

# GUIDANCE DOCUMENT

## Food Safety Management System (FSMS)

Food Industry Guide to Implement GMP/GHP  
Requirements



Food Industry Guide to implement GMP/GHP requirements

# Flour Milling Industries

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

First Edition November 2017

Online available at [www.fssai.gov.in](http://www.fssai.gov.in)

## 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 II 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



The continuing integration and consolidation of agriculture, food industries and the globalization of food trade are changing the patterns of food production, distribution, consumption as well as supply and demand. Trends in domestic as well as global food chain present new challenges to food safety.

Food safety needs to be given higher priority by Governments, industry and consumers themselves. It is essential to acquire the know-how and skills necessary to understand and manage food safety hazards. Food Safety and Standards Authority of India in association with experts from the technical panel of FSSAI developed this document.

This Guidance Document on Food Safety Management System (FSMS) for Cereals and cereal products till milling stage is prepared with the intent to provide implementation guidance to food businesses (especially the small and medium businesses) involved in manufacturing, packing, storage and transportation of Cereals and cereal products including grains flours, to ensure that critical food safety related aspects are addressed throughout the supply chain.

This document contains practical approaches which a business should adopt to ensure food safety; however, manufacturers may adopt higher or stringent levels, depending on the needs & complexity of operation. The use of this guidance is voluntary and food business operators may comply with the requirement of the regulation according to other established best practices.

It is important that food handlers involved in the supply chain are trained appropriately to implement the good manufacturing practices and good hygiene practices to ensure food safety. Any successful food safety programme will always need a shared responsibility among producers, industry, trade, government and the consumer. The FBO's should utilize this book to gain guidance about the Food Safety plan and its implementation strategies. We acknowledge the contribution of the experts from the technical panel of FSSAI for developing this document.

**Pawan Agarwal – CEO, FSSAI**

# SCOPE & USE

This document is applicable for food businesses involved in flour milling industries of the cereal and cereal products supply chain. The major activities in the milling industry comprise of the following:

- a) Procurement of grains from Mandi
- b) Transportation of the grains
- c) Grain Storage and Handling
- d) Blending/Quality Verification
- e) Processing
- f) Packaging and Labelling
- g) Storage/Handling of finished product

All the above activities may or may not be carried by the same facility. For example, requirements for the manufacturing of food grains will be different from manufacturing of flour. Accordingly, the process for these businesses would be different. Hence, based on their position in the segment, industry could use the guidance document accordingly as per the operations applicable to them.

The document is divided into five main sections. The first section gives an overview of the flour milling industry in India along with the rising need for food safety in the sector. 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 document has specified requirements where compliance is essential and obligatory for food businesses and in such cases the word “shall” is used. In addition certain good practices are also strongly advised for food safety operation & in such case “should” is used.

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. Tables of sample HACCP Plans have been taken from some established practising flour milling industries. 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.

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## **A. OVERVIEW OF FLOUR MILLING INDUSTRY IN INDIA**

## A. OVERVIEW OF MILLING INDUSTRY IN INDIA

India produces more than 200 million tonnes of different food grains every year. The huge demand for cereals in the global market is creating an excellent environment for the export of Indian cereal products. India's export of cereals stood at Rs. 40,624.46 crore / 6,074.16 USD Millions during the year 2016-17. The important cereals are - wheat, paddy, sorghum, millet (Bajra), barley and maize etc. About 15 per cent of the annual production of wheat is converted into wheat products. India is one of the leading exporters of the processed food products. It has a competitive edge over other countries due to the wide variety of crops cultivated as a result of geographical and climatic diversity

Flour milling facilities have been the cornerstone of agricultural processing for centuries like most agri-industrial production facilities. Global wheat consumption in the current 2016/17 season is forecast to reach a record-high 736m tonnes, showing a growth of 25% in the last 15 years. India, with its strongly growing flour demand, also has a very fragmented milling industry and almost two third of the flour is produced in small stone mills or chakki. The roughly 700 organised larger stone mills produce another 10 to 15 percent of the flour. The number of roller flour mills with a capacity of at least 100 tonnes per day has grown and is estimated at about 1100, producing about one fourth of the Indian flour.

The Indian packaged wheat flour market comprises few national players and large number of regional and private label brands operating at pan India or restricted geographic market based on their size and capacity. Easy availability of raw materials, changing lifestyles and favourable fiscal policies has given a considerable push to the industry's growth.

It is estimated that the industry loses more than 25 percent of its produce due to poor post-harvesting equipment, inadequate food processing technology and storage facilities. The major food safety challenges prevailing in this sector is improper post harvest management and contamination that occurs from farm and all along the food chain. Lack of proper hygiene at production, market, processing, packaging, distribution leads to food safety issues and awareness among the traders in the mandi, transporters etc. The common challenges faced by small and medium sized enterprises of India have difficulty in indentifying appropriate technology and assistance and lack of basic infrastructure facilities

Producing flour and flour products in accordance with food safety begins with obtaining safe wheat. In order to achieve flour safety from field to the table; wheat should be grown by good agricultural practices (GAP) and milled by good manufacturing practices (GMP) and good hygiene practices (GHP). Thus, the flour industrialist has the main responsibility for providing flour safety; and traders should also apply hygiene and sanitation rules in their operations.

## **B. IMPLEMENTATION GUIDELINES**

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## I. ESTABLISHMENT – DESIGN AND FACILITIES

In order to get safe flour from a flour mill; the inputs like wheat, processes like cleaning, storing and milling and final products like flour should be defined by evaluating in terms of food safety. The condition of raw material and process and then the risks during the processing stages should be determined.

### 1. Location and surroundings

The flour mill shall be located away from environmental pollution and industrial activities that produce disagreeable or obnoxious odour, fumes, excessive soot, dust, smoke, gaseous emissions and pollutants sanitary landfills, incinerators, junk yards and service depots and which pose a threat of contaminating food or areas that are prone to pest infestations or from where solid or liquid wastes cannot be effectively removed.

The surrounding area shall be maintained by taking appropriate measures to protect the food manufacturing area from any potential contamination if any polluting industry is located nearby and also taking following actions on regular basis:

- land, roads, yards, parking lots outside the factory building shall be free of debris and refuse and from any source of pollution and that areas should not constitute a source of contamination due to dust or any stagnation of water.
- removal of litter, waste, weeds and grass within the immediate vicinity of buildings or structures, as such growth accumulation may constitute an attractant, breeding place, or harbourage for pests.
- Cleaning of dust debris, sweeping shall ensure that fine dust and contaminants are not contaminating the raw grains or processed products in any ways
- drainages are devoid of any stagnation of water to prevent contamination. Drains should have grated covers
- Precautions shall be taken to prevent contamination from trucks, vehicles, forklifts or by foot

The site boundaries shall be clearly identified with appropriate access control to prevent any chances of theft and sabotage. Dogs, cats or other pet animals shall not be allowed to enter the premises. High walls of at least a 3 meter should be built to prevent rodents from entering mill from this area

Vegetation, especially tree branches should be trimmed to prevent the entry of rodents and birds. Shrubs should not be too close to building. It is preferred to have an 18 ft vegetation-free barrier zone. Precautions should be taken to preclude, as far as possible, birds from nesting or perching on the grounds of the plant.

Hard paving of at least 45cm in width should surround the exterior of all the production and storage buildings. Parking, walkway and traffic areas should be paved to avoid excessive dust. Areas that serve the establishment shall have hard, paved surfaces which should be suitable for wheeled traffic. Protection from the weather for the receiving and dispatch areas as well as for all materials or products in transit, should be provided

The manufacturing premises shall be located away from flood prone area. Where the premises are located in areas prone to flooding, it is recommended that height of the manufacturing area should be suitably elevated to prevent the risks due to flooding.

If the building is used for residential purpose, then there should not be any direct access to the food premises. The activities should be compartmentalized if feasible to prevent cross contamination.

Locations close to applicable transportation and infrastructure are essential for facility operation.

## **2. Premises and rooms**

### **2.1 Layout**

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, pre-processing (viz. packaging, etc). The storage and processing areas should be enclosed to avoid direct exposure to external environment and to facilitate access control

The building shall provide adequate space with a logical flow of materials, products, personnel and physical separation of raw from processed areas.

The plant layout should have a proper space for inward and outward vehicle movement. Conveyors and openings intending for transfer of materials shall be designed to minimize any cross contamination from foreign matter, pests, etc. All the loading and unloading points should have shades to prevent grains from rain water contamination.

Openings for piping, conduits, conveyors, vents etc. should be well grouted and the edges should be smooth. It is advised that openings at or near to ground level should be covered with screen. Electrical cables and wires should where possible be enclosed in conduit or orderly arranged on screens. Electrical trunking and cable trays should be kept free from dust, cobwebs etc.

The construction style, choice of the machines and food safety conditions in the establishment should be taken into consideration. The business and the storages should be constructed as to be convenient for filling, evacuation, internal transport and cleaning and not to include dead points

### **2.2 Internal structures**

#### **a) Floors**

Floors shall be maintained in a sound condition to minimize the accumulation of dirt, condensation and growth of undesirable moulds. They should be made of impervious material and should be smooth and easy to clean with no flaking paint or plaster.

It is recommended that the wall-floor junction is rounded. Examples are- Kota stone flooring, Flooring should be continuous with Epoxy resin with Ironite (to withstand heavy duty trolley movement) Floors should be constructed of concrete or an approved synthetic material, where floor tiles are used only industrial type tiles that are properly sealed should be used.

Floors should be resistant to product spillage, cleaning agents and cleaning solutions. It should also be maintained in good condition at all times e.g. free from cracks, holes and corrosion. Floors shall be sloped appropriately to facilitate drainage.

Floors should be kept free from litter, oil, accumulated water etc. Floor coatings should be slip resistant cleanable and abrasion resistant. Epoxy or urethane finishes work well as floor coverings. Disinfectant should be used to clean the floors of sensitive production areas.

Damaged flooring should be repaired as soon as possible. A wood policy should be in place that allows proper cleaning and fumigation of wooden floors where present, to avoid the infestation of pests such as weevils.

Metal stairways should be constructed from non-corrosive material. Stairways in production areas especially over production or packing lines should be completely sealed. Stairs and elevators should be designed constructed and maintained in a hygienic condition in order to prevent contamination of the product. The maximum allowable load for an elevator should be clearly posted inside the elevator.

## **b) Drainage**

Drains shall flow in a direction opposite to the direction of food preparation / manufacturing process flow. Adequate control measures shall be in place to prevent insects and rodents from entering the processing area from drains. Example: Covering the openings of the drain with wire mesh in a manner to prevent insects and rodents from entering the processing area. Drainage entry and exit points into the building should be pest proofed.

Roofs, valleys and gutters shall be maintained and kept clear of debris to prevent the contamination of food or materials, by rain water or other impurities. Gutters, open drains, potholes and pools shall be monitored carefully and on a regular basis to prevent water from becoming stagnant. The capacity of the drainage system must be sufficient to cope with the maximum process requirements placed on it. All drains should be fitted with debris traps to ensure the retention of heavy debris. Any manhole covers should be properly greased and sealed.

Inadequate drainage and incorrectly sloped surfaces cause water to become stagnant and stagnant water should be eliminated. To prevent blockages and accumulation of debris, damaged drains should be replaced as soon as possible. Records of the maintenance of drains should be kept.

## **c) Doors**

Doors shall be made of smooth and non-absorbent surfaces so that they are easy to clean and wherever necessary, disinfect. The entrance doors to the production area should have openings less than 1 cm between the walls, floor and appropriate barriers to prevent insect ingress.

The doors should be able to be fully closed and do not allow dust and pests. Gaps if any between the door and the floor should be closed with suitable material like rubber strips, polyurethane etc. to avoid pest entry. Entry/exit points should be suitably protected with

such as strip PVC/air curtains/ wire mesh doors/ doors with self-closing devices etc. to ensure dust, insects, birds and animals are kept out

Doors, windows and window frames should be tight fitting at all times. Doors leading into the production areas other than the emergency exits shall be fitted with self-closing devices, air curtains or plastic strips. External doors should be kept closed and constructed in a manner as to prevent the entry of rain water and pests into the facility.

#### **d) Walls**

Walls and partitions shall have a smooth surface, impervious, made up of durable materials with no toxic effect in the intended use and preferably plastered. Walls and partitions shall be easily cleanable and there shouldn't be any flaking, swelling, exfoliation, recesses, projections and pits and maintained to prevent the accumulation of dust, minimise condensation, and shedding of particles. They shall be sealed to prevent the entry of dirt, dust and pests.

Wall floor joints should be covered in processing and packaging areas to facilitate cleaning. Junctions between walls and walls as well as between floors and ceilings should be closed and ideally covered. Joints on panelled walls should be sealed.

Wall coatings should be food safe and able to resist the multiple cleanings with chemicals. Acrylic or epoxy-based paint should be preferably used for the finish of walls. Epoxy paints on masonry, concrete and steel members are preferred. Sealers are preferred on exposed concrete. Where tiles are used, only the industrial type should be allowed and the joints between the tiles should be sealed with a non-absorbent material. The edges should be sloped to minimize dust accumulation. Food grade caulking should be used to seal all joints, connections, etc. where infestation can occur or water can penetrate

Proper maintenance of walls including the replacement of damaged tiles, sealing of cracks and joints on wall surfaces as well as getting rid of flaking paint should be done regularly

Walls such as those in the packing area should be protected from damage by moving equipment. Galvanized guard rails could be used for this purpose. Avoid placing fixtures, signs, switch boxes etc. on internal wall surfaces but where they are present; they should be properly sealed to avoid the accumulation of soil. Attachments such as shelves shouldn't be allowed as far as possible to prevent any horizontal surface to act as a dust trap.

#### **e) Ceilings and overhead fixtures**

Ceilings should be smooth, impervious to water and dust and easily cleanable. They shall be sealed free from flaking paint or plaster, finished and maintained in such a manner so as to minimize any accumulation of dirt, condensation and growth of undesirable moulds and shedding of paint or plaster particles.

The overhead fixtures shall be suitably protected so that they do not act as contaminants in case of breakage. Openings in ceilings for conveyors, vents, piping etc. should be properly sealed and the edges should be smooth. No Asbestos Sheets shall be allowed in Ceilings.

The design should also be taken into consideration installation of access-platforms and cat walks to permit the overhead cleaning of pipe, conduit, ductwork and equipment. Access

doors should be provided in the pipe chases for inspection and cleaning. Overhead pipe work and structures should be minimized to facilitate cleaning and shall be fixed above ceilings, into walls or fixed at least 40 mm away from ceilings.

#### **f) Windows, roof vents, doors and all other openings**

Windows, doors & 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 doors be fitted with automatic closing springs.

The mesh or the screen should be of such type which can be easily removed for cleaning. They shall be constructed to minimize the accumulation of dirt. Windows, roof vents or exhaust fans that open to the external environment shall be fitted with removable and cleanable insect-proof screens. Where open windows would result in contamination, windows must remain closed and fixed during operations. The ends should be secured to prevent the entry of pests.

If window panes made of glass, it should be laminated. Glass windows in the production areas should be protected or constructed of alternative materials such as PVC to ensure that the product is not contaminated by breakages.

The doors and windows at the lower floors should be made of metal, tight windows and doors, barriers such as elevated docks, metal flashings, overhangs and rung steps discourage and prevent rodent access. The frames of exterior windows should fit properly and it should be completely sealed to prevent insect ingress. Cracks and crevices should be sealed. Doors, windows and window frames should be free from mould, flaking paint etc. and kept clean as well as in good condition. Cracked or broken windows should be replaced immediately

### **3. Equipment and containers**

Equipment should be properly designed, maintained, calibrated and should always be in proper working condition. It should not add any contaminants to the process.

It should be designed and constructed so that all parts are accessible for inspection and pest control. It should allow adequate space inside, around and under equipment for easier cleaning and maintenance. In general, a clear distance of 36 inches all around equipment is considered the bare minimum.

The material used for equipment should not transmit toxic substances, odour or taste or cause colour changes. For dry manufacturing process like flour milling, ideal construction materials for equipment support is mild steel painted with epoxy base paint, Stainless steel or inert materials should be used All food contact surfaces should be smooth, noncorrosive, non absorbent, non toxic, free from cracks and crevices and capable of withstanding repeated cleaning. Materials such as wood that cannot be properly cleaned and disinfected should be avoided. Different metals should not be used where electrolytic deterioration can take place.

Equipment with interior surfaces that are in direct contact with the product should be self-emptying or self- draining. The sieves, filters and gaskets should be checked and maintained on a regular basis. Equipment in the production area shall be cleaned after every

maintenance procedure. Agitator motors, their mounting frames and oil trays should be kept free from rust and flaking paint.

Storage and blending bins should be fitted with suitable, close-fitting covers. Food conveyors to and from filling and closing machines, carrying open containers should have suitable covers to protect the open food containers and product from overhead contamination

Mounting of equipment could take place directly on the floors or walls as long as they are adequately sealed to prevent the infestation of micro-organisms. Equipment mounted to the floor should be at least 60 cm from the adjacent walls and other equipment and at least 30 cm from the floor to give easy access to all parts for cleaning and should be elevated or properly sealed to prevent the harbourage of micro-organisms.

Equipment such as sieves, carter disks, treur cylinders, de stoners, separators, combiners, scourers, magnets and metal detectors should be used to control foreign body contamination by cleaning the incoming wheat as well as to protect the final product. Equipment such as sifters, purifiers, roller stands etc. should be designed in such a manner as to allow both inspection and cleaning simultaneously. Equipment such as a flashlight, equipment opening tools, spatula, sample containers, sieves, pans etc. should be available for inspection.

It is important that the wheat debranning system is cleaned and maintained on schedule. Where these systems are in use, it is important for management of that specified mill to lay down minimum and maximum requirements for the offal screenings

Adequate, designated storage space should be provided to allow for the complete segregation of clean, dry utensils. Cleaned utensils should be stored in a clean, well maintained storage area and the utensils stacked in a manner to prevent recontamination. To prevent mould growth, good draining and drying of equipment and utensils should be present and where necessary adequate ventilation should be provided.

Canopies that cover equipment, air vents and air vent covers and screens should be kept clean and dust free.

Utensils used in production areas such as brooms, brushes, dust mops and vacuum cleaning systems should be made of materials such as metal and plastic and should be colour coded to prevent contamination.

## Chemicals

Chemical substances used in cleaning and maintenance and other dangerous substances shall be identified and stored separately to prevent malicious or accidental contamination of food. Such chemicals shall be stored under controlled access and shall not be issued without authorization of competent personnel in the organization

All non-food chemicals received should be inspected and the procedure documented to ensure that damaged goods that could cause spillage are not brought into the mill without appropriate measures being taken to avoid contamination.

Pesticide (insect and rodent pesticides) should be kept locked in a special storage by being grouped in terms of their species and features. A pesticide storage area ( large enough for

proper and efficient storage of pesticides )should be separated from the production area or a separate building on the premises secured by lock and key.

All application equipment should be identified and a procedure for the disposal of empty pesticide containers shall exist. This area should also be equipped with safety and first aid equipment. Emergency procedures should be in place in the case of an accident or spillage

All openings such as manholes, inlets, outlets, draining out of points, etc. should be made such that they can be locked and/or effectively sealed.

## **4. Facilities/ Utilities**

### **a) Water supply:**

Potable water meeting the requirements of BIS standard on drinking water i.e. IS 10500 as an ingredients shall be used for operational and cleaning needs. Water shall be tested for compliance at least once a year. Water used for food handling, washing, should be of such quality that it does not introduce any hazard or contamination to render the finished food article unsafe.

Where it is necessary to store water, storage facilities including the storage tanks and water pipes shall be adequately designed, made of material that is non-toxic, corrosion resistant material and periodically cleaned (at least once in a year /six months) and maintained to prevent contamination and records of the same should be maintained. The tanks shall be covered to prevent access by animals, birds, pests and other extraneous matter. The manholes to the tanks shall be locked and access shall be granted to authorised personnel.

Non potable water pipes shall be clearly distinguished from those in use for potable water. Non potable water can be used only for non-food purposes or non-food contact uses, such as cleaning of equipment not coming in contact with food, fire fighting, refrigeration equipment etc.

### **b) Cleaning of Utensils / Equipments**

Adequate facilities for cleaning, disinfecting of utensils and equipments shall be provided. The facilities must have an adequate supply of hot and cold water if required. Such facilities shall be away from processing areas

Installing Clean-in-place (CIP) systems and Clean-out of place (COP) can help cleaning in much less time, reduce cost and improve cleaning quality, eliminating conditions leading to pest breeding. A good CIP system include wet central cleaning system which pipe a supply of hot water and in some cases cleaning chemicals, throughout the entire facility. The volume and pressure of the water are provided to accommodate the cleaning need. It also includes a central vacuum system for both wet and dry pickup and specially designated areas for cleaning of mobile or portable equipment

Clear segregation shall be provided for separating cleaned utensils and equipments to avoid cross contamination. Adequate racking, self-draining (if wet cleaning is practised) stations shall be provided to hold cleaned utensils until transfer to point of use.

Cleaning section shall be thoroughly cleaned and sanitized periodically to prevent off odors, microbiological contamination. It is advised that a separate facility should be provided for the cleaning and sanitizing of equipment used for inedible materials e.g. the cleaning of brushes

etc. Separate and adequate facility shall be provided to store cleaning tools used for utensil cleaning.

#### **d) 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 equipment, buildings, and roadways on the premises as well as the environment in general is avoided. Waste disposal bins with a proper cover (preferably not hand operated), should be available in the premises for collection of waste material.

The plant layout should also include provisions for handling solid wastes such as product offal, plant refuse and other debris, in addition to liquid wastes. These facilities should be located at the back of the plant and be completely isolated from the milling process. Periodic disposal of the refuse / waste shall be made compulsory. Food waste should be emptied on a daily basis whereas non-food waste could be emptied once weekly to minimize pest infestation. Waste disposal should be monitored and records kept

Product and non-product debris should be handled separately in easily identifiable enclosed containers. Waste should be removed and facilities and containers cleaned and sanitized frequently to minimize contamination. Regular cleaning and disinfecting of the area and receptacles is essential.

Waste storage facilities shall be designed to eliminate the entry and harbourage of pests and to avoid the contamination of the product. There should be no cross-connection between the sewage system and any other waste effluent system in the mill, nor should it pass directly over or through production areas unless it is properly controlled to prevent contamination. The system should be appropriately equipped with traps and vents

Only bona fide waste containers shall be used for waste disposal and these containers shall be of such that they cannot be mistaken for food containers. Flour mills should also have a good dust collecting and discharge system

#### **e) Personal hygiene facilities and Employee facilities**

Personnel hygiene facilities shall be provided to ensure the maintenance of an appropriate degree of personal hygiene in order to avoid any cross contamination. Adequate clothing and safety footwear shall be provided to employees working in processing areas. Appropriate facility for hand washing and drying of hands and sanitizing before touching food materials including wash basins and a supply of hot and /or cold water as appropriate shall be available at the entrance of production and packaging area.

Adequate number of toilets facility shall be provided depending on the number of employees (male /female) in the establishment and they should be made aware of the cleanliness requirement while handling food.

Separate toilets for males and females should be constructed in the establishment. Appropriate Rest & refreshment room facility should be provided for employees. It should not directly open to manufacturing/processing/packaging areas. Adequate changing facilities for personnel should be suitably located, not to open directly into food processing, handling or 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. Special signs should be present in the plant to inform and remind the personnel about the smoking policy. No eating and drinking signs should also be posted in areas where such activities are prohibited. Signs to guide personnel to fire exits, stairs, elevators etc. during emergencies should also be present. Adequate health check up shall be conducted for all food handlers as per local regulation

Hand wash sinks and drying facilities should not be used for utensil or general purposes. A medical room with adequate equipment for the first aid treatment of illness or injury is essential. First aid equipment should be kept secure in a locked cupboard and should only be issued by trained staff. All treatments should be fully recorded in a medical record book together with the patient's name, date, disease and the medical supplies issued.

#### **f) Air quality & ventilation**

Ventilation systems 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. Proper ventilation (naturally and mechanically) that provides sufficient air exchange to prevent unacceptable accumulation of dust as well as to remove contaminated air, is of utmost importance in the milling environment.

Ventilation systems should be kept clean and maintained in good condition. The design of all ventilation and extraction systems should be of the sort that allows proper cleaning. Air-intake points shall be fitted with fly screens which should be fitted with dust filters. These air-intake points shall be located so as to avoid the intake of air contaminated by micro-organisms, dust aerosols, chemicals and smoke. The air- intake levels should be at least 1 m above the internal floor levels and outside surfaces.

Within a dusty environment such as a mill, it is advised that dust extractors should be installed where necessary; the units should be inspected and maintained to ensure their functionality

#### **g) Lighting**

Adequate natural or artificial lighting shall be provided in the flour mill, to enable the employees/workers to operate in a hygienic manner.

Lighting fixtures should be appropriately protected to ensure that food is not contaminated by breakages of electrical fittings. Bulbs, tubes shall be enclosed in protective casings to ensure no spread of broken pieces in case of breakage. The artificial lighting should not alter colours and white light should be used where the colour of the food is a critical quality parameter and it has to be monitored.

Selection of lighting systems and mounting location is important consideration to prevent flying insects invading the structure. Selecting sodium vapour lighting systems, which are less attractive to insects and installing lights mounted on poles or ground at least 20ft away from building can greatly help in minimizing insect settling on building and gaining access inside. Insects are attracted to ultra-violet light emitted by mercury vapour lights and are also attracted to the warmth around light systems. Fluorescent strip lights should be protected by shatterproof diffusers or sleeve covers in production areas. White lights should

be away from buildings to prevent pest ingress. High pressure sodium lights can be provided near buildings & No lights should be there near doors and windows

## **h) Storage Facilities**

Storage of materials in bulk quantity shall be done off the floor on pallets/tarpaulins and the walls to ensure easy and adequate cleaning and prevent harbouring of any insects, pests or rodents. Stack numbering scheme (layout) should be displayed in each warehouse/godown clearly labelling the location and number of each stack. Each material/lot should be stacked separately, ensuring no mix-ups. Follow FEFO / FIFO system while releasing the material from the store.

Storage may be of either concrete or steel construction. Corrugated steel bins can also be used as whole grain storage. Improve pallet spacing for good inspection 30-60 cm between pallets and 12 inches of space between the wall and pallets, 6 inches off the floor. Some of the major considerations in building a storage structure to minimise losses are:

- the structure should be elevated and away from moist places;
- as far as possible, the structure should be airtight, even at loading and unloading ports;
- rodent-proof materials should be used for construction of storages;
- the area surrounding the structure should be clean to minimise insect breeding; and the structure should be plastered with an impervious material to avoid termite attack, or attack by other insects.

## **II. ESTABLISHMENT – CONTROL OF OPERATIONS**

Control of operation is necessary to produce safe food which is fit for human consumption and is free from contamination and/or cross contamination by:

- (a) Developed and validated methods of manufacturing and handling of food items throughout procurement, storage, processing, packaging, warehousing, and
- (b) Designing, implementing, monitoring and reviewing effective control systems.

### **1. Food receipt**

Raw materials should be purchased from approved suppliers. A system should be in place to evaluate the delivered ingredients such as the raw materials and packaging materials. No raw material or ingredient should be accepted if it is known to contain insects, micro-organisms pesticides, veterinary drugs or other toxic substances that would not be reduced to an acceptable level by further processing downstream.

A suitable, qualified person should be available to identify, list and establish the appropriate chemical, functional and organoleptic specifications for all raw materials and in-process materials.

Wheat is usually received at the mill by truck or rail. The sample should be inspected and tested for impurities, moisture content, insect infestation and sprout damage. If it is found

that the quality is acceptable as is stated on the grading certificate received, the wheat can be unloaded.

Certificates of acceptability for raw materials and a certificate of analysis (COA) for ingredients, raw materials and packaging materials should be received with each deliver and maintained. Written specifications for all materials purchased as well as for the finished product should be established by the manufacturer to ensure that the food source is free from foreign bodies. All raw materials as well as the packaging materials should have a batch code and accompanying documentation to identify them in storage and processing. Raw material reception areas and distribution areas should be isolated from the other process steps.

## 1. 1 Transportation

The list of factors such as temperature, humidity, moisture, ventilation, biotic activity, gases, odour, contamination, self-heating, mechanical influences, shrinkage, shortage, and insect infestation/disease, play a role **in transportation**. For example, wheat requires specific temperature, humidity, moisture and ventilation conditions to be transported safely

Each vehicle must be inspected before loading for infestation, spills, rodents, insects/pests as well as any vehicle damages or spillages and residual grains which may be allergenic in nature coming from transport of such grains by the vehicle. It should also be checked to ensure, that they are weatherproof and to certify the absence of humidity, material incompatible with a food product

Ensure that transportation vehicles are dedicated for food products and there is no cross-contamination from other non-food commodities. The bottom of the delivery vehicle should be covered with hygienic and infestation-free tarpaulin and after loading the grain, cover the surface as well with a clean tarpaulin.

The dead ends in bulk tankers where old product can accumulate should be cleaned on a regular basis. Conveyances, containers and bulk transport should be suitable for food use. The internal surfaces of the vehicle body should be impervious to water, easy to clean and the vehicle body should be sealed to avoid the entry of pests, exhaust fumes or other sources of contamination. The outside of an insulated container or vehicle body should be weatherproof, clean and in good condition

Doors and latches should be tight to prevent the entry of moisture and pests. Hatch covers must be in weather-tight condition.. Broken or contaminated pallets should not be used for transportation. Food carriers should be loaded, arranged or unloaded in a manner that prevents damage, contamination or deterioration of the food and packaging materials. The load should be equally distributed on the vehicle. Records should be kept of daily checks and maintenance.

Reception and unloading of foodstuffs must be performed by adequately trained personnel. The receiving company should establish proper receiving and unloading procedures to ensure that the product is not contaminated at the point of receipt. Damaged or infested goods shall not be accepted

## 1.2 Raw material receiving & Sampling

### 1.2.1 Truck inspection should be carried out to ensure:

- ✓ stock is fully covered with tarpaulin
- ✓ there is no physical damage to the stock
- ✓ Factories receiving Grain via rake
  - Sampling shall happen from different spots across the vehicle in composite form
  - Materials of different varieties/from different seller shall be sampled separately to adequately assess quality and maintain traceability
  - Unloading of Grain should be done in individual Stacks, with tarpaulin layer or on the floor directly, provided it is non-absorbent.
  - All parameters should be analysed as per specification
  - If any infestation is found, the corresponding stacks should be segregated for fumigation

### 1.2.2 Factories with storage facility and receiving raw material via trucks

- ✓ Sampling should be done for assessment of grain quality as per specification from externally visible bags in the truck
- ✓ If heavy infestations as well as larvae are not found, then material can be unloaded for in-house fumigation.
- ✓ Checks for infestation should be done in the evening time (between 16:30 hrs to 19:00 hrs) as the likelihood of finding infestation is high at this time.

### 1.2.3 Millers supplying milled product as raw material for further food processing should have controls to ensure infestation free product to the subsequent user in the Supply Chain.

1.2.4 Even if the stock is fumigated before despatch, there must be pre-despatch sieving as final check prior to despatch.

## 2 Storage and handling

Adequate storage facilities (silos) should be provided for the storage of incoming wheat. Separate storage areas should be provided for processed and unprocessed foods. Different grades of wheat shall be stored separately in different silos. The raw product storage area and packing area should also be separated physically.

Wheat storage silos should be rodent-, insect- and bird proof, should be kept in a hygienic condition and cleaned and fumigated regularly. Maintenance of silos should take place regularly. Silos should be constructed of suitable materials such as cement and fitted with suitable close-fitting covers kept in place at all times.

The interior of these grain storage bins should be smooth and free from cracks and crevices. In cases where these storage tanks are vented, the venting should be maintained and designed to not contaminate the contents. Inlet valves and pipe work should be kept in a hygienic condition and precautions taken to avoid access to the pipe work by rodents, birds and insects.

Incoming materials such as fortificants and packaging materials should be handled and stored in a manner as to prevent damage, deterioration and contamination. Where appropriate, rotation is also required.

## Stacking of Grains

Stack numbering scheme (layout) should be displayed in each warehouse/godown clearly labelling the location and number of each stack. Unloading of Grain should be done in individual Stacks, with at least One Meter gap with next immediate stack or the wall. This is for people movement, cleaning/house-keeping as well as for proper sealing of the stack for any future fumigation.

Stack the Grain with a tarpaulin sheet on the floor, with the sheet extending at least half-a-meter beyond the stack. Each material/lot should be stacked separately, ensuring no mix-ups. Size of each stack should be a maximum of 180MT (around 20 layers high), for easy and efficient fumigation. Stack register should be maintained which shows the entire history of each stack. Infestation check should be done on regular basis, preferably weekly in the evening time for all stacks and a report of this Commodity Health Register (CHR) should be maintained. The dose and duration of fumigation exposure should depend on the counts obtained in CHR.

All fumigated stocks should be always kept under covering to avoid cross-infestation. Alternately, un-fumigated stocks can be kept under covering to avoid chances of cross-infestation. Stack card for each stack should be displayed prominently and should be always accessible. The data should be updated immediately after completion of stacking or issuance or any treatment/disinfestations.

Unused gunny bags, any chemicals/pesticides or any other ancillary equipment should be always kept away from Grain stacks in covered condition. There should be a dedicated area for the sand bags, which should be under a covered roof – not left in the open area.

Infestation control including fumigation must be carried-out by a trained and experienced fumigator, holding a recognised, approved and current/valid certification. Fumigation activity must capture all details including, date, temperature, fumigation sheet sand bags, compound used, dosage, area and service person's initials

Stacks/bags under fumigation must be adequately covered and sealed to ensure no open ends or loose seals are present. Stocks under fumigation must be identified and labelled. Floor must be flat and free of stones and other sharp objects, drains, so that a gastight seal can be made between the sheets and the surface

If a concrete floor is cracked or has unsealed expansion joints, these gaps should be cleaned out and sealed with good-quality cement mortar, asphalt, or other sealant. It should be made sure the area around the stack is swept clean so that a good floor seal can be achieved, especially remove and clean any spillages beneath the tarpaulin sheet or under the stack.

## Handling the Damaged Goods

The damaged goods should be stored in a designated area in order to not expose other products within the storage facility to contamination or probable infestation. Returned,

damaged or goods segregated for reprocessing should be physically segregated from other finished product to avoid contamination. An entire different storage facility for recall work shall be preferred. Where damaged goods should be disposed, all labeling should be removed to prevent the products from re-entering the distribution chain.

### **3 Blending and quality verification**

Approved and rejected material must be clearly marked and segregated. Being an agricultural commodity, there is inherent variability in the grain quality. Therefore, blending becomes a critical aspect to ensure consistent product quality.

Prior to issuance of any grain consignment/stack for production, sampling must be done to ensure representative quality as per specification and absence of infestation is ascertained. All the records must be preserved till the shelf-life of the product or one year whichever is longer. All samples should be retained till the declared shelf-life of the product.

### **4 Food processing including pre-processing**

The accepted wheat is unloaded at the weigh bridge and on its way to the silos, undergoes the first cleaning phase where it passes through magnets to get rid of ferrous materials. Excess dust is also removed by aspiration. Before storage the wheat gets fumigated in order to get rid of all forms of live insects

Before cleaning can take place, a process called gristing takes place where different types of wheat is mixed in different proportions in order to produce the right quality flour. Now the wheat undergoes a cleaning process in order to get rid of foreign materials and impurities. These various steps in cleaning are referred to as the cleaning house and involve a number of cleaning machinery. Aspirators, de-stoners, combi-cleaners, seed removers, treur cylinders and carter disks are used at various places and in different combinations varying from mill to mill, to get rid of foreign materials.

The temperature in various sections of the mill should be controlled and well ventilated in order to protect the quality of the product. A formalized procedure for the issue of food ingredients such as fortificants from stores shall exist. The amount issued, batch code and date of issue should be documented. When these ingredients are moved it should be done in such a way that their identities are not lost.

Where an operator add an ingredient manually to a batch, the addition of each ingredient to the batch should be recorded at the time of manufacturing to ensure traceability of ingredients and to minimize the risk of accidental omission. Food processing operations flow diagram and standard operating procedures shall be documented, implemented for should be displayed at particular operations site. Intermediate in-process samples should be taken and tested for critical parameters and test results records should be maintained.

Manufacturing equipment must be kept clean and hygienic so as to ensure no accumulation of undesired residue.FBO must have a periodic cleaning & maintenance schedule for all manufacturing equipment and this schedule should outline specific details of each equipment cleaning & maintenance procedure.

Personnel entry must have provision for air curtain to ensure dust and other extraneous matter is not carried in to processing area. Alternately, provision for change rooms can be provided to changeover from street wear. Items such as jewellery, rings, watches, chains, bracelets etc. must be removed before entering production area.

Head-covers or caps, masks, gloves, shoe-covers (where product is directly touched) and such other hygiene measures must be in place as appropriate to ensure product contamination risk is avoided. Systems shall be in place to prevent contamination of foods by foreign bodies such as glass, metal shards from machinery and dust. In manufacturing and processing, suitable detection or screening devices shall be installed where necessary. Procedures to be followed by food handlers in the case of breakage shall be in place. Equally systems shall be in place to prevent contamination of foods by harmful chemicals. Access to processing area by outsiders should be restricted or controlled. Where risks are particularly high, access to processing areas shall be only via a changing facility.

## **5 Food packaging**

Packing area must be designed to ensure no external contamination and care must be taken to avoid product being directly exposed to the environment. Air-curtains, strip curtains, wire-mesh, partitions etc. must be in place to avoid any contamination.

All personnel involved in packing must be vaccinated annually and records of the same must be maintained. All personnel involved in packing and handling of product must have protective covering. Recycling of packaging or product rejects must be done with prior approval from quality control department and with extreme care so as to avoid contamination. All "Industrial" packaged products like sacks of 50 kg Maida must have details such as Lot No, FSSAI logo, Lic No., Veg logo, Ingredient name, for immediate identification in supply chain.

Packages are usually tailored to fit the product and designed to last throughout its shelf life, Innovative packaging material can also help minimize insect invasion. Specifications for packing materials should be followed. It should protect the food, also be free from contamination, should not taint the food or impart off- flavours or off-odours to the product.

The flour should be re-screened by the flour screen both before transportation in bulk and the final packaging. Seals and closures can be improved by changing the type or pattern of sealant glue.

Closures on bag bottoms are prone to insect entry. Reinforcement as much as top closures can help to eliminate this risk. Another packaging problem involves smell. Insects are attracted to packages that allow food odors to escape. Certain plastic film overwraps that fit tightly around a package can help prevent insects from smelling its contents. An odour neutralizer can also be incorporated into packaging materials. Thus, preventive maintenance becomes the necessary element, paramount for product safety. Packing materials should be stored in a separate area which is dust free and pest proof

## **6 Finished product storage**

Finished product must be stored in clean area and not directly on the ground. It should be palletized, stored on pallets with a cardboard or plastic layer (slip sheet) to avoid splintering. Tarpaulins and/or pallets must be used as appropriate. Sampling and quality testing of the product must be carried-out in parallel to production. Approved, Rejected and under test product must be clearly segregated and stored. Quality testing and approval of the product is mandatory before despatch of the product. Records of the same must be maintained.

The finished product should be stored in containers constructed of suitable materials, fitted with suitable close-fitting covers and kept in place at all times. Containers shall be designed to ensure proper cleaning and maintenance. Storage areas should be maintained in a dry, clean conditioned and in a well ventilated state. All materials should be stored off the floor on clean pallets and at least 20 cm from the wall in order to allow proper cleaning, pest control and ventilation. Bulk storage bins should not allow condensation and therefore when constructed of concrete, should have double-constructed or heated outside walls. Steel bulk storage bins should be enclosed in a structure where temperatures around the outside of the bin can be regulated.

It shall be stored away in separate areas from other chemicals, raw materials or materials used in the process. It should be rotated on a first in first out basis and handled under conditions to prevent damage or deterioration

Broken or contaminated pallets shouldn't be used to transport finished product. A physical inspection of the pallet before it's used is advised. Prior to the release of the finished product, the finished product should be checked and approved by the quality assurance department. Examples of tests that could be done on the final product: test for moisture %, protein%, ash %, colour, falling number, alveograph, mixograph, particle size, vitamins and baking quality. Records should be kept. Batches of finished product that has been approved by the quality assurance team should be stored in separate areas and under appropriate conditions

Batches of finished product that doesn't meet the required specifications, should be quarantined, labelled clearly and held in a separate area to prevent accidental use. A formalized procedure should exist that deals with the consequences of accidents or damage during storage and distribution.

## **7 Rework & control of non-conforming products**

All rework material should be labeled, stored, handled and used in such a way that product safety, quality, adulteration, traceability and regulatory compliance are maintained. Where rework is incorporated into a product as an "in-process" step, the acceptable quantity, the process step and method of addition, including any necessary pre-processing stages, shall be defined

Standard operating procedure should be defined and documented for handling any rework or non-conforming products. Control of non-conforming product

- ✓ All non-conformance incidents shall be recorded and assessed.
- ✓ There shall be a defined storage area and handling procedure for non-conforming raw material, intermediate product, finished product or packing material.
- ✓ There shall be a procedure about actions to be taken when a non-conformance has been detected in-house.

## **8 Food transportation**

Ensure that transportation vehicles are dedicated for food products and there is no cross-contamination from other non-food commodities.

Each vehicle must be inspected before loading for infestation, spills, rodents, insects/pests as well as any vehicle damages or spillages.

## **9 Food traceability and food recall**

FOs shall have a traceability system for assigning codes or lot numbers to incoming materials, packaging materials and finished products, etc. This will help to identify products backward & forward complete traceability. FBO shall have a documented and effective product recall plan in place in accordance with the Food Safety & Standards Recall Regulations. Such a plan shall allow the FBO to effectively locate all affected food products that may cause a potential threat to public health and enable the complete, rapid recall of the implicated lot of the product from the market.

Where a product has been recalled because of an immediate health hazard, other products which are produced under similar conditions which may also present a hazard to public health shall be evaluated for safety and may need to be recalled

Recalled products shall be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed/reworked in a manner to ensure their safety. Product recall procedure should be internally tested and documented through mock recalls at least once in year by facility recall team.

## **10 Food testing**

Representative samples from material lots as well as finished product lots shall be tested for all quality parameters, residues, contaminants, toxins etc., at least once in six months. This can be either at an in-house lab or any external NABL accredited lab. Laboratory facilities on site should implement good laboratory practices, should have adequate space and should also have the appropriate equipment required for tests to be done. Access to laboratory areas should be restricted to authorized personnel only.

### III. ESTABLISHMENT – MAINTENANCE & SANITATION

#### 1. Purpose

In flour mills, maintenance of facility and equipments play equivalent role as adopting right sanitation practices. Equipments not looked after well become places creating chemical, physical, biological hazards and sometimes safety hazards too. The main purpose of sanitation in mills shall be to create environment that will discourage pests/insects harbourage and growth. Only deployment of pest management program will not be sufficient to control pests and insects in the mills, pest management shall be strongly supported by robust maintenance, cleaning and sanitation programs.

#### 2. Sanitation strategies

Flour mills shall adopt adequate strategies inclusive of but not limited to:

- Clean exterior grain handling areas and equipments
- Clean processing areas and equipments
- Clean finished goods handling areas

Entire flour milling facility shall be periodically inspected and cleaned to avoid development of dust and flour particles layers, unintended debris built up in difficult to access areas. Placement of flour milling equipments and their sanitary designs shall be such that they can be cleaned adequately.

Sanitation Methods: Flour mills shall adopt dry cleaning methods and avoid introduction of water unless mill design permits appropriate discharge, drainage and complete drying of wet cleaned areas.

Common practices are

- Brooming/sweeping
- Dry wiping
- Vacuum Cleaning

Milling equipments shall be dismantled to the best extent possible to clean. Equipments shall be cleaned to avoid/prevent development of spots that accumulate flour dust, broken grains to become harbourage for insects. High pressure air cleaning shall not be used in flour mills due to the cross contamination risks from flour dust and potential accumulation of dust particles at blind spots.

Mill shall develop a daily, weekly, fortnightly and monthly master sanitation schedule covering all areas and equipments in the mill. Mill shall develop SSOPs for all the milling equipments detailing specific methods of cleaning.

#### 3. Factory dis-infestation

Manufacturing facility must be dis-infested with approved agents or thermally at periodic intervals. This is different from grain fumigation. The objective is to reduce infestation load in the manufacturing facility to negligible level.

## 4. Fumigation

The most effective method to ensure food safety against pests is fumigation with phosphine (PH<sub>3</sub>) gas. Phosphine fumigation is preferred because of leaving little amount of residuals and ease of application. 650 ppm phosphine gas concentration of the storage atmosphere in the fumigation is determined as the optimum value for pest control.

As the phosphine gas is oxidized into the phosphoric acid with the existence of light, it is more suitable to make the fumigation applications in the evening. Besides, as phosphine gas reaches high concentration (>1.79) in the closed atmosphere, great attention is needed in terms of job security. Phosphine application is extremely effective in the modified atmosphere environment. All pests and even resistant flour lice are killed easily within 15 hours of phosphine application when the environment temperature is 40°C and the atmosphere CO<sub>2</sub> rate is over 70 % at a flour mill that is closed firmly and where impermeability is provided.

### • Fumigation with Phosphine

- ✓ Fumigators must remember that the exposure period is deemed to start from the time that the fumigant is first found to be evenly distributed inside the fumigation enclosure.

Phosphine must not be used:

- when there is no trained, qualified and properly protected fumigation team
- in unsealed enclosures
- when the temperature is below 10°C
- where resistance to it is known to exist in an insect population
- where a rapid treatment is required, i.e. less than 7 days
- in immediate vicinity to workspaces and places where people live.

- ✓ Before gassing an enclosure for fumigation, a warning placard with a warning symbol must be displayed.
- ✓ Aluminium phosphide (ALP) products usually release 33% Phosphine from the total weight of the product i.e. tablets weigh approximately 3 grams and release 1 gram of phosphine gas and pellets weigh approximately 0.6 grams and release 0.2 grams of phosphine gas.
- ✓ The generation of phosphine generated from ALP formulations may be delayed by about 15 minutes after they are exposed to air. In hot, humid conditions, phosphine is produced almost immediately on exposure to the air, so the dispensing process must be completed within 15 minutes.
- ✓ ALP Formulation Dose: (a) Tablets: keep @ 10 tablets (10 tablets X 3 grams = 30 grams) in a cloth bag (or) (b) Sachets: 34 grams sachet.

- ✓ Fumigation period – at least 7 Days for the control of all live stages
- ✓ Target Phosphine concentrations more than 700 ppm for 7 days for grains in flat storage
- ✓ Increasing the dosage above the rate(s) recommended on the label will not compensate for poor gas-tightness.
- ✓ Post Fumigation Protection of Fumigated stacks: Prophylactic spray with approved agents like Deltamethrin 2.5%WP as per recommended dose on all sides of the stack

## 5. Allergen control management

Any Allergen Control Plan should address the below minimum requirements:

- Listing of all allergen ingredients: Display all the allergens at the relevant places in the processing and storage areas for awareness among all the employees. The allergens may include:
  - ✓ All that are used intentionally
  - ✓ All that enter the factory unintentionally (staff food, via contractors, transport, neighbours (air borne, carry over from ingredients etc.)
- Supplier monitoring
  - ✓ When reviewing specifications, the responsible person should look for formulations of the listed ingredients of the raw material.
- Factory Movement of Materials
  - ✓ Maintain all ingredient flow during the manufacturing from non-allergen using areas to allergen using areas. This will help prevent cross-contamination.
- Raw material storage
  - ✓ All raw materials that are allergens should be labelled as “Allergen.” The label can be made Bold and with Bright color for quick identification.
- Color coding system for allergen specific utensils
  - ✓ Dedicated scoops, utensils shall be used for specific allergens.
  - ✓ Bright colors and words can be used for easy identification of different allergens.
- Production scheduling and Cleaning
  - ✓ Thorough cleaning should be done between allergen containing product manufacture and non-allergen containing product manufacture. Process should be in place to ensure no allergen residue on the production line. Once in a year the Unit should validate the claim of effective control of cross contamination/ allergen management, through an external or in-house laboratory.
  - ✓ Handling of Rework/ Add-back: It should be done in such a way, that the rework containing allergen should not cross-contaminate other food material during processing, handling and storage.

## 6. Common pests & control plan

Grain and grain products in flour mills are at risk of being contaminated by foreign material, insects, microbes and vertebrate pests. There are three types of pests that affect milling process and product quality. Besides structural and exterior pests (such as cockroaches, ants, rodents, birds and exterior flying insects), the type of pests that are most critical to flour mills are stored product arthropods (internal and external feeder insects and mites) found within the commodity (grain and flour). Good engineering for food safety and sanitation are first and most important considerations while setting up a flour mill to avoid these pests

As an important risk element, bird residues and faeces are known as the main contamination source for salmonella bacteria's contamination to the flour which can cause serious food poisonings, because of their numbers and breeding speed insects and mites constitute the most important pest group that gives damages to the grains and threatens the flour safety.

The rats that threaten the flour safety are split into three groups as *Rattus norvegicus* (Norway rat, brown rat), *Rattus rattus* (roof or ship rat, black rat) and *Mus musculus* (home rat); birds are defined as local bird species living in the business area.

Pests such as *Sitophilus granaries* L. (weevil), *S. oryzae* L. (rice louse), *S. zeamais* (corn borer), *Trogoderma granarium* (Khapra beetle), *Rhizopertha dominica* F. (crop hump beetle), *Tribolium confusum* and *T. castaneum* (half-blood lice), *Ptinus fur* L. (white-spotted spider mite), *Nemapogon granellus* L. (crop warehouse moth), *Ephestia kuehniella* (mill moth), *Acarus siro* L. (flour mite) are the common insect and mite species that create important risks on flour safety.

Stored grain and flour are subject to insect infestations and deterioration from molds and bacteria. High grain temperature and moisture, along with dockage and broken kernels and even milled flour, provide conditions that accelerate mold and insect development.

Some insects damage grain by developing inside kernels, feeding on the inner endosperm and producing holes in the kernel through which the adult insect exist. These insects are called "internal feeders". The cycle is repeated when the female lays eggs inside the kernels. Examples of internal feeders are maize weevil, rice weevil, granary weevil, lesser grain borer, and Angoumois moth. The grain (maize, rice, granary) weevils are small recognizable as a group because the head projects forward as a prolonged snout. The adult's lesser grain borer head projects downward, not forward, and does not bear a snout. The Angoumois grain moth lays its eggs on grain kernels and the larvae bore into the kernels and feed there.

Other insect species that do not develop within the kernels, although they may hide inside cracked grain, making detection very difficult are flat grain beetle, rusty grain beetle, and the foreign grain beetle. They primarily feed on mold. Other species such as the saw-toothed grain beetle, the red and confused flour beetles, the Indian meal moth, and the larger black flour beetle feed on damaged grain or fines.

Stored product insects are one of two types – invaders and penetrators. The invaders, like red flour beetle, confused flour beetle, saw-toothed grain beetle, Indian meal moth, and almond moth look for opportunities to get inside food containers by searching for cracks, crevices and holes. The penetrators like the lesser grain borer, cigarette beetle, warehouse beetle, and rice moth chew holes even into multi-layered packages.

## Prevention of infestation

### Stored grain:

Stored grain management is the organised, long-term approach to maintaining the quality, minimizing chemical control inputs, and preserving the integrity of the grain storage system. Techniques can be integrated into grain storage systems to prevent or minimise losses from

insect and mold infestations. These management techniques must focus on the factors that regulate storability, including grain temperature, grain moisture, storage air relative humidity and storage time.

Most insect and mold activity is greatly reduced at grain temperatures below 15°C. Planned temperature reductions by controlled aeration can significantly reduce insect population. Mold populations follow similar temperature control patterns. Aeration is the forced movement of air through grain to lower or equalise grain temperatures. Higher levels of grain moisture increase the potential for high populations of stored-grain insects and molds. To achieve safe storage moisture contents, force heat or natural air drying of some crops is necessary.

### **Packaged grain:**

Packaged and stored grains can be protected from getting infested by having a comprehensive integrated pest management programme that ensures regular monitoring, timely intervention of corrective actions based on (IPM) Hazard Analysis Critical Control Point (HACCP), evaluation and follow ups

Although packages can become infested anywhere along the production to marketing chain, they are most likely to become infested during long-term storage. Inside the warehouse, insects attack vulnerable packaging and later jump to sturdier material. To avoid such invasion, packaged products should be rotated sold/distributed or consumed on first-come first-out basis within the shelf-life period.

Packaging should protect the commodity from the point of manufacture to the point of consumption.

### **Pest control plan**

- Pest Control must be designed as a comprehensive system at food manufacturing facilities. This must include,
- A flour mill should consider installing heat sterilization units, a system of sufficient capacity to provide the higher temperatures needed to kill stored product pests. In addition, mechanical equipment can also be added to the milling systems to destroy and remove insect pests. This equipment includes infestation destroyer impact machines, aspirators, sifters, and scalpers. In case of large scale operations, installation of instrumentation delivering modified atmospheric treatments should also be considered.
- Modified atmosphere treatments involve alteration of the proportion of the normal gaseous constituents of air (oxygen, nitrogen, carbon dioxide, and trace gases) to provide an insecticidal atmosphere.
- The design of storage bins should allow regular monitoring, aeration to reduce issues related to moisture, mold and pest infestation. The insect and their eggs can be destroyed and separated by using the entolation operations working with screening, aspiration and pulse technique integrally. In order to destroy the insects and the eggs without giving any harm to the wheat, the entoleter speed should be 1750 d/d inside wheat and 2900 d/d inside the flour.

- One of the most important methods for pest control is using trap. Covered or sticky traps can be used effectively for pest control by making the traps attractive with light
  - ✓ Insect light traps with catch-pan: should not be above 6 feet height from the floor and not be directly visible from outside– tubes must be changed at defined intervals basis specified hours of operation
  - ✓ Rodent Control: Roda-boxes must be placed at both sides (externally place rodent boxes with bait must be fixed and always be locked all entry points)
  - ✓ All pest control devices must have serial number and a master lay-out depicting its position
  - ✓ All windows and exhaust duct/openings in the manufacturing facility must have at least 600 micron mesh covering to avoid pest entry and all doors and shutters must have strip/air-curtains with outer stream of air flow.

S. No	Treatment name	Recommended Frequency	Area	Against
1	Integrated Fly Management (IFM)	Daily thrice	In & Around Building, Entry Points(Doors & Shutters) & Breeding Grounds	House Flies
2	Disinfestation (HPM)	Weekly	In & Around Building, Entry Points(Doors & Shutters) & Breeding Grounds	House Flies, Cockroaches, Silver fish, Ants and Bed Bugs
3	Rodent Management	Daily Check & 15days Change	First Line of Control	Rodents
		Daily Check & 15days Change	Second & Third Line of Control	Rats, Mice & Bandicots
4	Prophylactic Treatment	Monthly (Nov - Feb) Fortnightly (Mar - Oct)	Insect Hiding Places	Crawling Insects
5	Lizard Management	Weekly	Outside Plant Area	Lizards
6	Cockroach Management	Monthly	Cracks & Cervices	Cockroaches

	nt			
7	Pest O Flash	Daily Cleaning (4 nos)	FG Godown, Bran Collection, Coding Room, Packing Room	Flying Insects
8	Fumigation	45 days (As and When required)	Grain	Store Grain Pest
		45 days (As and When required)	Grain, All equipment	Store Grain Pest

**Following documents must be available on site**

- Pest control plan- lay out, pest control devices, treatment details
- License copy of pest control service provider
- Labels of pesticides used
- MSDS of pesticides used
- ID proof copy of PCO ( Pest control operator) representative on site and his liability insurance certificate as well as his training/qualification certificate
- If pesticides are stored on site- a dedicated access controlled area must be available to store pesticides
- Pest sighting log

## IV. ESTABLISHMENT – PERSONAL HYGIENE

### 1. Health of food handlers

Food handlers 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.

A system shall develop by Food Business Operators, whereby any person affected by illness or symptoms of illness shall report to the management and medical examination of a food handler shall be carried out apart from the periodic checkups, if clinically or epidemiologically indicated.

Food handlers / employees of the establishment shall be medically examined 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.

The factory staff shall be compulsorily inoculated against the enteric group of diseases as per recommended schedule of the vaccine and a record shall be kept for inspection.

In food-handling areas, personnel with open cuts, wounds or burns shall be required to cover them with suitable water-proof dressings before starting operations. Any lost dressing must be reported to supervision immediately. The dressings should preferably be brightly coloured and metal detectable

### 2. Hygiene of food handlers

Food handlers shall maintain a high degree of personal cleanliness.

Food business shall provide to all food handlers adequate and suitable clean protective clothing, head covering, face mask, gloves and footwear and the food business shall ensure that the food handlers at work wear only clean protective clothes, head covering and footwear every day.

Head-covers or caps, masks, gloves, shoe-covers (where product is directly touched) and such other hygiene measures must be in place as appropriate to ensure product contamination risk is avoided.

Food handlers 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 sanitizers must be placed at the entrance of production area.

Toilets and canteen for employees must be away from production area. All toilets must be equipped with soaps or liquid detergents and provision for uninterrupted water supply. Food handlers engaged in food handling activities shall refrain from smoking, spitting, chewing, sneezing or coughing over any food whether protected or unprotected and eating in food preparation and food service areas.

Food handlers should trim their nails and hair periodically, does not encourage or practice unhygienic habits while handling food. Persons working directly with and handling raw materials or food products shall maintain high standards of personal cleanliness at all times. In particular:

- ✓ they shall not smoke, spit, eat or drink in areas or rooms where raw materials and food products are handled or stored;
- ✓ wash their hands at least each time work is resumed and whenever contamination of their hands has occurred; e.g. after coughing / sneezing, visiting toilet, using telephone, smoking etc.
- ✓ avoid certain hand habits - e.g. scratching nose, running finger through hair, rubbing eyes, ears and mouth, scratching beard, scratching parts of bodies etc.- that are potentially hazardous when associated with
- ✓ handling food products, and might lead to food contamination through the transfer of bacteria from the employee to product during its preparation. When unavoidable, hands should be effectively washed before resuming work after such actions.

### **3. Visitors**

Food Business Operator should implement and display visitor control policy. The Food Business shall ensure that visitors to its food manufacturing, cooking, preparation, storage or handling areas must wherever appropriate, wear protective clothing, footwear and adhere to the other personal hygiene provisions envisaged in this section. Visitors do & don'ts rules shall be displayed at prominent areas

## V. PRODUCT INFORMATION AND CONSUMER AWARENESS

### 1. Product information & labeling

All packaged food products shall carry a label and requisite information as per provisions of Food Safety and Standards Act, 2006, Legal Metrology (Packaged Commodity Rules 2011) and Regulations made there under so as to ensure that adequate and accessible information is available to the each person in the food chain to enable them to handle, store, process, prepare and display the food products safely and correctly and that the lot or batch can be easily traced and recalled if necessary.

The label shall provide information to enable the food handler to store, process, prepare and display the food products safely. The label shall enable easy traceability and recall 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. All mills should at least have a redress system in place to eliminate any physical hazards that might be added to the final product by human error or operation's deficiency

## VI. Training

### 1. Awareness and responsibilities

All personnel shall be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers shall have the necessary knowledge and skills to enable them to handle food hygienically. Those handling strong chemicals or potentially hazardous substances shall be trained in safe handling procedures and techniques.

### 2. Training programmes

- Suitable trainings shall be given to all personnel handling food to enable them to have the required knowledge and skills in GHP and GMP for specific tasks along with personal hygiene requirements commensurate with their work activities, the nature of food, its handling, processing, preparation, packaging, storage, service and distribution.
- It should be clear to all food handlers what precautions to take in order not to contaminate the food source
- The training program includes appropriate training on the company's Hygiene Code of Conduct at the beginning of employment.
- It also comprise of the manner in which foodstuffs are handled and packed, the probability of contamination, the nature of the food, the food's ability to sustain growth of pathogenic or spoilage microorganisms, awareness of food safety issues; basic personal hygiene and hygienic and sanitary requirements of the equipment
- All production and quality assurance personnel should be fully trained in good manufacturing practices.
- Personnel employed as drivers should be adequately trained to meet the specific quality to the hygienic and safety requirements of the transported goods.
- By implementing regular hand swabs or contact plates before and after washing hands, the effectiveness of hand washing could be monitored. These results could then be used in hygiene training. This is advisable for the more sensitive areas where can be direct contact with the product.
- Cleaning operatives should be adequately trained so that they fully understand: the cleaning schedules; chemicals listed and safety precautions required; the need for protective clothing; the appropriate dilutions of cleaning agents; the personal hygiene standards expected of them as well as the use and care of cleaning equipment.
- Personnel employed to only fulfill a cleaning role, should be identified by either the use of different coloured protective clothing, design or colour of hat or by overall symbols.
- Personnel in the packing areas of mills should be extra cautious in order to prevent accidental finished product contamination. Proper hair restraints should be in place; only shirts without pockets should be allowed or in cases where shirts do have pockets, nothing in the shirt pocket should be allowed and no jewellery should be allowed.
  
- The person in charge of receiving the grain (wheat grader), should be well trained to do so, knowledgeable and dependable in order to do his specified task. A suitable wheat grading certificate that shows that the wheat grader is qualified should be kept on record. The wheat grader should have the authority to reject wheat if it does not conform to the minimum requirements or re-classify it into another class if necessary.

- These training programmes shall be delivered by qualified and trained personnel. Records of training shall be kept.

### **3. Instruction and supervision**

Periodic assessments of the effectiveness of training, instructions programmes as well as routine supervision and checks should be made to ensure that food hygiene and food safety procedures are being implemented correctly and effectively by all personnel.

Managers and supervisors of food processes shall have the necessary knowledge and skills in food hygiene (GHP and GMP) principles and practices to be able to judge potential risks and take necessary action to remedy deficiencies.

### **4. Management & supervision**

FBO management shall lead establishment of Food safety management systems in their premises. FBO management shall ensure providing necessary trainings & resources to their employees to develop food safety culture at plant site.

FBO shall appoint trained & competent managers and supervisors for management and supervision of food safety systems.

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. Management is responsible to arrange training for all food handlers regarding the hygienic handling of food as well as personal hygiene (good hygiene practices).

## VII. AUDIT, DOCUMENTATION & RECORDS

### 1. Self-evaluation and review

(i) 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. Necessary corrective actions based on self-evaluation results shall be taken.

(ii) FBO should also undertake a complete review of the systems including self-evaluation results, customer feedback, complaints, new technologies and regulatory updates at periodic intervals, but at least once in a year for continual improvement.

### 2. Documentation and records

Appropriate documentation & records of processing, production and distributions shall be maintained in a legible manner, retained in good condition for a period of one year or the shelf-life of the product, whichever is more.

Suppliers should have effective pre-requisite programs in place and should be verified annually. Audits should be carried out on suppliers of raw materials.

## **C. HACCP IMPLEMENTATION**

## SECTION B - HACCP IMPLEMENTATION

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.

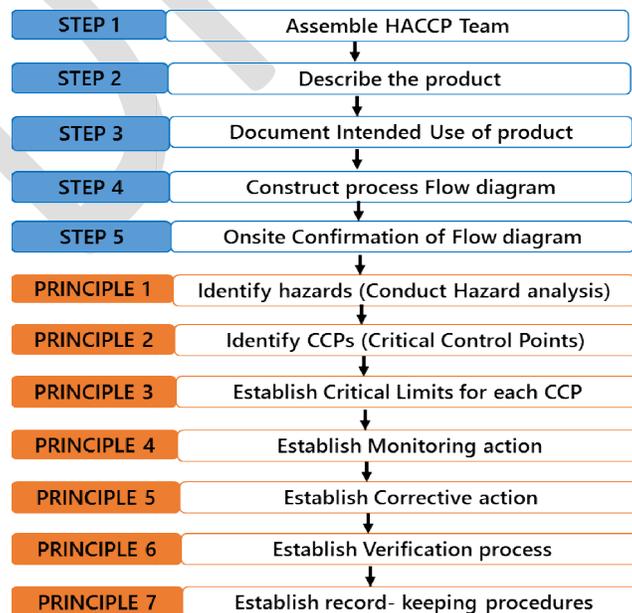
### I. INTRODUCTION TO HACCP

Hazard Analysis Critical Control Point (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. A HACCP plan consists of 5 initial steps and 7 major HACCP principles.



The requirements for Sanitation Standard Operating Procedures (SSOPs) along with Good Manufacturing Practices (GMPs) should be considered as Pre-Requisite for HACCP.

Risk assessment is a critical step in a HACCP plan. 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 event occurs?					
		Severe	Major	Significant	Minor	Insignificant	
Probability/ Likelihood	What's the chance of the risk occurring?	<b>Frequent</b>	Extreme	Extreme	Very High	High	Medium
	<b>Likely</b>	Extreme	Very High	High	Medium	Medium	
	<b>Occasional</b>	Very High	High	Medium	Medium	Low	
	<b>Seldom</b>	High	Medium	Medium	Low	Very Low	
	<b>Unlikely</b>	Medium	Medium	Low	Very Low	Very Low	

## II. INTRODUCTION TO DECISION TREE

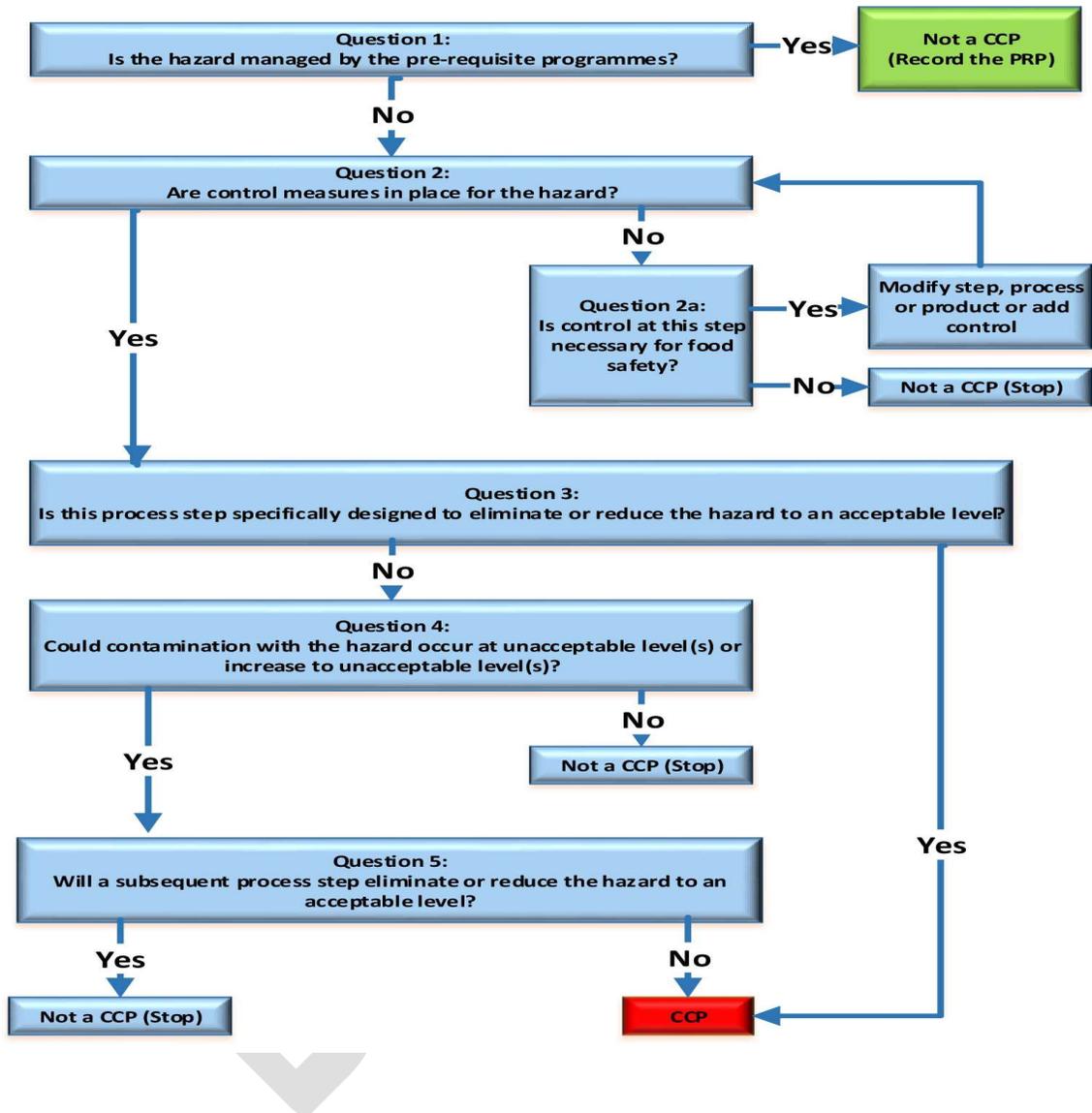
Hazard Analysis and Critical Control Point (HACCP) decision trees are tools that can be used to help you decide whether a hazard control point is a critical control point (CCP) or not. A CCP is a step at which control can be applied. However, it is not always possible to eliminate or prevent a food safety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

The purpose of a decision tree is to support the judgement 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.

# FOOD SAFETY MANAGEMENT SYSTEMS (FSMS) GUIDANCE DOCUMENT

## Cereal and Cereal products till milling stage



## 1. Possible hazards in Cereal and cereal product industries along with flow chart

### Wheat Milling and Possible Hazards

#### 1. Physical Risks

The physical risks mostly coming with the wheat consist of animal and vegetable organic substances like stalks, straw, food waste, gum, cigarette butts, weed seeds, rodent hairs, insect parts, feces, etc. and inorganic substances like stone, soil, sand, metal and glass. All organic and inorganic substances should be separated from the wheat well before the storing and milling operations because of both the risks in their chemical components and the microbial loads they carry. As the inorganic impurities cause disruption of the integrity of grain and the grains not matured enough include high grain water content, they both can become the source of mold infections.

#### 2. Biological Risks

The most important biological risks endangering flour safety are microorganisms and pests. Grains are really open to the microorganism and pest contamination due to production, harvesting and transport conditions. There is an important amount of bacteria, yeast and mold load on the grains because of these contaminations. Molds create more important risks on flour safety compared to bacteria and yeasts as they can breed in low water activity and heat conditions due to their physiologies and form dangerous mycotoxins with high heat resistance.

Salmonella spp., Escherichia coli, Bacillus cereus are common pathogen bacteria that threaten the food safety of flour. Using flour as the main element in the kitchen and mixing the flour and food that can also be consumed as raw intentionally or unintentionally can cause serious food poisonings occurred due to the flour containing pathogenic bacteria. Consuming Salmonella bacteria with food even in little amounts like 1 log cfu/g can cause serious diseases.

Livings like insect, mite, rat and bird are called as pests. Known also as vertebrate pests, rats and birds threaten the flour safety seriously by contaminating the microorganism and parasites in their bodies and feces to the flour. As a result of these pest activities, various serious diseases like typhoid fever, paratyphoid fever and salmonellosis can develop.

Mold growth depends on environmental factors like heat, relative humidity and oxygen content and the water content of wheat kernel. Mold activity increases together with the heat increase after the kernel water exceeds 14 % value that is the critical water content and the relative humidity of the environment exceeds 65 % that is the critical relative humidity rate. The mold types of these species can create important threats on flour safety as they produce dangerous toxic metabolites called mycotoxins such as aflatoxin, ochratoxin, zearalenone, patulin, deoxynivalenol, trichothecene and fumonisin.

Mold growth can be seen at uncontrolled points of some parts where the washing and annealing units inside the flour mill and at some points where vapor is intensified inside the closed systems. This vapor is formed by the separation of water from the product inside the equipment like roller, screen and purifier. These molds can cause health problems for the consumer because of both themselves and the mycotoxins they produce by mixing with the flour in time.

### **3. Chemical Risks**

Chemical factors that threaten the flour safety consist of pesticides used in the fields, pesticides used in the businesses for insects and rodents, fumigation, hygiene and sanitation products, personal hygiene materials, metals, heavy metals, dyes, radioactivity, etc. Besides the mycotoxins formed by the molds, the chemicals in the insect feces and rash and the alkaloids of the weeds also risk the flour food safety.

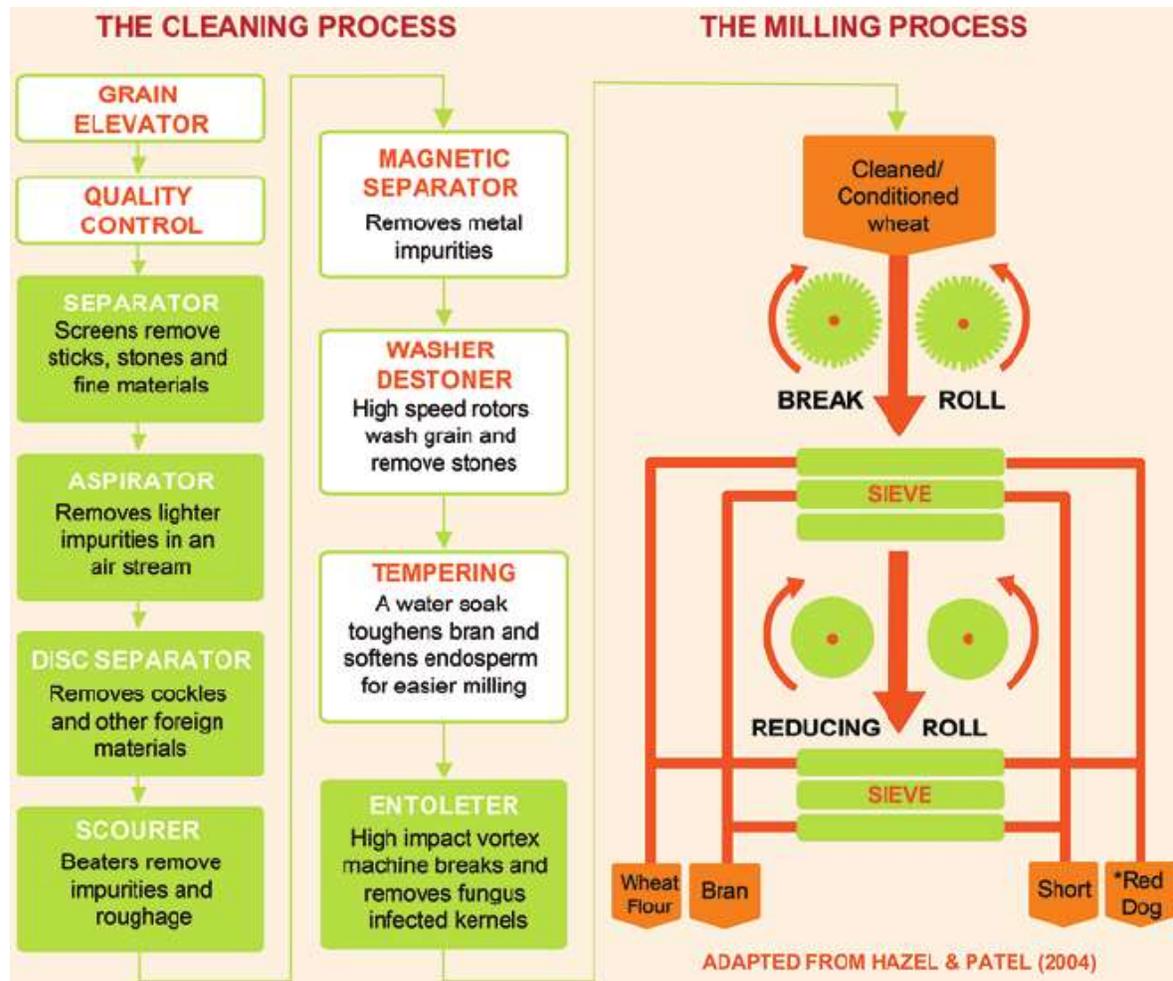
### **CRITICAL CONTROL POINTS IN SAFEFLOUR PRODUCTION**

Besides the quality analysis during wheat purchases to the business; other analysis that give an idea about food safety and intended for determining the risks like insect, mold and aflatoxin should be done.

In order to provide food safety in the flour mills critical control points (CCP) should be determined pursuant to HACCP principles.

Raw material procurement, storing, cleaned annealed wheat and flour packaging stages should be considered as critical points. Also, before the cleaning, milling and packaging processes the flour safety should be ensured by separating the metals from the products with a magnetic separator.

## Wheat Milling Process:-



Wheat Flour

Severity, Occurrence and Detections

Severity			Occurrence		
Severity if controls fail	Severity of affect if Hazard Occurs	Multiplier	Probability of hazard occurring if process fails	Frequency That Hazard Could Occur	Multiplier
Negligible	Mild disappointment to the consumer. May lead to a complaint, no business interruption. Minor consequences.	1	Almost Impossible	Less than once a year, no history of it occurring	1
low impact (momentary sickness feeling)	Very minor medical treatment, Consumer disappointed.	2	Un-Likely	Very occasional, has been known to occur	2
moderate (short term illness)	Illness at home. Medical treatment not necessary.	3	Small Risk	Isolated event that result after manual operations	3
sever (long term illness)	Illness at home with medical treatment necessary.	4	Likely	Product or operational factors that can be expected to be present	4
very sever (causing death)	Hospitalization required/death. Significant risk of prosecution. Intervention by 'Crisis management team'. Damage to 'branded ' image.	5	Certain	Product or operational factors that the process is expected to control	5

Severity of the risk x Probability of the occurrence of the hazards = Risk Rating

**1-5 PRP (Pre Requisite Programme)**

**6-12 OPRP (Operational Prerequisite programme)**

**15+ CCP (Critical control point)**

**Assessment Criteria for Control Measure**

<b>Assessment criteria for control measure</b>	<b>Parameters</b>
a) Control measure effect on identify food safety hazard relative to the strictness applied	<ol style="list-style-type: none"> <li>1. Not eliminate completely.</li> <li>2. Reduce or control to meet acceptable level</li> <li>3. Reduce to within acceptable level or eliminate hazard completely</li> </ol>
b) Control measure feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrections)	<ol style="list-style-type: none"> <li>1. No feasibility</li> <li>2. Has limitation</li> <li>3. Feasible</li> </ol>
c) Control measure place within system relative to other control measures	<ol style="list-style-type: none"> <li>1. First</li> <li>2. Middle</li> <li>3. Final measure</li> </ol>
d) The likelihood of failure in the functioning of a control measure or significant processing variability	<ol style="list-style-type: none"> <li>1. High</li> <li>2. Medium</li> <li>3. Low</li> </ol>
e) The severity of consequence(s) in the case of failure in its functioning	<ol style="list-style-type: none"> <li>1. Negligible effect</li> <li>2. Complaint</li> <li>3. Health implications</li> </ol>
f) whether the control measure specifically established and applied to eliminate or significantly reduce the level of hazard	<ol style="list-style-type: none"> <li>1. No</li> <li>2. Somewhat</li> <li>3. Definitely</li> </ol>
g) synergistic effects (i.e. interactions that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects)	<ol style="list-style-type: none"> <li>1. No</li> <li>2. Somewhat</li> <li>3. Yes</li> </ol>

**If a+b+c+d+e+f+g =**

**10 to 15 is OPRP**

**15+ is CCP**

Typical Hazard analysis- Wheat Flour

HAZARD IDENTIFICATION AND DETERMINATION OF ACCEPTABLE LEVELS, HAZARD ASSESSMENT, SELECTION AND ASSESSMENT OF CONTROL MEASURES

Process Step & Description	Hazard	Severity (A)	Frequency (B)	Risk adverse health effect (A x B)	Justification	Control measures	Assessment Criteria (Level of Effectiveness)							PRP/OPRP/CCP
							a	b	c	d	e	f	g	
<b>Wheat Receiving</b>	<b>PHYSICAL</b> Chance of Foreign matter such as Wood, Metal, Dust, Spoiled material, Inferior quality material, etc.	2	2	4	[1] Effective control of supplier & processing. [2] Effective PRP in place ( Due to source of material packing & transportation condition ) [3] Likely to occure.	[1] Approval, evaluation & re-evaluation of suppliers. [2] RM specification give to the supplier & purchase of material after approval of the sample [3] Vehicle Cleanliness check [4] Good handling & Good hygiene practices are follow. [5] Supplier visit - once / year for site visit. [6] Quality checking at the wheat	1	2	2	2	1	1	1	PRP



						communicated to follow food safety compliance.														
--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

[7] Supplier visit - once / year for site visit.

[8] Allergen declration and allergen control policy has been implemented and maintained.

DRAFT

**BIOLOGICAL**

Chances of microbial contamination due to improper handling of raw material by food handler, microbes contamination ( E. Coli, Salmonella etc.) and illness of the employee.

2

2

4

[1] Effective control of supplier & processing.  
[2] Effective PRP in place ( Due to source of harvesting, packing & transportation condition )

[1] Approval, evaluation & re-evaluation of suppliers  
[2] RM specification give to the supplier & purchase of material after approval of the sample  
[3] RM Inspection by QC at the time of material receiving.  
[4] Vehicle Cleanliness check  
[5] Good handling & Good hygiene practices are follow  
[6] Raw material product testing for chemical & microbial parameter.  
[7] Supplier visit - once / year for site visit.  
[8] PPE implemented and maintained. [9] COA procured for the microbial

1

2

2

2

1

1

1

						testing and third party testing for the assurance.											
<b>Packing material receiving</b>	<b>PHYSICAL</b> Foreign matter such as Dust, glass, Stones, Plastic foreign matter, Supplier source and transportation condition.	1	2	2	[1] Improper material supplied from the supplier and vehicle condition, Uncleanliness of processing machinery may hamper the product.	[1] Approval, evaluation & re-evaluation of suppliers [2] PM Specification. [3] PM Inspection. [4] Vehicle Cleanliness check. [5] Inspection of packing material at the time of receiving. [6] Supplier visit for food grade compliance and	1	2	2	2	1	1	1				PRP

					checking of the product.													
<b><u>CHEMICAL</u></b> Non Food grade / non virgin packing material used for the manufacturing of Packing bag / Inprocess Packing Material, transportation condition	1	1	1	[1] Non food grade chemical or ink and unapproved colour use hamper the product. [2] Other non food grade chemical residue. [3] Improper transportation condition may contaminate the product.	[1] Approval, evaluation & re-evaluation of suppliers [2] PM Specification [3] PM Inspection [4] Vehicle Cleanliness check [5] Food grade material compliance certificate from each supplier - Once / year [6] Supplier visit - once / year for site visit.	1	2	2	2	1	1	1						

	<b><u>BIOLOGICAL</u></b> Microbial contamination	2	1	2	[1] Improper material transportation and non food grade material and uncovered material contaminate the product.	[1] Approval, evaluation & re-evaluation of suppliers [2] PM Specification [3] PM Inspection [4] Vehicle Cleanliness check [5] Material comes with the covered condition only.	1	2	2	2	1	1	1	
<b>Packing material inspection</b>	<b><u>PHYSICAL</u></b> Improper uncovered material i.e. dust and other foreign matter contamination	1	1	1	[1] Improper material comes in the vehicle contaminate through the dust and foreign matter.	[1] Checking by the trained quality person. [2] Material COA procured where applicabel. [3] PPE implemented and maintained.	1	2	2	2	1	1	1	PRP
	<b><u>CHEMICAL</u></b> Non food chemical contamination and transport condition	2	1	2	[1] Improper transport condition and Improper checking of the material	[1] COA Procure and material procured in coverd condition only and trained chemist perform the analysis. [2] Food grade certificate are procured.	1	2	2	2	1	1	1	

	<b><u>BIOLOGICAL</u></b> Food handler contamination, Illness of the handler	2	1	2	[1] Insufficient implementation of the PPE and food handler contamination.	[1] Materail comes in propered coverd condition. [2] Trained chemist perform the analysis and ill person are not allowed in the manufacturing area or for sampling procedure. [3] Medical checkup of the employee has been done as per defined frequency.	1	2	2	2	1	1	1	
<b>Packing material storage</b>	<b><u>PHYSICAL</u></b> Bristles, hair , dust,broken gaskets.	2	2	4	[1] Improper storage of the packing material, Plant hygeine condition and improper handling.	[1] Plant hygeine and sanitation programme has been implementaed and maintained. [2] Trained workers for the material handling.	1	2	2	2	1	1	1	PRP
	<b><u>CHEMICAL</u></b> <b><u>Non food grade chemical</u></b>	2	1	2	[1] Non food grade material storage may contaminte the product.	[1] Food grade and non food grade material are seperated and stored physically seperated.	1	2	2	2	1	1	1	PRP

	<u>BIOLOGICAL</u> contaminate from the taurpolin over the storage time. Bacterial contamination. Pest and rodent droppings.	3	1	3	[1] Material may get contaminte through the improper storage, bird droppings and rodent droppings.	[1] All the material are properly stored in storage room. [2] FIFO or FEFO maintained. [3] Pest control programme has been implemented and maintained. [4] EFK monitoring.	1	2	2	2	1	1	1	PRP
<b>Raw material testing</b>	<u>PHYSICAL</u> Bristles, hair , dust,broken gaskets.	2	2	4	[1] Improper qc checking and improper PPE implementation.	[1] Bags are properly open for sampling and close it properly. [2] PPE implemented and maintained. [3] Trained chemist perform the analysis.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u> <u>N.A</u>	NA	NA	NA			1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Food handler contaminatation, Illness of the handler	2	1	2	[1] Improepr quality checking and PPE.	[1] PPE implemented and maintained. [2] Trained chemist perform the analysis.	1	2	2	2	1	1	1	PRP

<b>Raw material storage</b>	<b><u>PHYSICAL</u></b> Foreign matter such as Dust,dirt etc.	3	1	3	[1] Improper cleaning, Improper storage condition, Improper materail segreagation contaminate the product.	[1] Material stored away from walls [2] Leak proof roofs [3] Storage condition inspection [4] Stock rotation (FIFO) [5] Daily plant sanitation checklist has been implementaed.	1	2	2	2	1	1	1	PRP
	<b><u>CHEMICAL</u></b> Food and non food grade materail contamination	2	2	4	[1] Cross mixing of the food and non food grade material contamination.	[1] Material are seperated and stored properly on pallet or tarpaulin. [2] Chemical are stored seperately and tagged properly. [3] Worker are trained for the material identification and seperation food and non food material.	1	2	2	2	1	1	1	PRP

	<b><u>BIOLOGICAL</u></b> Pest infestation by Live insects,Y&M, salmonella. Etc.	5	1	5	[1] Effective PRP in place ( Due to storage adjacent to wall, broken bags during storage , pest infestation due to open window, in effective pest control )	[1] Material stored away from walls [2] Leak proof roofs [3] Storage condition inspection [4] Stock rotation (FIFO) [5] Daily pest control checklist has been implemented and maintained. [6] Daily personnel and plant checklist has been implemented and maintained. [7] Glass checklist implemented and maintained. [8] Pest control programme has been implemented and maintained.	1	2	2	2	1	1	1	PRP
<b>Wheat intake</b>	<b><u>PHYSICAL</u></b> Bristles, hair , dust,broken gaskets,insects, stones, metal particles, big threads.	4	1	4	[1] Due to source of procurement and improper handling. [2] Maintenance schedulde.	[1] Proper housekeeping,hand ling practice of employee. [2] Preventive maintenance schedulde carried	1	2	2	2	1	1	1	PRP

						out.											
	<u>CHEMICAL</u>	NA	NA		NA	NA	1	2	2	2	1	1	1				PRP
	<u>BIOLOGICAL</u> Microbial contamination occur over a time	3	1	3	[1] Unlikely to occur improper cleaning of hopper and cross contamination pathogen from food handler.	[1] Strict monitoring, verify after clean and personnel hygiene checking and after illness. [2] Fumigation of the machine done as per defined frequency.	1	2	2	2	1	1	1				PRP
<b>Magnet</b>	<u>PHYSICAL</u> Foreign metal matter contamination	2	2	4	[1] Product source and Machine it self.	[1] Periodically cleaning and checking of the magnet. [2] As per defined frequency magnets are calibrated.	1	2	2	2	1	1	1				PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1				PRP
	<u>BIOLOGICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1				PRP

Cleaning separator	<u>PHYSICAL</u> Bristles , hair , dust, broken gaskets, stones, metal particles, wooden sticks and other food grain	1	2	2	[1] Unlikely to occur improper cleaning and Likely to occur during maintenance (after cleaning). [2] Improper air aspiration system may not get desired output. [3] Sieve cleaning and its integrity.	[1] An effective preventive maintenance program and routine (daily) inspection of equipment for wear or missing parts. SOP for Cleaning and Sanitation. [2] Proper aspiration system has been implemented and maintained. [3] Sieve integrity checking and replace record has been implemented and maintained.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Microbial contamination from material itself	2	2	4	[1] Unlikely to occur improper cleaning.	[1] Plant machinery cleaning and fumigation done as per defined frequency.	1	2	2	2	1	1	1	PRP

Raw wheat bin storage	<u>PHYSICAL</u> Bristles, hair , dust,broken gaskets, stones	2	2	4	[1] Unlikely to occur improper cleaning and Likely to occur during maintenance (after cleaning).	[1] An effective preventive maintenance program and routine (daily) inspection of equipment for wear or missing parts. SOP for Cleaning and Sanitation.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Microbial contamination form material itself	3	1	3	[1] Unlikely to occur improper cleaning.	[1] Routine frequency cleaning has been implemented and maintained. [2] Fumigation done as per defined frequency.	1	2	2	2	1	1	1	PRP
Destoner	<u>PHYSICAL</u> Bristles,dust,broken gaskets, stones, mesh condition	2	2	4	[1] Unlikely to occur improper cleaning and Likely to occur during maintenance (after cleaning). [2] Improper cleaning and maintenance activity hamper the integrity of the mesh. [3] Improper working of the destoner may result unseperation the	[1] An effective preventive maintenance program and routine (daily) inspection of equipment for wear or missing parts. SOP for Cleaning and Sanitation. [2] Preventive maintenance	1	2	2	2	1	1	1	PRP

					material.	carried out.											
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1				PRP
	<u>BIOLOGICAL</u> Bacterial proliferation occurs over time	2	2	4	[1] Unlikely to occur improper cleaning.	[1] Routine cleaning and fumigation of the machine carried out. [2] Hygiene clearance record also implemented and maintained.	1	2	2	2	1	1	1				PRP
<b>Surface Cleaner</b>	<u>PHYSICAL</u> Extraneous matter and crease dust, metal particles, husk removal.	2	1	2	[1] Effective PRP in place. Improper cleaning and operation of machine may increase the chance of the food safety hazards.	[1] Effective Preventive maintenance and supervision has been implemented and maintained. [2] Sieve integrity and condition checking and monitoring record.	1	2	2	2	1	1	1				PRP
	<u>CHEMICAL</u>	NA	NA		NA	NA	1	2	2	2	1	1	1				PRP

	<u>BIOLOGICAL</u> Chances of microbiological contamination due to improper cleaning or proliferation due to prolonged unclean surface of machine. Mud particles, wheat outer husk and crease microbes and dust	2	2	4	[1] Due to improper cleaning of equipment transfer surface contamination occur which will be food safety hazard. [2] Crease dust, wheat outer husk layer may increase the microbial contamination and may lead food safety risk.	[1] Hygiene clearance record has been implemented and maintained. [2] Preventive maintenance record implemented and maintained. [3] Sieve integrity checking and material pass through scourer.	1	2	2	2	1	1	1	PRP
	<u>PHYSICAL</u> Extraneous matter and dirt	1	1	1	[1] Effective PRP in place. Free of foreign material which constitute food safety hazards.	[1] Effective Preventive maintenance and cleaning in place. [2] monthly water tank cleaning carried out.	1	2	2	2	1	1	1	PRP
<b>Water feeding System</b>	<u>CHEMICAL</u> Non listed water treatment chemicals	2	1	2	[1] Improper quality of water.	[1] UV treated water is used in the processing and daily water analysis carried out. [2] External/Internal water testing carried out as per IS 10500.	1	2	2	2	1	1	1	PRP

	<p><b>BIOLOGICAL</b> Chances of microbiological contamination due to improper cleaning or proliferation due to prolonged unclean surface of machine and pathogen contamination from use of non potable water. Moisture content of the product.</p>	2	2	4	<p>[1] Due to improper cleaning of equipment transfer surface contamination occur which will be food safety hazard. [2] Moisture content and time ratio will affect on the product quality .i.e Acidity and shelflife may get affect in the final product.</p>	<p>[1] Cleaning after preventive maintenance maintained. [2] Moisture content of the wheat before water addition maintained in between 9 to 10 % for desired quality outout.</p>	1	2	2	2	1	1	1	PRP
Resting silo	<p><b>PHYSICAL</b></p>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<p><b>CHEMICAL</b></p>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<p><b>BIOLOGICAL</b> Improper storage may lead to microbial growth and moisture content of the product with affection of product quality and time.</p>	2	2	4	<p>[1] Time and moisture content may affect the product quality i.e. Acidity and shelflife of the product may affect.</p>	<p>[1] Proper moisture and time ratio monitored and for the desired quality output.</p>	1	2	2	2	1	1	1	PRP

<b>Magnet</b>	<u>PHYSICAL</u> Foreign metal matter contamination	2	2	4	[1] Product source and Machine it self.	[1] Periodically cleaning and checking of the magnet. [2] As per defined frequency magnets are calibrated.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
<b>Pneumatic lift through air lock</b>	<u>PHYSICAL</u> Flour dusting	1	1	1	[1] Improper cleaning of the lift.	[1] Proper cleaning carried out. [2] Preventive maintenance schedule carried out.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Material accumulation and air contamination	2	2	4	[1] Accumulated material and air may get contaminate the product.	[1] Cleaning of the machine carried out. [2] Fumigation of the machine and cleaning carried out. [3] Air filter provided in the input of air and changing as per defined frequency.	1	2	2	2	1	1	1	PRP

Screw conveyor	<u>PHYSICAL</u> foreign matter and sifter integrity	1	3	3	[1] Likely to occur rarely.	[1] Inspection are carried out. [2] Sifter integrity and foreign matter checking carried out.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Pathogen contamination from sifter and improper cleaning and material itself.	2	2	4	[1] Unlikely to occur improper clean and personel practice, material accumulation.	[1] Fumigation activity carried out. [2] Machine cleaning carried out and inspection.	1	2	2	2	1	1	1	PRP
Pneumatic lift to storage silo	<u>PHYSICAL</u> Flour dusting and foreign matter contamination.	2	2	4	[1] Rarely to occur foreign matter contamination due to improper cleaning, improper maintenance activity.	[1] Cleaning of the silo. [2] Air filter provided and preventive maintenance carried out.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Material accumulation	3	2	6	[1] Material accumulation contaminate the product.	[1] Proper cleaning activity carried out and fumigation of the machine with supervision carried out.	1	2	2	2	1	1	1	PRP

Flour storage silo	<u>PHYSICAL</u> Deflagration and foreign matter and metal contamination	3	2	6	[1] Likely to occur and if not proper monitoring and dur to flour deflagration.	[1] Storage of the flour and transfer to another silo to avoid deflagration. [2] Cleaning of the silo as per defined frequency.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u> N.A	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> microbial contamination from the matrial itself.	4	2	8	[1] Improper storage condition may contaminate the product.	[1] Fumigation carried out to avoid microbial contamination and cleaning with supervision.	1	2	2	2	1	1	1	PRP
Final Sieve	<u>PHYSICAL</u> Foreign matter contamination	4	4	16	[1] Unlikely to occure due to improper cleaning of the machine.	[1] Proper preventive maintenace schedulde carried out. [2] Weekly Cleaning of the machine aslo carried out. [3] Weekly sieve intigrity checking carried out. [4] Every 3 hours wheat flour seiving is carried out by quality	2	2	1	3	2	3	3	<b>CCP</b>
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP

	<u>BIOLOGICAL</u> Bacterial proliferation occur due to uncleaning of the machine.	2	2	4	[1] Unlikely to occur. [2] Improper fumigation activity.	[1] Preoper cleaning and fumigation activity carried out with supervision.	1	2	2	2	1	1	1	PRP
<b>Magnet</b>	<u>PHYSICAL</u> Foreign metal matter contamination	3	4	12	[1] Product source and Machine it self.	[1] Periodically cleaning and checking of the magnet. [2] As per defined frequency magnets are calibrated.	2	2	1	3	2	3	3	<b>CCP</b>
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
<b>Packaging of product</b>	<u>PHYSICAL</u> Dust and foreign matter, Packaging dust	2	2	4	[1] Unlikely to occur.	[1] Strong cleaning of the storage room. [2] QC verification done before packing and clean and material stored in covered condition.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u>	NA	NA	NA	NA	NA	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Microbial contamination due to presence of moisture.	2	2	4	[1] Microbial contamination in the product.	[1] Water activity of the product is very low to support any microbial growth	1	2	2	2	1	1	1	PRP

Storage	<u>PHYSICAL</u> Dust and cowebs	2	2	4	[1] Storage room condition.	[1]Storage of products away from wall, above the pallets or tarpaulin. [2] Effective cleaning of the storage room carried out.	1	2	2	2	1	1	1	PRP
	<u>CHEMICAL</u> Non food grade chemical	3	1	3	[1] Non food grade material storage may contaminte the product.	[1] Food grade and non food grade material are seperated and stored physically seperated.	1	2	2	2	1	1	1	PRP
	<u>BIOLOGICAL</u> Microbial contamination due to long stoarge of products or misplacement of bags, bird and rodent droppings	4	1	4	[1] Bird droppings,Excreta of Rats.	[1] Products to be stores in pallets or tarpaulin, away form wall with identifiacion as per QA approval with bag no, lot no and type of bag. [2] Effetive pest control progarmme implemented and maintained..	1	2	2	2	1	1	1	PRP
Dispatch	<u>PHYSICAL</u> External foreign matter contamination , dust.	2	2	4	[1] Rarely to occure.	[1] Dispatch of the product is in the closed container with properly covered condition.	1	2	2	2	1	1	1	PRP

<u>CHEMICAL</u> Chemical traces from vehicle	3	1	3	[1] Contamination through despatch vehicle.	[1] Effective cleaning of vehicles and QA clearance.	1	2	2	2	1	1	1	PRP
<u>BIOLOGICAL</u> Cross contamination from stacking and loading material employees, rain water cross contamination and pest roddent dropping in vehicle	4	1	4	[1] Likely to occur and bacterial proliferation occure. Personel hygiene. Contamination through vehicle.	[1] Strict monitoring and product recall procedure. Strictly follow personel hygiene. Efective cleaning procedure.	1	2	2	2	1	1	1	PRP

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## D. INSPECTION CHECKLIST

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

S. No.	Audit Question	Scoring	
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2	
<b>I</b>	<b>Design &amp; facilities</b>		
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*	<i>Potable water (meeting standards of IS:10500) is used as a product ingredient or in contact with food or food contact surface &amp; tested for quality semi annually. Check for records.</i>	4	
14	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2	
<b>II</b>	<b>Control of operation</b>		
15	Incoming material procured as per internally laid down specification & from an approved vendors. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2	
16	Raw materials is 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 practised.	2	
18*	<i>Requisite time and temperature is being achieved, maintained, monitored &amp; recorded while manufacturing/processing. Check for records.</i>	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	73

<b>III</b>	<b>Maintenance &amp; sanitation</b>		
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*	<i>Pest control program is available &amp; pest control activities are carried out by trained and experienced personnel. Check for records.</i>	4	
29	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2	
30	Drains are designed to meet expected flow loads and equipped with traps to capture contaminants.		
31	Food waste and other refuse are removed periodically from food handling areas to avoid accumulation.	2	
32	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	2	
<b>IV</b>	<b>Personal Hygiene</b>	2	
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*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails &amp; water proof bandage etc) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc).</i>	4	
36	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2	
<b>V</b>	<b>Training &amp; Complaint Handling</b>		
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*	<i>Appropriate documentation &amp; records are available and retained for a period of one year or the shelf-life of the product, whichever is more.</i>	4	

**Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable (NA)**

**Total points ...../90**

Asterisk mark (\*) questions may 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 –**

<input type="checkbox"/>	<b>A<sup>+</sup></b>	80 - 90	Compliance – Exemplar
<input type="checkbox"/>	<b>A</b>	72 - 79	Compliance – Satisfactory
<input type="checkbox"/>	<b>B</b>	45 - 71	Needs Improvement
<input type="checkbox"/>	<b>No grade</b>	<45	Non Compliance

## **E. PROFORMAS**

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# Mandatory Proformas

## 1.1 Medical Fitness Certificate for Food handlers

### PERFORMA FOR 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

FORM E  
Form of Guarantee

Date of sale	Nature and quality of article/brand name, if any	Batch No. or Code No.	Quantity	Price
1	2	3	4	5

Invoice No. \_\_\_\_\_

From: \_\_\_\_\_

To: \_\_\_\_\_

Place: \_\_\_\_\_

Date: \_\_\_\_\_

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 Proformas

### 2.1 Approved Supplier List

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

### 2.2 Incoming Vehicle Inspection Record

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 sharp edges / points in the interior of vehicle	
Any pests detected	
Any grease /oil detected	

Authorized Singature

## 2.3 Incoming Material Inspection

*Includes all type: Raw materials, Ingredients, Food additives, Processing aids, Packaging materials, Cleaning and sanitation chemicals, etc.*

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 (If applicable)		
Certificate Of Analysis (COA) received (Yes/No)		
Remarks		
Clearance Date		
Authorized Signatore		

## 2.4 Operation Log Sheet (Template for Temperature Control)

S.No.	Date	Time	Temp. Gauge Number	Specification / Range allowed	Actual Result	Remarks	Sign

## 2.5 Product Release Record

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

## 2.6 Non-conforming Material/Product

**HOLD:**

**REJECT:**

**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:**

**Corrective Action:**

**Preventive Action:**

**Remarks:**

*Signature:*

*QC Executive*

*Quality Manager*

*Mfg. Manager*

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## 2.7 Rework Record

<u>Batch No</u>	<u>Date</u>	<u>Qty</u>	<u>Material</u>	<u>Source</u>	<u>Time</u>	<u>Finished Product</u>

## 2.8 Outgoing Vehicle Inspection Record

Date of Outgoing Vehicle:

Vehicle Type:

Material in Vehicle to be dispatched:

Date of Manufacturing:

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 Singature

## 2.9 Product Recall record

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

## 2.10 Product Identification and Traceability

### Traceability Detail Format

#### Product Description

Plant Name:  
Product Name:  
Pack Size:

Manufacturing Date:  
Manufacturing Time:  
Batch/Lot no.:

#### Traceability Details

Investigation Date:  
InvestigationTime Start:

InvestigationTime End:  
Total Time Taken:

#### A. CIP Details

Equipment Name	CIP Details		Person responsible	Remarks
	Date	Time		

#### B. Ingredient Details

Material Description		Remarks
Name	Batch/Lot No.	

#### C. Water Treatment Details

Chemical/Material Description		Remarks
Name	Batch/Lot No.	

#### D. Primary Packaging

Material Description		Remarks
Name	Batch/Lot No.	

#### E. Manufacturing Details

Date	Shift	Cases Manufactured	CCP Compliance	Remarks

#### F. Analytical Details

Date	Shift	Analytical 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

## 2.11 List of Monitoring and Measuring Devices and Records of Calibration

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

## 2.12 Preventive Maintenance Schedule

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 Preventive Maintenance Record

Machine/Equipment Name.:

Machine/Equipment No.:

Location:

S.No.	Maintenance Check Point	Frequency of check					Signature	Remarks
		Daily	Weekly	Monthly	Half Yearly	Yearly		

## 2.14 Pest Management Plan

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

## 2.15 Pest monitoring record

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

## 2.16 Monitoring of Personnel hygiene

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															

*Jewellery* wrist watches, cufflinks, ear rings, glass bangles, stick bindis

## 2.17 Customer/ Consumer Complaint Log

Complaint Number: \_\_\_\_\_

Date: \_\_\_\_\_ Time recorded: \_\_\_\_\_  am  pm

Quality related:  Food safety related:

**Customer Details**

Customer Name: \_\_\_\_\_

Phone: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_

State/Province: \_\_\_\_\_ Zip code: \_\_\_\_\_

Email: \_\_\_\_\_

**Product Consumed**

Product name: \_\_\_\_\_

Batch Code/Lot no.: \_\_\_\_\_

Package size: \_\_\_\_\_

Location purchased: \_\_\_\_\_

Date of purchase: \_\_\_\_\_ Date consumed: \_\_\_\_\_

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

## 2.18 Training Record

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				

## 2.19 Training Effectiveness record

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							
7							
8							
9							
10							

Effectiveness can be based on: Improvement in quality of work, Improvement in work output, Behavioural change, Overall usefulness of training, etc.

DRAFT