP) is crucial for any food manufacturing process. A HACCP plan covers the total supply chain, from inbound logistics, through storage, processing, sanitation and maintenance to the final use by the consumer. Across the operations, it must be ensured that procedures are available for internal logistics, processing specifications, working instructions, hygiene procedures and preventive maintenance plans. These procedures must cover start-ups, shutdown and unexpected stoppages during processing. The requirements for Sanitation Standard Operating Procedures (SSOPs) along with Good Manufacturing Practices (GMPs) should be considered as Pre-Requisite for HACCP.

1. Introduction of HACCP

HACCP is not a stand-alone program but is part of a larger control system. HACCP is essential to carry out to identify the weakness of the production line and to suggest critical limits in compliance with legislation and therefore the preventive and corrective measures.

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

During implementation of HACCP, it is imperative to set controls at each point of the production line at which safety problems (physical, chemical and microbiological) are likely to occur. A HACCP plan is required to be in place before initiating the HACCP system. HACCP is a system which identifies specific hazard(s) (i.e. any biological, chemical, or physical property that adversely affects the safety of the food) and specifies measures for their control. A HACCP Plan consists of 5 initial steps and 7 major HACCP principles.



1.1 Risk assessment

Risk assessment is a critical step in a HACCP plan. Risk is the combination of the likelihood (probability) of Occurrence & Consequence(s) (sometimes referred as severity) of a specified hazardous event occurring.

So the risk is defined as:

$$\text{RISK} = \text{OCCURRENCE} * \text{CONSEQUENCE}$$

The following scales can be used for the measurement of the likelihood of Occurrence & the consequences; hence the risk as well.

Criteria for Likelihood of Occurrence				
Likelihood of Occurrence	Criteria			Rating
	Frequency of occurring at least once in		Description	
	<i>Routine job</i>	<i>Irregular job</i>		
Very High	Daily	5 batches	Persistent, will occur if not attended to	5
High	Fortnightly	50 batches	Frequent chance of occurrence	4
Moderate	Monthly	100 batches	Occasionally could occur	3

Low	Yearly	1000 batches	Relatively some chance of occurrence	2
Remote	In 5 years	5000 batches	Unlikely to occur	1

Consequence (Severity)		
Rating	Severity	Effect
5	Very High (Catastrophic)	Death
4	High (Critical)	Serious Illness
3	Moderate	Illness/Injuries
2	Low	Un-comfort
1	Remote	No injuries

Nature of Control over Risk

Rank of Risk	Risk Index Value	Level of Control	Significant
R1	16-25	Avoidance/Special Process	Significant Hazard
R2	9-15	Physical Control/Monitoring	Significant Hazard
R3	5-8	Formal Control	Non-Significant Hazard
R4	0-4	Informal Control / Training	Non-Significant Hazard

The level of risk could help to identify the level of control as per the following:-

R1: Avoidance:	Precluding the possibility of a given hazard, it may be the modification of the process if necessary.
R2: Physical Control:	Continuous control & monitoring of the actual physical process.
R3: Formal Control:	It is the management of the conditions of an operation to maintain compliance with documented criteria.
R4: Informal Control and Training:	It is the monitoring/check of the process without formal recording.
	It is the teaching of the staff responsible for the process about what is to be done in order to prevent the hazard.

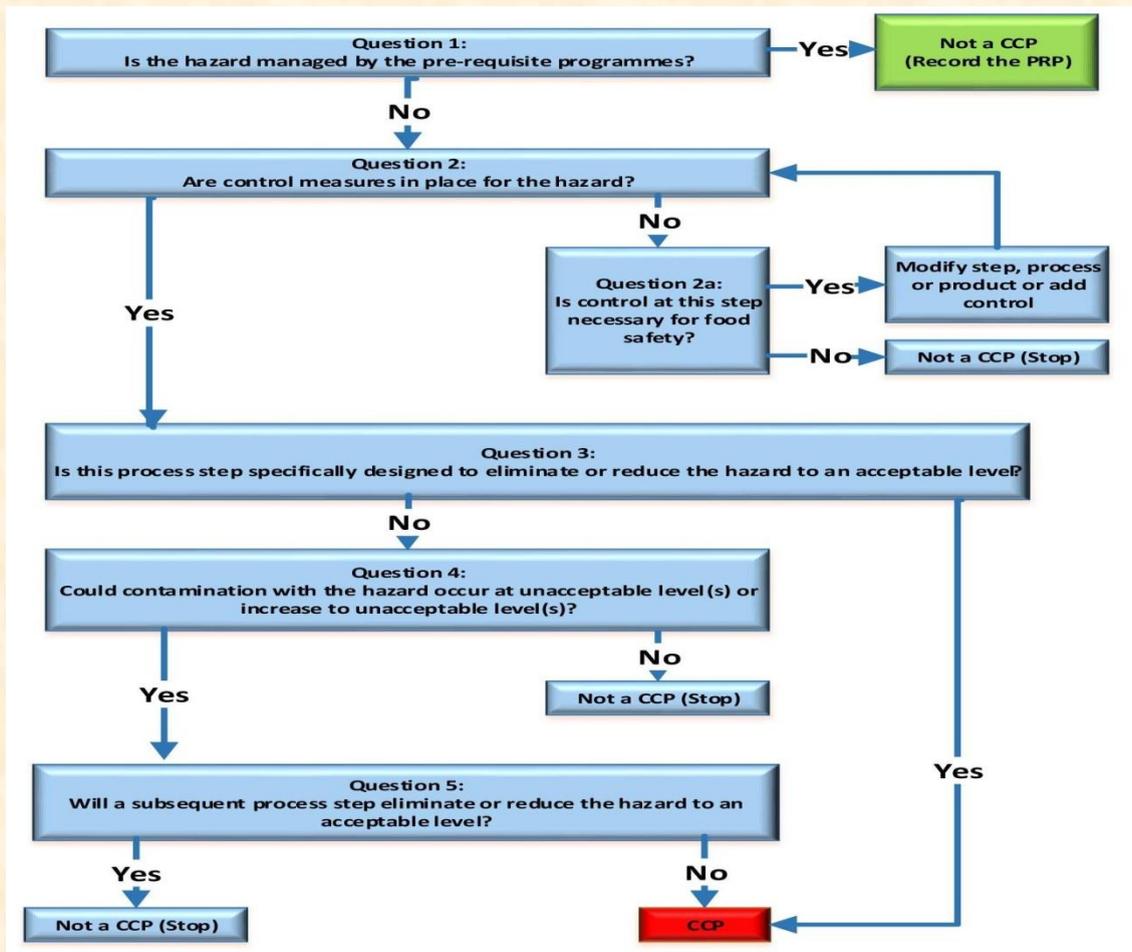
Below is a template to determine what severity and probability a processing step is involved with and therefore what level of criticality is holds in the processing line.

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

1.2 Introduction to Decision Tree

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

The purpose of a decision tree is to support the judgment of the team and help you to confirm whether the hazard needs more food safety controls. Decision trees are not mandatory elements of HACCP but they can be useful in helping you determine whether a particular step is a CCP. It is vital that you determine the correct CCPs to ensure that food is managed effectively and safely. The number of CCPs in a process will depend on how complex the process is and how many hazards are present.



1.3. Sanitation standard operating procedures (SSOPs)

Each plant should adopt sanitation standard operating procedures (SSOPs). These are written instructions describing each sanitation procedure, how to properly complete the task, the frequency with which each procedure is performed, and the need to record the identity of the person(s) responsible for the implementation and maintenance of the SSOP. SSOPs should address:

1. Safety of the water that comes into contact with food or food contact surfaces;
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and clothing;
3. Prevention of cross contamination from insanitary objects to food, and from raw product to processed product;
4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
5. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces;
8. Exclusion of pests from the food plant.

2. Possible hazards in Spices Processing

Hazard Types

There are three primary types of hazards to consider when conducting a hazard analysis. They include the following: - Chemical Hazards; Physical Hazards & Biological Hazards.

Chemical Hazards

A wide variety of chemicals are used in food production and processing. Some chemicals, such as pesticides used in growing spices, cannot be removed by a subsequent process thus their control needs to be prior to the intake of the facility. This would normally be through controls in GAP (Good Agricultural Practices) or through product testing / rejection upon arrival.

However, there are chemicals in processing facilities and manufacturing plants that should be rigorously controlled. These include such items as sanitizers, lubricants, pest control chemicals used within a processing facility and water treatment additives, plus chemicals added to the manufacturing process for a specific process. While most of these chemicals do not pose a health hazard when used properly, some are capable of causing serious health problems if used incorrectly.

Types of chemical hazards found with spices, in addition to those used in the processing facilities include:

- Naturally occurring mycotoxins such as aflatoxin
- Added Chemicals
- Agricultural products, pesticides, fertilizers, antibiotics, other field chemicals
- Toxic elements, lead, mercury, and other heavy metals
- Food additives, such as preservatives, flavor enhancers, color additives.

As with pesticides and heavy metals, mycotoxins will not be affected by the process so their control should take place prior to entering the facility. It is critical that all routes of cross-contamination must

be considered including airborne contaminants, reworked products, storage of potential contaminants, etc.

Physical Hazards

For the spice industries, a major objective is to remove physical hazards. This is true for any industry that deals with field or comparable materials. Physical hazards usually result in personal injuries, such as a cut from glass or a case of choking from foreign materials.

Physical hazard points of entry into the products are in the field, in-transit, deliberate by employees or others, equipment failure, and poorly maintained facilities and equipment. Controlling foreign objects in raw materials can be started by specifications, letters of guarantee and vendor inspection and certifications.

List of equipment capable of removing the physical impurities that can contaminate raw spices:

1. Aspirator (Air separator)
2. Rotary knife cutter
3. Destoner
4. Vacuum gravity separator (Air table)
5. Clinder separator (Indent)
6. Sifter Aspirator
7. Plain sifter
8. Spiral gravity separator
9. Air screen separator.

Biological Hazards

One of the greatest risks for illness or injury from food comes from microbiological hazards. For an illness to occur, the pathogen must be present in the food and must grow to high enough numbers to cause an infection or to produce toxin. The food must be capable of supporting growth of the pathogen and must remain in the growth temperature range long enough for the organism to multiply.

Due to the environment in which they are grown, spices often harbor large numbers of bacteria and fungi, including potential spoilage organisms and occasionally organisms of public health significance. In general, roots, berries, and herbs carry a greater microbial load than bark and seed products. Although a number of microorganisms are killed during the drying of spices, many bacteria and molds survive. If the products are not stored and shipped properly, problems may

occur. The bacterial and fungal species in spices include aerobic spoilage organisms, spore forming bacteria, high heat stable toxin producing bacteria, proteolytic and gas-producing bacteria, and mycotoxin-producing microorganisms.

Common microorganisms found in spices are:

- Bacteria: Salmonella, C. perfringens, Bacillus cereus, E. coli, Staphylococcus aureus.
- Fungi, Yeast and Molds : Aspergillus, Penicillium ssp.

Mycotoxins : Examples of mycotoxins include but are not limited to: Aflatoxin, Ochratoxin and Vomitoxin.

Sources of microbial contamination are:

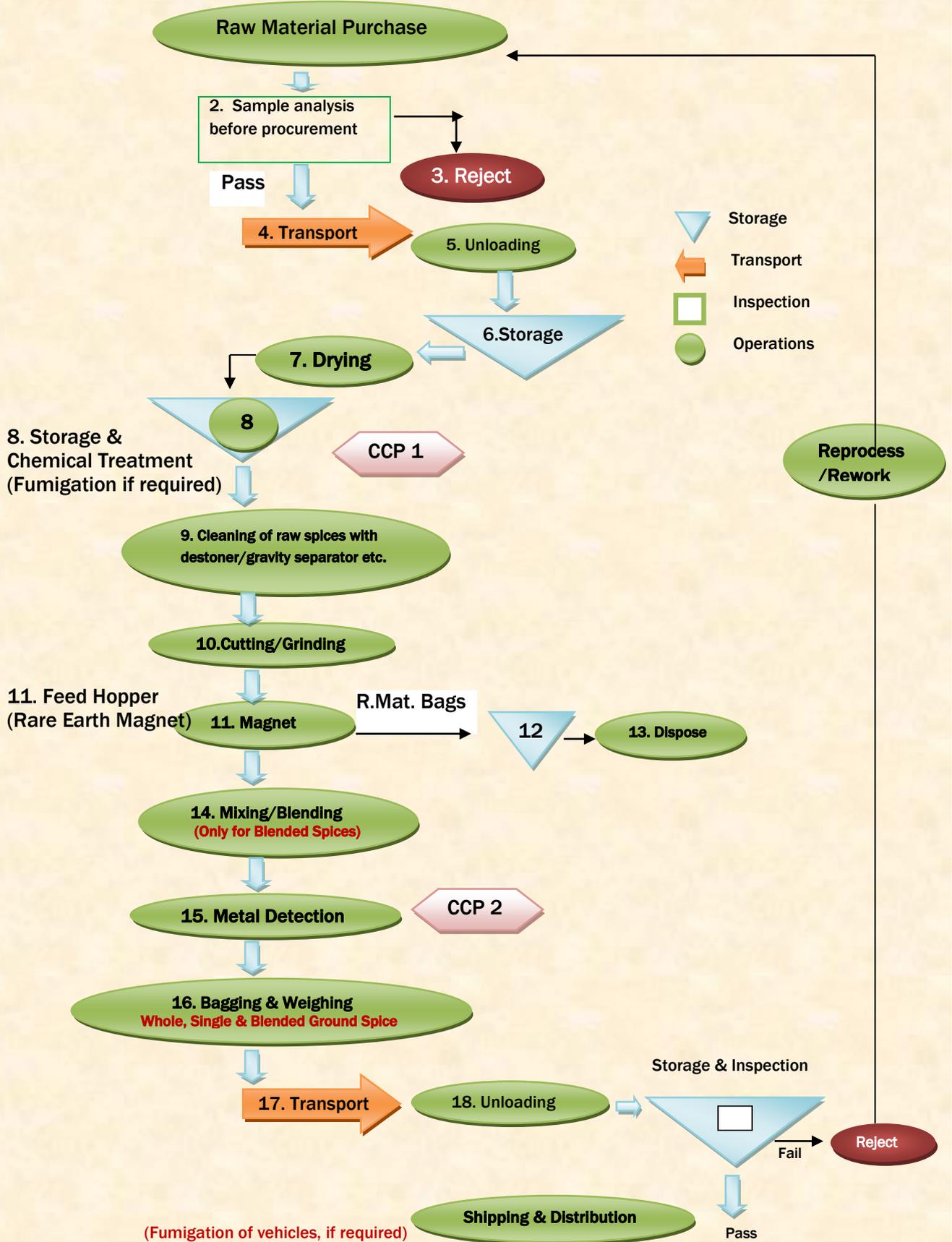
Growing, drying, and harvesting; Processing; Improper storage and distribution temperatures and handling; Poor personal hygiene among food handlers and production workers.

Indicator Organisms: Indicator organisms do not usually represent a direct health hazard. In some cases, however, they serve to indicate that the potential is present for a health hazard to exist.

Common indicator organisms include:

- Standard Plate Count
- Coliforms : Fecal Coliforms :E. coli

3. Process Flow Charts-Hazard Analysis (Flow Diagram: SPICES)



PRODUCT DESCRIPTION	
Product / Product Category (e.g. Name, type, size)	Spice Powder
Process (e.g. Cold pack, hot fill, aseptic, freeze dried)	Refer 'Flowchart on Spice Powder Manufacturing'
Food Safety Characteristics (e.g. pH, Aw, % salt, pasteurisation, cooking, preservatives, refrigeration)	The water activity of spice powder is less than 0.9. Hence, it is low risk for bacterial growth.
Target Market (e.g. General public, age, adult, child, retail, food service, countries, regions, national)	It is consumable by generic public.
Consumer / Customer Use (e.g. Ready to consume, heat and consume, mix and consume)	<p>Spice powder for Cooking purpose and not for Direct Consumption-</p> <p>This Spice powder is to be used in Cooking purpose; and not for direct consumption.</p> <p>Spice powder for Direct Consumption-</p> <p>This Spice Powder is treated with anti-microbial treatment methods.</p>
Labelling/Label Instructions (List Only Those Ingredients Containing Allergens, Sulphites) (e.g. Preparation, storage needs, use by, best when used by)	The FSS (Packaging and Labelling) Regulation's requirements are complied.
Packaging (e.g. Foil , plastic, glass, cup, can, hermetically sealed, gas permeable, tamper evident, modified atmosphere packaging)	The packaging material used is described here.
Shelf Life (e.g. Days and temperature conditions)	Shelf life is determined as per NABL Laboratory's testing procedure.
Storage & Distribution (e.g. Ambient, refrigerated, frozen, relative humidity, high altitude)	Keep this product in ambient storage condition.
Raw Materials and ingredients used (composition);	Refer the product label for ingredients used.
General Product Specifications such as appearance;	This is powder form of spices.
Specific Product Specifications such as chemical, microbiological and physical characteristics	This spice powder is dry and in powder form.
Identification of potential mishandling of the product.	If the seal is leaked or tampered, then do not buy this product.

4. Hazard Analysis and Identification

Table-Hazard and CCP Identification

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

Process Step	Type of hazard	Hazard description	Hazard Assessment			Q1a: Do control preventive measure (s) exist at this step? YES: Go to Q2. NO: Go to Q1b					
			Likelihood	Severity	Risk	Q1a	Q1b	Q 2	Q 3	Q4	CCP (Y/N)
1.Receiving	P	Foreign Material such as wood, glass and other non-metallic material	3	3	9	Yes	No	--	--	No	GMP (Good Manufacturing Practices) & SSOP (Sanitation Standard Operating Procedure)

2. Storage	C	Mycotoxins	2	4	8	Yes	No	--	--	No	Vendor Selection and Evaluation; Supplier Certificates of Analysis
	B	Salmonella Sp.	2	4	8	Yes	No	--	--	No	Microbial Reduction Process
	P	Limited opportunity for additional physical contamination									GMP; Pest Control and Warehouse Sanitation Programs
	C	Contamination by sanitation chemicals	2	4	8	Yes	No	--	--	No	Master Sanitation Programs & Record.
3. Treatment	B	Contamination by Pests									GMPs and Pest Control Program
	C	Chemical Residue	1	3	3	Yes	No	--	--	No	Treatment monitoring and Records
	B	Survival of pathogens like Coliforms, Salmonella etc due to inadequate treatment	4	5	20	Yes	Yes	--	--	Yes	Treatment log and control charts. Process Records.
4. Cleaning & Grinding	P	Foreign matter such as stones, dirt, wire, string, stems, sticks, foreign seeds,	2	4	8	Yes	No	--	--	No	Preventative Maintenance program; GMP; Self Inspection Programs, Quality Testing; Allergen Control & Label Control Programs and Records.

5. Metal Detection	P	excreta, other animal contamination Presence of metal pieces in product, thus choking and/or laceration hazard.	4	4	16	Yes	Yes				CCP 2	Monitoring of metal detector using test samples. Detection at present levels typically 1.0-1.5mm for ferrous and 2.0-2.5mm for non-ferrous.
6. Bagging & Weighing	P	The opportunity for additional physical contamination is limited	--	--	--	Yes	No	--	--		No	GMP's; Allergen Control, Label Control, Preventative Maintenance & Self Inspection Programs and records.
7. Shipping/ Distribution	B C P	Nil	--	--	--	--	--	--	--		---	Shipped in a tamper-proof sealed container which has been inspected prior to stuffing

5. HACCP Plan

Table HACCP Plan :(Example for 2 CCP's)

CCP No	Activity	Hazard Description	Monitoring parameters	Critical Limits	Monitoring		Corrective actions	Responsibility	Records	Verification
					Procedures	Frequency				
CCP 1	Treatment	Survival of Pathogens like Coliforms, Salmonella etc after treatment resulting from inadequate treatment.	Temperature, Pressure and Time	As specified in the process control sheet	Reading of process parameters in the Digital Meters	Hourly	Review the process control settings and repeat the process Re-adjust settings Inform HACCP team leader if deviation persists	Operator	1. Treatment log & Control charts. 2.Process checklist for steam treatment	Analysis of Pathogens for every consignment and TPC for every Batch.
CCP 2	Metal Detection	Presence of metal pieces in product, thus choking and/or laceration hazard.	Detection of test metals	Fe– 1.0mm Non-Fe – 1.5mm Stainless – 2.0mm	Pass product through metal detector On-line/offline detector inspection	Hourly	Hold and review including inspection of rejects.	Supervisor	Metal detector log and inspection results	Screening of test samples

D. ANNEXURE

D. ANNEXURE

Annexure 1: Type of Adulterants in Spices

Sr. No.	Spices	Adulteration
1.	Mustard seed	Addition of Argemone seed.
2.	Black pepper (whole & powder)	Mixing of Papaya seeds, light berries and may even add filler such as saw dust.
3.	Spices (Ground)	Added starch, Powdered bran and sawdust.
4.	Turmeric powder	Coloured saw dust, Lead chromate, Metanil Yellow, Chalk powder or yellow soap stone powder.
5.	Chillies powder	Brick powder, salt powder or talc, powder, Artificial colours and dyes, Water soluble coal tar colour, grit, sand, dirt, filth.
6.	Asafoetida (Hing)	Soap stone or other earthy material, Starch, Foreign resin.
7.	Coriander powder	Dung powder, Common salt and sawdust.
8.	Oregano	addition of other similar herbs and plant leaves
9.	Cumin (whole & powder)	Cumin seeds are mixed with Grass seeds coloured with charcoal dust, powder can be mixed with sawdust.
10.	Salt	can be mixed with talc and other impurities
11.	Saffron	Can be made of coloured gelatin strands or stretched with dyed maize filaments (corn silk)
12.	Cinnamon	With Cassia
13.	Cloves	Can be mixed with exhausted cloves

Annexure 2: FSMS Related Document & Record Templates

1. MANDATORY

1.1 Medical Fitness Certificate for Food handlers (Template)

MEDICAL FITNESS CERTIFICATE FOR FOOD HANDLERS

(FOR THE YEAR.....)

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

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

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

***Medical Examination to be conducted:**

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

1.2 FORM E

Form of Guarantee

(Refer Regulation 2.1.14(2))

Invoice No. _____

Place: _____

From: _____

Date: _____

To: _____

Date of sale Nature and quality of article/brand name, if any Batch No or Code No. Quantity Price

1	2	3	4	5
---	---	---	---	---

I/We hereby certify that food/foods mentioned in this invoice is/are warranted to be Of the nature and quality which it/these purports/purported to be.

Signature of the manufacturer/Distributor/Dealer

Name and address of

Manufacturer/Packer

(in case of packed article)

License No. (wherever applicable)

2. Recommendatory Performas

2.1 Utensil Monitoring record (Template)

S. No.	Item number	Item placed at	Condition (OK/Not OK)	Correction done	Remarks

2.2 Approved Supplier List (Template)

S. No.	Item/Material Name	Location of Use	Primary Approved Supplier(Name & complete address)					Secondary Approved Supplier (Name & complete				
			Complete Address	Contact Person	Contact No.	Email id	Fax	Complete Address	Contact Person	Contact No.	Email id	Fax

2.3 Incoming Material Inspection Template

<i>Includes all type: Raw materials, Ingredients, Food additives, Processing aids, Packaging materials ,Cleaning and sanitation chemicias,etc.</i>		
Material Name:		
Supplier Name:		
Identification/Location of Supplier:		
Quantity received:		
Pack size received:		
Material Receipt Date:		
Transport Mode:		
Rejected(Yes/No):		
Reason for Rejection:		
PARAMETER EVALUATED	STATUS/RESULTS	Signature
Temperature (Degree Celsius)		
Visual Inspection Condition(OK/Not OK)		
Packaging & Labelling Condition(OK/Not OK)		
Production Date/Shelf Life Date/Expiry Date		
Vehicle Inspection Condition (OK/Not OK)		
Quality Lab Results (Ifapplicable)		
Certificate Of Analysis(COA) received (Yes/No)		
Remarks		
Clearance Date		
Authorized Signatory		

2.4 Incoming Vehicle Inspection Record (Template)

Date of Incoming Vehicle:	
Vehicle Type:	
Material in Vehicle received:	
Number of Persons accompanying Driver:	
PARAMETER EVALUATED	REMARKS
Security lock	
Type of carrier (full covered/Open Roof)	
Mode of covering products (in case of Open Roof)	
Overall Hygiene in the interior	
Overall Hygiene on the exterior	
Any	
Any pests detected	
Any grease/oil detected	
Authorized Signature	

2.5 Product Release Record (Template)

Name of Product:	
Date of Manufacturing:	
Time of Manufacturing:	
Batch/Lot No.:	
Best Before/ Expiry Date:	
Quality Acceptance	
Analytical	
Microbiological	
Sensory	
Others, if any	
Quality Lab signature	

2.6 Non-conforming Material/Product (Template)

HOLD: <input type="checkbox"/>	REJECT: <input type="checkbox"/>
Material Type:	
Finished Product	Raw Material
In-Process Product	Packaging Material
Material Name:	
Date of Manufacturing/Receipt:	
Quantity of Manufacturing/Receipt:	
Lot/Batch No.	
Quantity used:	
Lot/Batch No.	
Quantity Hold:	
Lot/Batch No.	
Quantity Rejected:	
Lot/Batch No.	
Reason for Hold:	
Reason for Rejection:	
Rectification Measure:	
Preventive Action:	
Remarks:	
<i>Signature:</i> QC Executive	<i>Quality Manager Mfg/ProductionManager</i>

2.7 Outgoing Vehicle Inspection Record (Template)

Date of Outgoing Vehicle: Vehicle Type: Material in Vehicle to be dispatched: Date of : Time of Manufacturing: Batch/Lot No.: Number of Persons accompanying Driver:	
PARAMETER EVALUATED	REMARKS
Security lock	
Type of carrier (full covered/Open Roof)	
Mode of covering products (in case of Open Roof)	
Overall Hygiene in the interior	
Overall Hygiene on the exterior	
Any sharp edges /points in the interior of vehicle	
Any pests detected	
Any grease/oil detected	
Authorized Signature	

2.8 Product Recall record (Template)

S. No.	Date of Complaint	Nature of Complaint	Results of Investigation	Product/ Batches & Quantity recalled	Mode of Disposal

2.9 Product Identification & Traceability (Template)

Traceability Detail Format				
Product Description				
Plant Name:		Manufacturing Date:		
Product Name:		Manufacturing Time:		
Pack Size:		Batch/Lot no.:		
Traceability Details				
Investigation Date:		Investigation Time End:		
Investigation Time Start:		Total Time Taken:		
A. Cleaning Details				
EquipmentName	Date	Time	Person responsible	Remarks
B. Raw Material Details				
Material Description		Remarks		
Name	Batch/Lot No.			
C. Utility Details				
Chemical/Material Description		Remarks		
Name	Batch/Lot No.			
D. Primary Packaging				
Material Description		Remarks		
Name	Batch/Lot No.			
E. ManufacturingDetails				
Date	Shift	Cases Manufactured	Compliance	Remarks
F. QC Details				
Date	Shift	QC compliance	Product blocked, if any	Remarks
G. Dispatch Details				
Invoice No.	Date of Dispatch	Quantity Dispatched= Total produced- (Rejected+ Control samples+ Warehouse retained)	Dispatch Destination	Remarks

2.10 List of Monitoring & Measuring Devices and Records of Calibration (Template)

S. No.	Name of Equipment	ID. No.	Location	Range	Least Count	Frequency of Calibration	In house calibration Done On	In house calibration Due On	Remarks	Sign

2.11 Equipment Breakdown Maintenance report (Template)

Date:		Period of Report:					
S. No.	Name/Code No. of the Machine/ Equipment	Location	Nature of Breakdown	Details of repairs carried out	Breakdown Period	Work Done by	Remarks

2.12 Preventive Maintenance Schedule (Template)

LIST OF MACHINERY AND EQUIPMENT FOR MAINTENANCE										
S. No.	Name of Machine/ Equipment	Code/ Identification No.	Specification /Supplier	Location of place of the Machine/ Equipment	Frequency of check					Remarks
					Daily	Weekly	Monthly	Half Yearly	Yearly	

2.13 Pest Management Plan (Template)

Type of Pest	Mode of Control	Station (locations) monitored	Number designated	Frequency of Monitoring	Remarks

2.14 Pest Monitoring record (Template)

Date	Type of Pest	Mode of Control	Station (locations) monitored	Number designated	Frequency of Monitoring	Clean (ok/Not ok)	Remarks	Sign

2.15 Waste Disposal Record (Template)

S. No.	Amount of waste						Daily disposal (Yes/No)
	Chemical/Hazardous waste	Food material waste	Package material waste	Other waste (Dry)	Other waste (Wet)	%of total waste	

2.16 Pre-employment medical record (Template)

Name of Candidate: Father's name: Address: Date of Birth: Designation applied For: Age: Name of hospital/laboratory tested:	
Medical Examination	
Heart : Chest : Abdomen: Blood Pressure: Eye Sight : C.N.S. :	Blood Group : Blood Sugar : Haemoglobin : T.L.C. : D.L.C.: P L M E
X.Ray Chest: E.C.G.:	Urine Examination: Stool:
Final Medical Report: Signature of Candidate	
Signature of Medical Examiner: Reg. No .of the Medical Examiner:	

2.17 Regular Medical Checkup record (Template)

Name of employee:	
Date of medical test conducted:	
Next Medical test due on:	
Name of hospital/laboratory tested:	
Tests done for:	
Status of acceptance (Yes/No):	

2.18 Monitoring of Personnel Hygiene (Template)

Date:															
S. No.	Employee Code	Employee name	Area of work	Hand wash, sanitize (and Gloves where necessary)	Clean & trimmed Nails	No open Wounds	No Jewellery	Covered Hair	Clean outer garments / protective clothing	Clean Shoes/ shoe covers	Infectious Disease /Skin infection / Allergy, if any	No Tobacco/ Smoking / Chewing	Overall Hygiene Status upon examination(Yes/No)	Action needed on non-compliance	Re-examination status (Yes/No)
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															
14															
<i>Jewellery wristwatches, cufflinks, earrings, glass bangles, stickbindis</i>															

2.19 Visitor Record (Template)

Date of visit:	
Time of entry:	
Time of exit:	
Name of visitor:	
From(location):	
Whom to meet:	
Purpose of visit:	
Type of visitor:	<i>Please Tick: Type I(Critical areas: Internal processing areas) Type II(Outside processing areas) Type III(Office areas)</i>
Any Allergy/Infectious disease declaration:	
Belongings description:	
Signature of visitor:	
Signature of Security in-charge:	
Signature of person visited:	

NB: Pls adhere to all the food safety and quality; and company policies and rules during your visit

2.20 Product Information (Template)

S. No.	Description	Specifications
1	Product Category/Name	
2	Composition (Raw materials, Ingredients, etc.)	
3	General & Specific product specification	
4	Legislative requirements, Customer requirements	
5	Storage	
6	Labeling	
7	Transportation	
8	Product Shelf-life	
9	Packaging material	
10	Hazardous for any group of customers	
11	Food Category	
12	INTENDEDUSE	

2.21 Customer/Consumer Complaint Log (Template)

Complaint Number: _____

Date: _____ Time recorded: _____ am pm
 Quality related: Food safety related:

Customer Details
 Customer Name: _____
 Phone: _____ City: _____ Zip code: _____
 Address: _____
 State/Province: _____
 Email: _____

Product Consumed
 Product name: _____
 Batch Code/Lot no.: _____
 Package size: _____
 Location of purchased: _____ Date consumed: _____
 Date of purchase: _____
 How was the product stored? _____

Nature of Complaint
 Foreign object Off/Unsatisfactory Flavor Allergic
 Packaging Illness Others

How many people consumed? _____ Ages? _____
 Symptoms/Additional Problem Information: _____

Has the Customer
 Seen a Doctor? _____ Gone to Hospital? _____
 Spoken to a public health? _____ Contacted Regulatory Agency? _____

Comments & follow up action

Feedback from client- Status or date finalized

2.22 Determination of Customer Satisfaction (Template)

We would like to know how well we are succeeding in meeting your needs. Following is the questionnaire about what you wanted from us. Answers will be treated with complete confidentiality. Please answer the questions using the scale (Please TICK that you choose).

('1' being the worst score;'5' being the best score)

S.No.	QUESTIONS	SCORE				
1	How well do we communicate with you?	1	2	3	4	5
2	Do we give you the information you need?	1	2	3	4	5
3	Do we answer your queries promptly?	1	2	3	4	5
4	Do we respond positively to your problems & suggestions?	1	2	3	4	5
5	Do you feel we have a concern for quality & food safety?	1	2	3	4	5
6	Do we deliver quality & safe products consistently and on time?	1	2	3	4	5
7	Do we anticipate your needs?	1	2	3	4	5
8	Have we increased your understanding of quality & food safety?	1	2	3	4	5
9	Do we work with you as a team?	1	2	3	4	5

Any other comments?

Name and Address

2.23 Training Need Identification (Template)

Name of employee:		Date of Joining:
Qualification:		
Designation:		Department:
Key Responsibilities:		
Training(s) Required		
1	Managerial	
2	Technical	
3	On the Job	
4	General/Others	
Suggested Training institutions(applicable for external trainings):		
Any other suggestions:		
Signature of Dept. Head:		

Below topics of training to be determined, but not limited to:

- 1 Food safety policy*
- 2 Food safety objective and targets*
- 3 Actual or potential significant environmental impacts and unacceptable risks of the work activities*
- 4 Food Safety and hygiene related issues*
- 5 Compliance to legal requirements*
- 6 Roles and responsibilities of employees to ensure effective implementation of food safety*
- 7 Operational Control procedures*
- 8 Emergency Preparedness and response requirements*
- 9 Potential effects of deviation from documented procedures*

2.24 Training Record (Template)

Date of Training: Conducted By: Subject of Training: Brief summary of the subject: Duration of Training:				
S.No.	Name of person trained	Functional area	Remarks	Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

2.25 Training Effectiveness record (Template)

Date of Training: Subject of Training: Brief summary of the subject:							
S. No.	Name of person trained	Functional area	Pre-evaluation result	Post-evaluation result	Effectiveness status (Yes/No)	Comment on effectiveness	Signature of trainee
1							
2							
3							
4							
5							
6							
Effectiveness can be based on: Improvement in quality of work , Improvement in work output ,Behavioural change, Overall usefulness of training, etc.							

2.26 Training Calendar (Template)

S.No.	Topic of training	Month/Year: _____											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													

2.27 Internal Audit Schedule (Template)

Date of Audit:					
Standard of Audit:					
S. No.	Process Area	Auditee(s)& Functional Department	Auditor(s)& Functional Department	Date	Time
1	Store areas-Raw material, ingredients, chemicals, finished product				
2	Production/Manufacturing Area				
3	Housekeeping, Cleaning& Personal Hygiene				
4	Preventive Maintenance				
5	Internal Laboratory				
6	Management functions				
7	Packaging & Dispatch area				
8	Documentation				
9	Human Resource& Training				
10	Others				

2.28 Internal Audit Observation & Non- conformance report (Template)

Name of Manufacturing plant: Date of Internal Audit: Process Area Audited: Auditor(s): Auditee(s): Areas Covered:								
S.No.	Observation area	Compliance checkpoint	Status (Yes/No)	Non-Compliance details (if any in this area)	Corrective action planned	Responsibility	Target date of completion	Actual completed on

2.29 Internal Audit Plan (Template)

S. No	Process Area	Month/Year: _____													
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec		
1	Store areas-Raw material, ingredients, chemicals, finished product														
2	Process Area														
3	Housekeeping, Cleaning & Personal Hygiene														
4	Preventive Maintenance														
5	Internal Laboratory														
6	Management functions														
7	Packaging & Dispatch area														
8	Documentation														
9	Human Resource & Training														
10	Others														

Annexure 2: Inspection Checklist

Date		FBO Name	
Food Safety Officer		FBO's representative	
FBO License No.		Address	

Indicate the following—Compliance(C), Non-Compliance (NC), Partial Compliance (PC) or Not Applicable (NA)

Sl. No.	Audit Questions	Scoring	
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2	
	Design & facilities		
2	The design of food premises provides adequate working space; Permit maintenance & cleaning to prevent the entry of dirt, dust & pests.	2	
3	The internal structure & fittings are made of non-toxic and Impermeable material.	2	
4	Walls, ceilings & doors are free from flaking paint or plaster, condensation & shedding particles.	2	
5	Floors are non-slippery & sloped appropriately.	2	
6	Windows are kept closed & fitted with insect proof screen when opening to an external environment.	2	
7	Doors are close fitted to avoid entry of pests.	2	
8	Equipment and containers are made of non-toxic, impervious, non-corrosive material which is easy to clean & disinfect.	2	
9	Premise has sufficient lighting.	2	
10	Adequate ventilation is provided within the premises.	2	
11	Adequate storage facility for food, packaging materials, chemicals, personnel items etc available.	2	
12	Personnel hygiene facilities are available. (Adequate number of hand washing facilities, toilets, change rooms, rest & refreshment room etc).	2	
13*	Potable water (meeting standards of IS:10500) is used as a product Ingredient or in contact with food or food contact surface & tested for quality semi-annually. Check for records.	4	
14	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2	
II	Control of operation		
15	Incoming material procured as per internally laid down specification & from an approved vendor. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2	
16	Raw materials are inspected at the time of receiving for food safety hazards.	2	

17	Incoming material, semi or final products are stored according to their temperature and humidity requirement, in a hygienic environment. FIFO & FEFO is practiced.	2	
18*	Requisite time and temperature is being achieved, maintained, Monitored & recorded while manufacturing/processing. Check for records.	4	
19	Food manufactured/processed is packed in a hygienic manner.	2	
20	Packaging materials is food grade & in sound condition.	2	
21	Cleaning chemicals & other hazardous substance are clearly Identified & stored separately from food.	2	
22	Transporting vehicle for food use are kept clean and maintained in Good repair.	2	
23	Transporting vehicle are capable of meeting requisite temperature (where applicable).	2	
24	Recalled products are held under supervision & destroyed or Reprocessed / reworked in a manner to ensure their safety. Check for records.	2	
III	Maintenance & sanitation		
25	Cleaning of equipment, food premises is done as per cleaning Schedule & cleaning programme.	2	
26	Preventive maintenance of equipment and machinery are carried out Regularly as per the instructions of the manufacturer.	2	
27	Measuring & monitoring devices are calibrated periodically.	2	
28*	Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.	4	
29	No signs/evidence of pest activity or infestation in premises (eggs, larvae,	2	
30	Drains are designed to meet expected flow loads and equipped with traps to capture contaminants.	2	
31	Food waste and other refuse are removed periodically from food handling area as to avoid accumulation.	2	
32	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	2	
IV	Personal Hygiene		
33	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the Vaccine is done. Check for records.	2	
34	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2	
35*	Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage etc) and personal behavior (hand washing, no loose jewellery, no smoking, no spitting etc).	4	
36	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover, wear caps/masks/gloves during food handling	2	

V	Training & Complaint Handling		
37	Internal /External audit of the system is done periodically. Check for records.	2	
38	Food business has an effective consumer complaints redressal mechanism.	2	
39	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2	
40*	Appropriate documentation & records are available and retained for a period of one year or the shelf-life of the product, whichever is more.	4	

Total points...../90

Asterisk mark (*) questions significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark (*) questions, will lead to Non-compliance

Grading –

- A + 80-90 Compliance –Exemplar
- A 72-79 Compliance/Satisfactory
- B 45- 71 Needs Improvement
- No grade <45 Non-Compliance

D. REFERENCES & SUGGESTED READINGS

E. REFERENCES & SUGGESTED READINGS

References

1. General requirements on hygiene and sanitation; Schedule 4; Part II; Food Safety and Standards (Licensing and Registration of Food Business), Regulations 2011
2. Codex code of hygienic practice for spices and dried aromatic plants (CAC/RCP 42-1995)
3. <https://www.astaspice.org/>

Suggested Readings

1. Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 & amendment there under (if any);
2. Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011 & amendment there under (if any);
3. Food Safety and Standards (Packaging and Labelling) Regulation, 2011 & amendment there under (if any);
4. Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011 & amendment there under (if any);
5. Food Safety and Standards (Food Recall Procedure) Regulation, 2017 & amendment there under (if any);