

GUIDANCE DOCUMENT

FOOD SAFETY MANAGEMENT SYSTEMS

***FOOD INDUSTRY GUIDE TO IMPLEMENT GMP/GHP
REQUIREMENTS***



MILK AND MILK PRODUCTS

Food Industry Guide to implement GMP/GHP requirements

MILK AND MILK PRODUCTS

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

First Edition February 2018

Online available at 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 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

This Guidance Document on Food Safety Management System (FSMS) is prepared with the intent to provide implementation guidance to food businesses (especially the small and medium businesses) involved in manufacturing/processing, packing, storage, distribution, retail and transportation of Food Supplements, 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 whole supply chain of Milk and Milk products are trained appropriately to implement the good manufacturing practices and good hygiene practices to ensure food safety.

We acknowledge the contribution of the experts from the technical panel of FSSAI for developing this document.

Pawan Agarwal – CEO, FSSAI

SCOPE

This document is applicable for food businesses involved in the Dairy sector which includes all milk and milk products:

- a) Liquid Milk
- b) UHT milk, condensed milk, fermented milk and flavoured milk
- c) Ghee, butter, cream
- d) Dairy Whitener (WMP & SMP)
- e) Curd, yoghurt, butter milk, paneer, cheese

All the above product categories may or may not be handled by the same facility. Hence, based on the product category handled, a food supplement 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 dairy 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 III of Schedule 4 of Food Safety & Standard (Licensing & Registration of Food Businesses) Regulation, 2011. The document has all 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 manufacturing flow chart & 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) along with recommended corrective actions and other related information. Sample HACCP Plans have been taken from some established practising dairy industries. These 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.

TECHNICAL EXPERTS, REVIEWERS & CONTRIBUTORS

Dr. S.K Bhalla
Director, M/S Gopaljee Dairy Foods Pvt. Ltd.

Mr. Kuldeep Sharma
Suruchi Consultants

Ms. Shabnam Chopra
In-charge QA, Head PCDF, Lucknow

Mr. Keyur M. Ghodke
GCMMF Ltd.,Amul, Anand

Dr. Kajal Debnath
Head – Regulatory Affairs, Mother Dairy

Dr. D K Sharma
GM (QA & PPD), NDDB

Mr Vijay Gaur
Sr. Regulatory Affairs Manager, Danone India

Dr. Anirudha K. Chhonkar
Corporate Regulatory Advocacy Manager, Nestle India Ltd.

Dr. B B Garg
Consultant

Mr. R.K Gupta
DC(DD), MOA & FW DADF

Dr. Rubeena Shaheen
Director, FSMS Div., FSSAI

Dr. Sujata Singh
Assistant Director, FSMS Div., FSSAI

Contents

Glossary.....	7
A. OVERVIEW OF MILK INDUSTRY IN INDIA.....	8
B. PRE-REQUISITE PROGRAMMES	9
I. ESTABLISHMENT – DESIGN AND FACILITIES.....	10
1. Location and Surroundings	10
2. Building Design, construction & Layout.....	10
3. Equipment Design and Installation.....	12
4. Facilities/ Utilities.....	13
II. ESTABLISHMENT - CONTROL OF OPERATIONS.....	20
1. Supplier Approval and Food receipt	20
2. Storage and Material Control	20
3. Milk Processing	21
4. Milk and Milk Product Packaging and Warehousing	24
5. Rework & Control of Non-Conforming Product.....	26
6. Transportation & distribution	27
7. Traceability and Recall	29
8. Quality Control & Testing.....	30
III. ESTABLISHMENT - MAINTENANCE AND SANITATION.....	36
1. Cleaning and Sanitation	36
2. Maintenance	41
3. Animal and Pest control.....	43
4. Drainage and Waste Disposal	45
IV. ESTABLISHMENT - PERSONAL HYGIENE AND EMPLOYEE FACILITIES.....	46
1. Health Status and Illness & Injury	46
2. Personal Cleanliness.....	46
3. Personal Behaviour	47
4. Work wear and Grooming.....	47
5. Visitor Control	47
V. ESTABLISHMENT - PRODUCT INFORMATION AND CONSUMER AWARENESS	48
1. Product information and Labelling	48

2. Consumer Awareness and complaint Handling	48
VI. ESTABLISHMENT - TRAINING AND MANAGEMENT	49
1. Awareness and Responsibilities	49
2. Training Program.....	49
3. Instruction and supervision	49
4. Refresher Training.....	49
5. Management and Supervision	49
VII ESTABLISHMENT – AUDIT, DOCUMENTATION AND RECORD KEEPING	51
1. Self-evaluation and review	51
2. Documentation and records	51
C. SUBCONTRACTING OPERATIONS.....	53
1. Terms of Agreement/ Contract.....	53
2. Technical Agreement.....	53
D. HACCP IMPLEMENTATION.....	54
I. INTRODUCTION TO HACCP.....	54
II. APPLICATION OF HACCP SYSTEM.....	56
1. HACCP Implementation steps.....	56
2. HACCP Plan.....	60
E. INSPECTION CHECKLIST.....	73
F. PROFORMAS/TEMPLATES	76
ANNEXURE 1: GMP and GHP to be followed at the level of village collection, MCC and BMC level	88
ANNEXURE 2: Sample design and layout of milk processing plant.....	89
ANNEXURE 3: Floors for dairy manufacturing facilities	92
ANNEXURE 4: General guide to packaging material	93
ANNEXURE 5: Milk Condensate Recovery	94
ANNEXURE 6: Recommended MILK CONDENSATE RECOVERY (CoW Water RO Plant)	95
ANNEXURE 7: Relevant BIS Standards adopted in FSSAI	97

Glossary

FBO – Food Business Operator

UHT – Ultra High Treatment

CAGR – Compound Annual Growth Rate

SOP – Standard Operating Procedure

IPM – Integrated Pest Management

MS – Mild steel

COA – Certificate of Analysis

QC – Quality Control

CIP – Cleaning In Place

CAPA – Corrective Action Preventive Action

SS – Stainless Steel

FIFO – First In First Out

FEFO – First Expired First Out

FMFO – First Manufactured First Out

HACCP – Hazard Analysis & Critical Control Point

CCP - Critical Control Point

RH – Relative Humidity

VLC – Village Level Collection

BMC – Bulk Milk Cooler

MCC – Milk Chilling Centre

SMP – Skim Milk Powder

WMP –Whole Milk Powder

A. OVERVIEW OF MILK INDUSTRY IN INDIA

India has been the leading producer and consumer of dairy products worldwide since 1998 with a sustained growth in the availability of milk and milk products. Dairy activities form an essential part of the rural Indian economy, serving as an important source of employment and income. India also has the largest bovine population in the world. However, the milk production per animal is significantly low as compared to the other major dairy producers. Moreover, nearly all of the dairy produce in India is consumed domestically, with the majority of it being sold as fluid milk. On account of this, the Indian dairy industry holds tremendous potential for value-addition and overall development. According to the latest the dairy market in India reached a value of INR 7,916 Billion in 2017. Despite this, the majority of the Dairy Industry in India is still highly unorganised dominated by small and marginal dairy farmers. As the industry possesses huge untapped opportunities, it has attracted a number of private companies and investors. In addition, the Indian government has also been taking initiatives towards the development of the dairy sector by providing support to the milk cooperatives and rural milk producers. Moreover, the sustained growth of the Indian economy has led to a rise in the spending power of consumers, rapid urbanisation as well as changes in the dietary patterns. With an increase in the working population, hectic lifestyles and increasing health consciousness among the consumers, there has been a shift towards healthy and ready-to-eat dairy products.

Along with offering profitable business opportunities, the dairy industry in India serves as a tool of socio-economic development. Keeping this in view, the Government of India has introduced various schemes and initiatives aimed at the development of the dairy sector in the country. For instance, the “National Dairy Programme (Phase-I)” aims to improve cattle productivity and increase the production of milk expanding and strengthening and expanding the rural milk procurement infrastructure and provide greater market access to the farmers. On the other hand, the private participation in the Indian dairy sector has also increased over the past few years. Both national and international players are entering the dairy industry, attracted by the size and potential of the Indian market. The focus is being given to value-added products such as cheese, yogurt, probiotic drinks, etc. They are also introducing innovative products keeping in mind the specific requirements of the Indian consumers. These players are also improving their milk procurement network which is further facilitating the development of the dairy industry in India. Looking forward, the market is expected to reach a value of INR 18,599 Billion by 2023, exhibiting a CAGR of around 15% during 2018-2023.

B. PRE-REQUISITE PROGRAMMES

I. ESTABLISHMENT – DESIGN AND FACILITIES

1. Location and Surroundings

- i. The milk and milk products production facility shall be situated away from environmentally polluted areas like open sewage, drain, public lavatory or any factory which produces disagreeable or obnoxious odour, fumes, excessive soot, dust, smoke, chemical or biological emissions to avoid risk of contamination from external environment. In case it is already existing, appropriate control measures shall be taken.
- ii. The site boundaries shall be clearly identified with appropriate access control to prevent the chances of theft and sabotage. Dogs, cats or other pet animals should not be allowed to enter the premises.
- iii. The manufacturing premise shall not have direct access to any residential area.
- iv. 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.
- v. The surrounding areas of the establishment shall be kept in good order. Roads, yards, parking lots outside the factory building should be free of debris and refuse, and from any source of pollution.
- vi. There should not be any stagnant water surrounding the facility. Where buildings are surrounded by grassed or planted areas, a clear space should be provided between the grassed planted areas and the building. Such grassed/planted areas should be regularly tended and maintained.

2. Building Design, construction & Layout

2.1 Building Design & Layout

- i. The design and layout shall be such as to preclude contamination. The establishment shall be housed in a building of permanent nature affording sufficient protection from the environmental contamination.
- ii. The layout of different sections shall be such as to facilitate smooth and orderly flow of work and to prevent possible cross contamination and backtracking.
- iii. There shall be adequate lighting and ventilation and light fixtures shall be protected with proper covering.
- iv. The layout shall ensure sufficient space in different sections for machinery, equipment, personnel etc. without congestion.
- v. The building shall provide sufficient protection against the entry and harbourage of rodent, insects, animals etc. Entry points shall have suitable air curtains/fly killers or other suitable arrangements to prevent the entry of flies/insects.
- vi. Non-operative areas inside the establishment shall be properly cordoned off to avoid possible cross-contamination.
- vii. There shall be a raised platform for receiving the material and the sides and roof of the platform shall be so constructed to provide protection from extraneous contamination.
- viii. Raw milk receiving section shall be sufficiently separated from processing area to prevent cross contamination.
- ix. Signboards directing the employees to wash and sanitize hands before entering and after each absence shall be installed.
- x. Narrow windowsills are recommended with the slope of at-least 45° to prevent buildup of dust as well as items being left there.

- xi. Infrastructure for cleaning tanker from outside and milk contact surface of barrel after unloading milk.

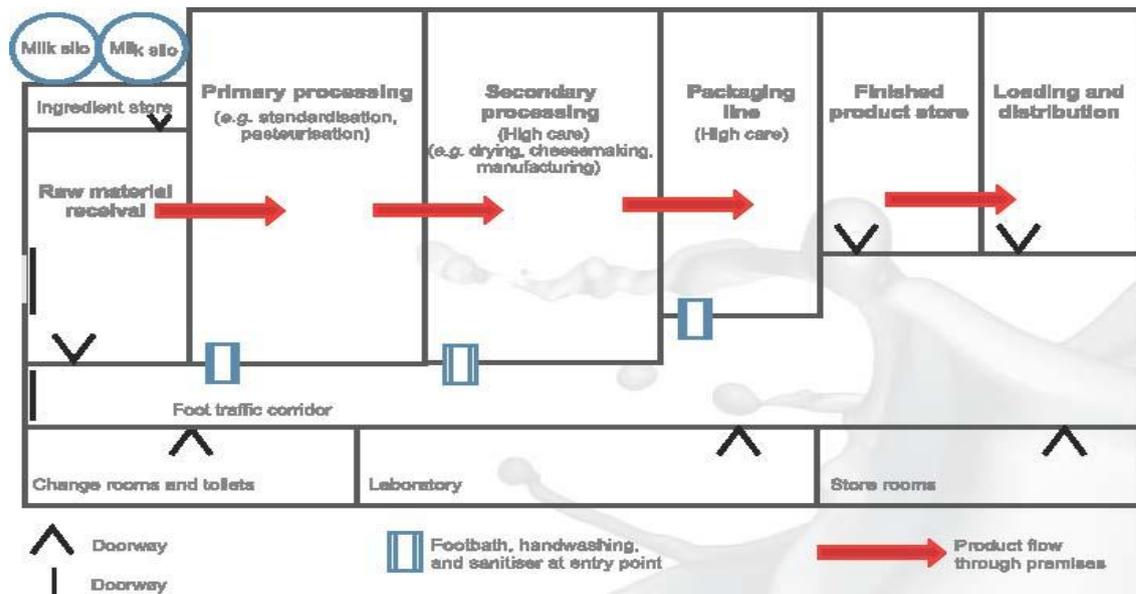


Figure 1: Example of plant layout with a one-way flow

2.2 Internal Structures

All interior structures (including floors, walls, ceilings, doors, windows, partitions, overhead fixtures, working surface, stairs, elevators, etc.) shall be soundly constructed of materials that are durable, impervious to food particles, grease and water, with no toxic effect in intended use, shall be unable to provide pest harbourage, as far as practicable; and be easily and effectively cleaned and where appropriate, disinfected. Structures where glass breakage could result in the contamination of food, shall be constructed of alternative materials or be adequately protected. Well integrated to avoid crevices. Hollow space shall be minimized. Gaps need to be minimized at all levels of building for steel structured buildings in particular. All edges must be rounded off, pillars must be chamfered and any flat surface arising out of structured must be smoothed with a slope to avoid dust accumulation at any stage. In addition, following specific conditions are necessary to be met to protect the safety and suitability of food:

2.2.1 Walls and Partitions

- i. They shall be soundly constructed of materials that are durable, cleanable, and impervious to food, grease and water with no toxic effect in intended use. For example: emulsion oil paint (which is easily cleanable by wiping); tiles (which are less porous and causes less crevices).
- ii. Premises shall be free of flaking paint and plaster to prevent the accumulation of dust, minimise condensation, and shredding of particles.
- iii. Wall floor joints should be curved in processing and packaging areas to facilitate cleaning.
- iv. Wall and pillar guards (SS) should be used to avoid daily wear and tear of the surfaces.
- v. Floor shall be sloped appropriately, to allow adequate drainage such as 1/4" per foot slope for processing hall, 1/8" per foot slope for cold store etc. for proper cleaning, and non-slippery prevent water stagnation on the floor.
- vi. Sealed to prevent the entry of dirt, dust and pests.
- vii. The wall to floor and wall-to-wall junctions shall preferably be rounded off to facilitate easy cleaning.

- viii. The walls shall be durable, smooth and easy to clean and disinfect. The walls shall preferably have glazed tiles/ other tiles up to a height of minimum six feet.
- ix. All floor areas coming under plant and machineries shall be visible, accessible and cleanable as much as possible.
- x. All the provisions made on the walls for crossing over of process and utilities pipes and electric cable trays etc. shall be sealed properly for any kind of dust accumulations along with harbouring of insects and pests.
- xi. If structural elements or fittings are suspended below the ceiling, suitable protection shall be given to prevent falling of debris and dust.

2.2.2 Ceilings and overhead fixtures

- i. **Ceilings-**
 - Shall be maintained in sound condition and constructed of materials that are durable, cleanable, and impervious to food, grease and water with no toxic effect in intended use.
 - Shall be sealed to prevent the entry of dirt, dust and pests.
 - Shall be free from flaking paint or plaster.
 - The ceiling shall be free from cracks, flaking paint or plaster and open joints, finished and maintained to minimize the accumulation of dust, condensation, mould growth, and shedding of particles and shall be smooth and easy to clean. The area covered under false ceiling shall be accessible for inspection and cleaning.
- ii. **Overhead fixtures**
 - Shall be suitably protected so that they do not act as contaminants in case of breakage.

2.2.3 Floors

- i. Shall be non-slippery, sloped appropriately, to allow adequate drainage. The drainage shall flow opposite to the flow of manufacturing process flow.
- ii. Shall be maintained in good repair with no cracks and crevices.
- iii. Shall be made of materials that are durable and easy to clean such as Epoxy coated floors or PU flooring or any other suitable flooring. Wet cleaning should be avoided. This causes slippery. Sweeping and mopping is more appropriate and cost effective.
- iv. The floor and the walls should not be damp or moist.
- v. The floor of the processing areas shall be smooth, impermeable and easy to clean and disinfect. Sample of floors for dairy manufacturing facilities is enclosed as Annexure.

2.2.4 Doors

- i. Shall have smooth, non-absorbent surfaces. Wooden doors are not recommended as it promotes mould growth, termites with ageing.
- ii. Shall be easy to clean.
- iii. Shall be close-fitting and with suitable precautions to prevent entry of pests.
- iv. Gaps if any between the door and the floor should be closed with suitable material like rubber strips, polyurethane etc. to avoid pest entry.
- v. To ensure dust, insects, birds and animals to be kept out of the premises entry/exit points should be suitably protected with such as strip PVC/air curtains/ doors with automatic self-closing devices etc.
- vi. External opening windows, roof vents or exhaust fan, where present, shall be adequately screened to avoid any external pest ingress.
- vii. Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes should be so situated and constructed as not to cause contamination of milk and milk products. They should also be well maintained.

3. Equipment Design and Installation

- i. Equipment and containers that come in direct contact with food (including food contact surfaces) and used for food handling, storage, processing, packing shall be:

- Located, designed and fabricated so that it permits necessary maintenance and periodic cleaning.
 - Kept in good order, repair and condition as to minimize any risk of contamination. These include free from cracks, crevices, open seams etc.
 - Made of impervious, corrosion free material which do not impart any toxicity to the food material and shall be easy to clean.
 - Chipped enamelled containers should not be used. SS/Al/glass containers, mugs, jugs, trays etc. suitably for cooking & storing shall be used.
 - Shall be placed to achieve easy and effective cleaning of adjacent areas like floors, walls, ceilings and other surfaces.
- ii. Equipment, containers and piping should be clearly labelled and identifiable especially, equipment and containers for waste, by-products & inedible or dangerous substances.
 - iii. 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.
 - iv. Manufacturing vessels, pipework, and material handling equipment are well bonded and smooth to prevent material build up and promote sanitary conditions.
 - v. Hygienic design features may include:
 - Pipes shall be sloped, with no dead-legs or right-angled bends,
 - Domed tops, curved sides, conical bases for vessels/tanks.
 - Flexible hoses shall have a smooth (not ribbed) internal surface and have fittings which are sanitary and easy to connect/disconnect
 - vi. All utensils/ container containing food products shall be covered with a properly fitted cover/lid or with clean gauze net/ any other material. This helps to completely protect food from dust, dirt, flies and other insects.
 - vii. All equipment should be placed and installed at a distance from the walls.
 - viii. All relevant equipment shall be labelled with their SOPs.
 - ix. In case, the equipment & utensils are also used for purpose other than preparation of milk and milk products, adequate control measures shall be implemented such as cleaning, sanitization etc. to ensure avoidance of cross-contamination.
 - x. There shall be appropriate facilities for cleaning and disinfecting the food contact equipment and instruments, and wherever possible Clean-In-Place (CIP) should be adopted.
 - xi. Equipment should be elevated on legs or/and wheels to provide clearance between the floor and equipment. The legs shall contain no hollow open ends.
 - xii. Defective equipment shall, if possible, be removed from production and quality control areas. If the equipment is such that they cannot be removed, they should be clearly indicated with their status.

4. Facilities/ Utilities

4.1 Boiler/Steam generation/Hot water generation

- i. The dairy processing unit shall have adequate capacity boiler/hot water generator for generating steam/hot water to cater to the requirements of processing and allied activities.
- ii. Boiler system shall have calibrated and functional gauges to indicate and control temperature, pressure of the system.
- iii. Properly designed pressure reduction station shall be in place and operational to ensure distribution of steam of required pressure from boiler to necessary areas/equipment.
- iv. Boiler system shall be connected to the plant facilities through well laid insulated pipes with condensate drain channels to remove/drain off condensate water from the lines.
- v. The water used for steam generation shall cater to requirements prescribed in IS 4251:1967
- vi. Steam generated from the boiler shall be filtered to remove any extraneous matter/dirt. Steam coming into direct contact with raw/finished product shall be of culinary grade and shall be filtered through necessary micro pore filters to ensure the same.

- vii. Boiler systems should be tested for pressure and structural integrity at prescribed intervals to ensure operational and safety aspects.
- viii. Boiler shall be operated by trained/qualified manpower as stipulated in law.
- ix. Boiler area shall be equipped with fire fighting mechanisms. Necessary precautions shall be taken to prevent fire/accidents in the boiler area
- x. Exhausts gases from the boiler system shall be discharged as per the prescribed pollution control regulations.
- xi. Access to boiler area should be limited and restricted.

4.2 Refrigeration System

- i. The dairy processing unit shall have adequate mechanical refrigeration system to cater to processing and storage requirements.
- ii. The refrigeration system shall be equipped with necessary temperature gauges, pressure gauges, strainers and filters to ensure smooth and efficient operations.
- iii. The gauges and control devices shall be functional and calibrated periodically
- iv. Necessary industrial safety precautions shall be taken to avoid mishaps occurring due to fire/refrigerant gas leakage.
- v. Periodic maintenance of the working elements of refrigeration system viz- compressor, condenser, throttle valves, evaporator coils/plate etc shall be undertaken to ensure safe and smooth operation.
- vi. Gas/liquid receiver tanks should be periodically tested for pressure and structural integrity.
- vii. Refrigeration's system shall be operated by trained and qualified manpower.

Ice bank tank (IBT) system

IBT is part of the refrigeration system in dairy processing units. IBT supply chilled water

- i. The dairy processing unit shall have necessary capacity IBT to for chilling raw and processed milk.
- ii. Water used in IBT shall adhere to the standards specified in IS 4251:1967
- iii. IBT shall be equipped with calibrated temperature gauges for recording and maintaining the necessary temperatures.
- iv. IBT water shall be periodically inspected for their visual quality and drained/replaced accordingly to comply with the requirements of IS 4251:1967.

4.3 Water Treatment plant

Dairy processing units shall have functional water treatment plant. It may comprise of following elements – Softener units, RO plants, Ultra/Nano/Micro filtration, UV/Sand/Activated charcoal filters and should be suitable to provide water as per prescribed quality in IS 4251: 1967 and IS 10500:2012.

- i. Softener units shall be of adequate capacity to supply water to boiler/processing and CIP plants
- ii. Areas with water having high TDS may be equipped with RO plants to supply water with low levels of dissolved solids
- iii. Sand/activated charcoal filters should be used to remove suspended particles/dust.
- iv. Water storage tanks/sumps/overhead tanks shall be cleaned at-least once in six months and inspected to maintain hygienic conditions.
- v. Access to water treatment plant/storage areas shall be limited.

4.4 Chillers & Cold room

- i. Chill rooms having adequate size with mechanical refrigeration system to maintain temperature at the required level as per the requirements of the product shall be provided in the processing section or outside.

- ii. The cold storage shall have suitable refrigeration system to maintain the required product temperature.
- iii. Doors should have proper gasket and lock system.
- iv. The floor, ceiling and walls of the cold storage and other storage rooms shall be smooth and easy to clean and disinfect.
- v. Proper steps shall be taken to avoid contamination of the materials stored.
- vi. There shall be adequate lighting with protective covers.
- vii. Walk in areas/ante rooms should be present outside the chilling rooms.

4.5 Water Supply

- i. Adequate supply of potable water shall be available to meet operational needs.
- ii. Water including steam/Ice used as a product ingredient or in contact with food or food contact surfaces or used for equipment and plant cleaning shall be potable.
- iii. Potable water quality shall be as specified in the latest edition of BIS standard on drinking water (IS 10500). Potable water shall be analysed at least semi-annually to confirm that it meets the requirements of this standard.
- iv. 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 periodic cleaned 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.
- v. Where water filters are used, they shall be regularly monitored or effectively maintained.
- vi. Recycled water used in processing or as an ingredient shall not present risk of contamination. It shall be of the same standard as potable water.
- vii. Non potable water (for use in, for example, steam production, firefighting & refrigeration equipment and other similar purposes where it will not contaminate food) shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.
- viii. The material of construction of pumps, valves, storage and distribution skids shall be non-reactive, non-corrosive, non-leaching and sanitary in design.
- ix. Water lines (used in internal Cleaning & as ingredients) shall be clearly separated and identified from others. Color coding of separate pipelines for potable water and non-potable water is recommended.

4.6 Personnel hygiene and employee facilities

4.6.1 Personnel Hygiene Facilities

- i. Personnel hygiene facilities shall be available to ensure that an appropriate degree of personal hygiene can be maintained to avoid any cross contamination. Such facilities shall be suitably located & designated.
- ii. Facility shall have following facilities- hand washing, lavatories, changing facility, rest and refreshment room. Such facility shall be suitable located and designated.

4.6.2 Hand washing facilities

- i. Facility with hot and cold or suitable temperature controlled potable water with suitable hygienic means of drying hands can be provided in such a position that the employee must pass them when entering the processing areas. This will help employees to automatically get an alert for hand washing without a miss.
- ii. Where hot and cold water are available, mixing taps should be provided.
- iii. Hand washing notices shall be posted on walls near hand wash stations.
- iv. Non- Perfumed liquid soap should be used in dispensers to wash hands as soap bars are a potential source of cross contamination.

- v. The design of taps should be such that there is no hand contact after washing while closing the taps. Preferably, elbow or foot operated taps are used in food manufacturing units.

4.6.3 Hand drying and sanitizing facility

- i. Hand drier where installed should be in working condition at all the times during working hours.
- ii. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near to each washing facility. Paper towel rolls should be covered from top at all time to avoid dust and dirt on them.
- iii. Generally, and preferably, hand driers are considered better than paper towels based on cost efficiency and effectiveness.
- iv. The dustbins used to throw the used-paper towels, should be foot-operated. This avoids any direct hand contact (washed hands) to open the dustbin.
- v. Self-drying hand sanitizer should be provided and should be used after drying of hands. This is the next step of disinfecting hands after cleaning.

4.6.4 Lavatories

- i. Lavatories shall be separate from other areas and shall not be directly connected to the storage and manufacturing areas.
- ii. Sufficient number and separate toilets/urinals for male and female should be provided. Industry best practice of 1:25 is followed for facility: employee ratio.
- iii. Adequate supply of water should be provided in toilets and urinals. Potable water should be used at the toilet wash basin stations, as the employees may need to touch food items while in production areas.
- iv. All toilet facilities should be clean and sanitized at all times of the working hours.
- v. Toilets should be so designed so as to ensure hygienic removal of waste matter.
- vi. Toilets should be well lit and ventilated and should not open directly into food handling areas.

4.6.5 Changing facilities

- i. Suitable and sufficient facilities for persons working in the processing areas should be provided for changing their clothes, keeping their personal belongings and Street footwear.
- ii. Separate areas should be provided for home personal clothes and company uniforms (in case there is a designated full uniform used by employees during processing).
- iii. It is advisable to also have a separate room between changing room and the processing rooms. This room should provide a kind of hygiene barrier between the working rooms and the changing rooms. Also, there can be facilities for storing necessary required items.
- iv. It is also recommended that the entrance from the outside to changing rooms and exit from there to the processing rooms are separated.
- v. Factory Footwear should be cleaned periodically and not to be used for external purposes

4.6.6 Rest and refreshment room

- i. Rest & Refreshment Rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas,
- ii. Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods.
- iii. Employees' own food shall be stored and consumed in designated areas only away from Process & storage area. Tiffin's and personal belongings also shall not keep in Lockers.

Note: A display board mentioning 'Dos' and 'Don'ts' for workers should be posted in a prominent place inside the premises, in English or local language, for all to understand. This will help all the employees to maintain their alertness on good hygiene practices.

4.7 In-house laboratory

The establishment shall have a well-equipped in house laboratory for testing microbiological and other chemical parameters. The testing shall be done by qualified and trained lab persons/veterinarian/Microbiologist/Dairy technologist (s).

4.8 Storage facilities

Separate stores for raw milk, finished products, chemicals and packing materials. Sufficient pallets are placed for storage of products. Where necessary, adequate facilities for the storage of food, ingredients, packaging, non-food chemicals and hazardous substances (e.g. cleaning materials, lubricants, fuel) shall be provided. The food storage facilities shall be designed and constructed to:

- i. Provide protection from dust, condensation, waste, pest access and harbourage and other sources of contamination.
- ii. Be dry, well ventilated and enable monitoring and control of temperature and humidity in storage areas where specified.
- iii. Be easy to maintain and clean. All materials and products shall be stored off the floor and away from the walls to allow inspection and pest control activities to be carried out.

Separate secure storage facilities for non-food chemicals and hazardous substances shall be provided. Such facilities shall be located where there is no possibility for cross-contamination of food or food contact surfaces.

4.9 Transportation Facilities

- i. Establishment shall have suitable and adequate facilities for the transportation of raw material, finished product etc. Vehicle shall be properly maintained. Food contact surface shall be made of non-corrosive material, smooth and easy to clean and disinfect.
- ii. Pre-chilling of the transport system should be done before loading wherever applicable.
- iii. Temperature should be checked during shipping, loading and unloading.
- iv. For frozen foods, proper curtains should be used to maintain the cold temperature in the vehicle during product loading.
- v. Vehicles should be regulated with temperature controller.
- vi. Proper maintenance of vehicle shall be done to avoid any abnormal vehicular emission which may contaminate food.
- vii. Washing and disinfecting of vehicle should be done after regular intervals

4.10 Waste disposal and drainage

- i. Dairy has two kinds of waste disposal i.e. solid waste and liquid effluent. There shall be a separate space in the premises for collection of waste material.
- ii. Containers for holding garbage shall be of adequate size, made of impervious material, leak-proof, clearly identified, easy to clean, and to disinfect. It should be kept closed, preferably foot operated.
- iii. Waste shall be segregated into wet and dry garbage and shall be removed periodically.
- iv. It shall be kept closed, preferably foot operated or arrangements for waste disposal at regular intervals shall be put in place.
- v. Drains shall be designed to meet expected flow loads, constructed so as to prevent accumulation or back flow of waste water. Drains shall be located so that they can be easily and effectively cleaned and inspected.
- vi. Drainage shall be equipped with appropriate traps to effectively capture contaminants.

- vii. Wherever existing, refuse stores shall be designed and managed in such a way as to enable them to be kept clean and free from animals, birds and pests.
- viii. Disposal of waste shall be done in a hygienic way in accordance with local solid waste management rules which are enforced from time to time.
- ix. Dairy processing facilities shall be equipped by suitable capacity Effluent treatment plant (ETP) to ensure effluent discharge conforming to PCB norms and regulations.
- x. ETP shall be separately located, away from the operational/processing area but within the premises.
- xi. The drain connecting processing area and ETP sump tank shall ensure no backtracking/reverse flow.
- xii. The hazardous waste from ETP shall be discharged as per PCB norms.
- xiii. ETP area shall be free from pests/animals/over grown vegetation growth.
- xiv. Discharges from ETP should be regularly tested for quality and conformance to PCB norms & regulations.

4.11 Cleaning facilities

- i. Adequate facilities, suitably designated shall be provided for cleaning food, utensils and equipment.
- ii. These facilities are to be constructed of corrosion resistant materials, be easy to clean and shall have an adequate supply of hot and cold potable water, where appropriate.
- iii. Utensil and equipment cleaning and sanitizing facilities shall be separated from food processing, storage, distribution and handling areas to prevent contamination.

4.12 Temperature control

Depending on the nature of the food operations undertaken, adequate facilities shall be made available for heating, cooling, cooking, refrigerating and freezing of food, monitoring & recording food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

4.13 Air quality and ventilation

- i. The air shall not flow from contaminated to clean areas, the ventilation systems shall be so designed.
- ii. Air filters, exhaust and air intake ports shall be examined periodically for physical filter integrity.

Product	Temp °C	RH %	Filter
Milk Powder	20 to 30	≤ 50	EU7
SCM	26	≤ 60	EU7
UHT	26	≤ 60	EU7
Chilled Dairy	26	≤ 60	EU7

Air Filter Class:

Filter type Efficiency %	Fractional efficiency % at different particle sizes			Dust spot efficiency as per Eurovent 4/5	Filter Class according to Eurovent 4/5
	0.35-0.45 µm	0.75-1.0 µm	2.0-3.0 µm		
40-50	6-12	10-15	60-65	40-50	EU5
-65	20-25	40-45	85-90	60-65	EU6
-85	63-70	80-85	90-95	80-85	EU7
-95	84-88	95-99	99-100	93-97	EU8/9

4.14 Lighting

- i. Adequate natural or artificial lighting shall be provided to enable the personnel to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading.
- ii. The intensity (that is, the lux level) should be adequate to the nature of the operation. Recommended lux level for processing areas) is at least 540 LUX, as per USFDA Food Code 2013.
- iii. Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in the case of breakages.

Area	Min Lighting requirement	Remarks
Processing areas	500 lux	RMRD, Pasteurisation, Cream separation
Product Manufacturing	500 lux	
Tanker reception	300 lux	Unloading area, washing
Inspection areas	1000 lux, with natural light color correction	
External areas	150 lux	
Storage areas	150 lux	

4.15 Compressed air and other gases

- i. Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.
- ii. Compressed air / gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water to ensure microbial quality and should be checked at least once in a year.
- iii. It is recommended to have an oil free Compressed air system.
- iv. The system shall be able to supply compressed air as per the operational requirements
- v. Compressed air shall be filtered and shall be free of extraneous matter dust/dirt/oil/rusting/moisture etc.
- vi. Compressed air system shall be equipped with necessary pressure, temperature and humidity gauges which are functional and periodically calibrated.
- vii. Wherever compressed air storage tanks are used they should be tested for pressure and structural integrity at periodic intervals.

Solid Contaminants		Water	Oil (Hydrocarbons)
Maximum particle size (µm)	Maximum concentration (mg/m ³)	Dew point of compressed air (°C maximum)	Maximum content (mg/m ³)
1.0	1.0	+2	0.01

II. ESTABLISHMENT - CONTROL OF OPERATIONS

These principles are intended to be applied in such a manner as to result in meeting acceptable levels of relevant hazards specified as Food Safety Objectives and/or related objectives and criteria, or end product criteria that have been established to express the level of protection for the specific situation.

1. Supplier Approval and Food receipt

- i. Vendor Quality Development Programme laying down the criteria for selection, approval, review and on going approval should be implemented.
- ii. All raw material, processing aids, ingredients consignments shall be procured from the vendors approved by FSSAI/FDA/ Ayush and registered or licensed from other regulatory authorities. An approved vendor should be evaluated as per the quality supplied and other relevant factors.
- iii. Raw materials received shall be according to the storage and processing capacity of the processing plant.
- iv. All raw materials and ingredients, wherever applicable, shall conform to all Standards laid down under the relevant regulations.
- v. All raw materials, ingredients and packing material and processing aids, wherever applicable, shall be inspected and sorted before processing. The manufacturer shall have procedures in place to confirm that the incoming materials meet the documented specifications through certificate of analysis, visual inspection, laboratory testing, review of label for allergens etc.
- vi. Records of raw materials or ingredients or any other material used in processing as well as their source of procurements shall be maintained for traceability.
- vii. All bulk tankers/ containers receipt if any shall be checked for seal integrity / previous cargo / inspection checklist at the time of receipt (see Annexure).
- viii. All packaged raw materials shall be checked for 'expiry date'/'best before'/'use by date', packaging integrity and storage conditions.
- ix. The incoming vehicles that bring the raw materials, shall be checked for cleanliness and hygiene i.e. the trucks are clean, with no pests or dirt, with no strong odour other than that of the raw material. (see Annexure).

2. Storage and Material Control

2.1 General

The condition of product in stock shall be assessed in appropriate intervals in order to detect deterioration due to various reasons, e.g. physical damage, shelf life, unsanitary conditions, and temperature abuses and pest infestation.

- i. Products should be properly identified like frozen, chilled and ambient with packing and date of receipt. An effective system like, FIFO, FEFO and FMFO shall be in place for all materials or finished products, as applicable.
- ii. Surfaces of electrical wiring to filling machines and other lines equipment should be cleaned to avoid microbial growth.
- iii. A routine program should be established to inspect all gaskets and seals in product line connections and should be manufacturing/packing plant specific.
- iv. The buildings, grounds fixtures and equipment of product storage areas and vehicles loading & unloading bays shall be designed, constructed, adapted and maintained to facilitate the operations carried out in them and to prevent damage.
- v. Raw materials, ingredients, packing material and finished goods shall be stored separately on pallets in clean, dry, well ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.

- vi. Materials and product shall be suitably stacked with due regard given to safety. Aisles should be kept clear and not used for temporary storage of materials.
- vii. Receiving and dispatch bays shall be provided for receiving of material and dispatching of finished product from the storage areas. These shall be designed to protect materials and products from the diverse weather conditions. Receiving areas shall be equipped to allow containers of incoming materials to be cleaned, where necessary.
- viii. Adequate space should be maintained from walls and between pallets to ensure sufficient movement and air circulation.
- ix. Periodic visual checks should be made of all pallets, racks and other storage infrastructure, w.r.t structural integrity and infestations.
- x. Raw material and ingredients shall be stored as per the storage conditions mentioned on the label or as specified by the vendor. Printed packaging materials shall be stored in safe, separate and secured manner.
- xi. All materials and product should be clearly marked with their relevant Identification/Lot Number, to maintain the traceability.
- xii. The identification marking should be easily accessible/ visible even when the material or product is stacked.
- xiii. Storage area temperatures shall be maintained and monitored regularly.

In case, fresh material of botanical origin is used as a raw material, it shall be stored in a separate dedicated area with appropriate controls.

2.2 Access to storage area

- i. Access to material and product storage areas should be restricted to authorised persons only.
- ii. Appropriate barriers, like air curtain/ strip curtain, should be provided at all entrances and exits opening to the external environment, in order to maintain the temperature conditions of the storage area at an appropriate level.
- iii. Insectocutors shall be installed, appropriately, at the entrance of storage area.

2.3 Damaged, Returned & Recalled Goods

- i. Damaged/ returned goods should be placed in a designated area, labelled and physically segregated for appropriate disposal.
- ii. Records for such returned or recalled materials, with action taken, shall be properly maintained as per the FSSR recall regulation 2017.

2.4 Cleaning of Storage area

- i. Effective cleaning of storage premises and equipment must be carried out at the defined frequency and using the methods and materials specified in well-designed cleaning schedules and procedures.
- ii. Cleaning standard operating procedures (SOPs) shall be defined and records demonstrating compliance shall be maintained.
- iii. Storage areas should be regularly inspected for cleanliness and good housekeeping.
- iv. Cleaning materials should be stored in a separate location in order to avoid contamination.

3. Milk Processing

3.1 General

- i. In dairy plants, equipment should be subjected to routine microbiological monitoring to verify the effectiveness of cleaning, e.g. milk cans, storage/holding/process/transport tank, ice cream

- freezer, HTST Plate Pasteurizer/ Heat Treatment pasteurizer, homogenizer and cream separator, filling machines and filling machines nozzles etc.
- ii. Food processing operations, flow diagram and standard operating procedures shall be documented, implemented and displayed at particular operations site. Standard operating procedures for process changeover from one kind of product to another shall be maintained and implemented.
 - iii. Critical food processing parameters like temperature / vacuum etc. records shall be maintained and recorded appropriately.
 - iv. Intermediate in-process samples to be tested for critical parameters and their test results shall be maintained.
 - v. Personnel shall put on clean protective clothing including footwear and wash their hands before entering.
 - vi. Cleaning schedule for equipment in the food processing sections shall be maintained to ensure entire operations are carried out in hygienic conditions.
 - vii. System shall be in place to screen/detect and prevent contamination of foods by foreign bodies such as glass, plastic, metal etc.
 - viii. Access to processing area by outsiders shall be restricted or controlled. Where risks are particularly high, access to processing areas shall be only via a changing facility.
 - ix. The presence of any allergens identified in food ingredients shall be informed to consumers appropriately.
 - x. In case steam is used directly on food during processing, the steam to be prepared from potable water and of culinary grade.
 - xi. All manufacturing operations shall be carried out under the supervision of authorised technical person. Each critical step in the process relating to the selection, weighing and measuring of raw material, addition during various stages shall be performed by trained personnel under the supervision.
 - xii. Adequate space, preferably separated from processing areas, shall be provided for cleaning and storing mobile equipment and utensils including the storage of cleaning materials.
 - xiii. Incoming materials and finished products shall be quarantined immediately, if required, after receipt or processing, until they have been released for use or distribution.
 - xiv. Intermediate products purchased and used as raw material shall be handled as ingredient on receipt.
 - xv. Operations on different products shall not be carried out simultaneously or consecutively in the same room unless there is no risk of mix-up or cross-contamination.

The contents of all vessels and containers used in manufacture and storage during the various manufacturing stages shall be conspicuously labelled with the name of the product, batch number, batch size and stage of manufacture. Each label should be initialled and dated by the authorised technical staff.

3.2 Water Treatment and Management

- i. Dairy processing establishments should have potable water (see annexure) available, which should meet the criteria specified by the competent authorities having jurisdiction and should be regularly monitored.
- ii. Proper maintenance of water treatment systems is critical to avoid the systems becoming sources of contamination. For example, filter systems can become sources of bacteria and their metabolites if bacteria are allowed to grow on the organic materials that have accumulated on the filter.

- iii. Water re-circulated or reused should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use.
- iv. Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in dairy processing. These criteria depend upon the origin and the intended use of the water. In case steam is used directly on food during processing, the steam to be prepared from potable water and of culinary grade.
- v. Reuse of water intended for incorporation into a food product should at least meet the microbiological specifications for potable water. Reconditioning of water for reuse and use of reclaimed, recirculate and recycled water should be managed in accordance with HACCP principles.
- vi. Any reuse of water should be subject to a hazard analysis including assessment of whether it is appropriate for reconditioning. Critical control point(s) should be identified, as appropriate, and critical limit(s) established and monitored to verify compliance.
- vii. Water treatment systems operation and maintenance shall be defined. Multiple barrier water treatment system is a carefully designed set of processes that work together to treat raw water to make it fit for its desired end use. It includes chlorination, enhanced filtration, activated carbon filter, polishing filtration etc. Methods like re-circulation, use of UV, heat and chemical sanitation can be used to minimize the risk of microbial contamination. A flushing shall be done after any chemical sanitation. The water quality shall be monitored periodically for chemical and microbiological contaminants.

3.3 Calibration and Inspection of Measuring, Testing and process control Equipment

- i. All measuring, testing, process control equipment for milk processing shall be identified and labelled with their calibration status. All test equipment shall be identified with:
 - a) Item identity / Serial No
 - b) Calibrated / Inspected Date
 - c) Calibration due / Inspection Due Date
- ii. Internal and external calibration schedule shall be maintained for all the equipment.
- iii. Calibration procedures shall have defined action plan if instrument fails during calibration.
- iv. Calibration frequency should be documented in the list based on the Standards like BIS or end use.
- v. Calibration should be done over the full range of use of the equipment or device and during calibration measurement range has to be considered.
- vi. Internal/External calibration should also be carried out using a reference material having traceability.
- vii. When no reference material is available, a suitable consensus material must be used.
- viii. Acceptance criteria should be mentioned and also corrective action if any instrument found out of specification.
- ix. If the error is more than the acceptance criteria, then the equipment/measuring device needs correction.

3.4 Allergen Management

3.4.1 Allergen handling

Major Allergens are –

- 1) Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- 2) Crustacean and products of these;
- 3) Eggs and egg products;

- 4) Fish and fish products;
- 5) Soybeans and products of these;
- 6) Milk and milk products (lactose included);
- 7) Peanut, tree nuts and nut products; and
- 8) Sulphite in concentrations of 10 mg/kg or more.”

3.4.2 Allergen Control and Management

- i. Display all the allergens at the relevant places in the processing and storage areas for awareness among all the employees. All raw materials that are allergens should be labelled with a tag that states “Allergen.”
- ii. Maintain all ingredient flow during the manufacturing from non-allergen using areas to allergen using areas. This will help prevent cross-contamination. Preferably products containing non-allergen ingredients should run before the products containing allergic ingredients and process line should be cleaned/ sanitised to eliminate chances of allergen carry over by designing validated CIP/COP. For composite products with multiple ingredients including possibly allergic ones, the consumers shall be appropriately informed through labelling.
- iii. Store all allergic foods or ingredients at a designated area. For partially used allergic packets, the production staff should ensure the partially used packet should be stored separately and completely sealed and identified with label.
- iv. Dedicated scoops, utensils shall be used for specific allergens. Thorough cleaning should be there between allergic containing product manufacture and non-allergic containing product manufacture.
- v. When production scheduling and cleaning operations are not performed between allergen containing production runs, allergen testing must be performed. For. E.g. ELIZA test kits are used to verify.
- vi. As for other food safety risks, critical control must be identified and characterized all along the food chain and then prevented, suppressed or mitigated through the implementation of an allergen HACCP plan.

4. Milk and Milk Product Packaging and Warehousing

4.1 Packaging and Wrapping

- i. The packaging design and materials shall provide protection for products in order to prevent contamination, damage and accommodate required labelling as laid down under the FSS Act and the Regulations there under. Only food grade packaging materials shall be used as primary packaging material. Packaging materials like aluminium, tin and plastic shall conform to the Indian standards as mentioned under the FSS Regulations from time to time.
- ii. The food packaging materials shall be inspected before use to avoid using damaged, defective or contaminated packaging, which may lead to contamination of the product. The food business operator shall have effective procedures in place to confirm that contaminated packaging is properly cleaned & sanitised before reuse, while damaged or defective are discarded, repaired or replaced, as appropriate, before re-use.
- iii. The packaging materials or gases where used, shall be non-toxic and shall not pose threat to the safety and suitability of food under the specified conditions of storage and use.
- iv. The wrapping and packaging of dairy products shall take place under satisfactory hygienic conditions and in rooms provided for that purpose.
- v. The manufacture of dairy products and packaging operations may take place in the same Room provided the room is equipped to ensure hygienic working condition
- vi. The rooms for storing the packaging material shall be free from vermin and from dust which could constitute an unacceptable risk of contamination of the product and shall be separated

- from rooms containing substances which might contaminate the products. Packaging shall not be placed directly on the floor
- vii. "Packaging materials shall be prepared/assembled in hygienic condition prior to use for batch/continuous systems"
 - viii. Packaging shall be done without delay followed by labelling. If it is not the case, appropriate procedure shall be applied to ensure that no mix-ups or mislabelling could occur. It shall be handled by separate group of staff having experience in handling and product wrapping and immediately after packaging; the dairy products shall be placed in the designated rooms provided for storage under required temperature.
 - ix. Filling, Bottling, wrapping, packaging etc. shall be carried out hygienically.
 - x. All weighing scale used in packaging section shall be checked regularly against certified standards and their records to be maintained.
 - xi. Packaging material/wrapping materials shall be protected from external environment/contamination during transport and storage. Facilities shall be established for safe and hygienic storage of packing materials at the dairy plant."
 - xii. Wrapping or packaging may not be re-used for dairy products, except where the containers are of a type which may be re-used after thorough cleaning and disinfecting.
 - xiii. "Packaging of milk and milk products shall be carried after processing. The packages should be designed so as to ensure they are tamper proof and are not easily damaged during general handling /operation. Once the packages are opened it should be easily identifiable and cannot be duplicated against a fresh/unopened package".
 - xiv. The ink used for printing of primary food packaging should be of food grade quality. This should comply with IS 15495 standards or other international standards for use in food packaging and printing.

4.2 Warehousing

Warehouses/Plant storing products are required to ensure the integrity and safety of the product is effectively protected. For instance –

Receive – Upon unloading, the transport vehicle and receiving materials must be thoroughly inspected for any unusual residual material such as powders, liquids, or other materials. The materials must be checked for physical integrity.

Storage – Products must be protected from unauthorised personnel at all times.

Dispatch – Physical integrity of product and package must be checked and the shipping vessel inspected for cleanliness prior to loading a shipment.

In charge of the ware house shall ensure that good warehousing practices should be followed by all personnel, visitors and contractors.

- i. Like soiled and dusty product/exteriors of crates/cartons or other product containers shall be cleaned before they are conveyed into warehouse or to customers.
- ii. Broken, spilled/damaged product shall be stored in properly demarcated area and be destroyed or routinely after necessary authorization/approvals.
- iii. Product spilled on floor should not be used and rejected and stored as described above.
- iv. Hand washing facilities shall be available for all persons operating at warehouse to maintain hygiene hands-
- v. Properly maintained toilets away from the main go-down with proper hand washing facility should be available.

- vi. The operator shall ensure that all employees receive appropriate training to allow them to perform their appropriate function.
- vii. Incoming materials inspections requirements should be laid down.
- viii. Hold and release programs should be there.
- ix. Sufficient number of pallets should be available to accommodate all materials.
- x. Direct sunlight on product shall be avoided.
- xi. For products that need to be stored at specified conditions and temperature, those conditions need to be verified and recorded.

S.No.	Area	Pallets to be used	Remarks
1	Raw material storage area	Plastic pallets	
2	Sampling booth	Plastic pallets	
3	Dispensing area	Plastic Pallets	
4	Processing area (Day Store, Silo, blender, Feeding)	Plastic Pallets	
5	Filling area	Plastic Pallets	
6	Secondary packing	Plastic	
7	Warehouse	Plastic	
8	Primary Packing Materials	Plastic	Dedicated storage for primary packing materials. Primary packing materials should not store intermixed
9	Secondary / tertiary packing materials	Plastic / wooden pallets (tertiary)	The wooden pallets must be in good state free from insect infestation, FBO must have periodic maintenance schedule in place.
Note: It is Industry's Best Practice to use Plastic pallets throughout the product processing chain.			

4.3 Storage of Hazardous Substances

- i. Hazardous substances shall be stored in rooms or cabinets used only for that purpose and handled only by authorised and properly trained persons.
- ii. Wet and dry chemicals shall be stored separately as per their compatibility to avoid accidental mixing due to leakage or spillage.
- iii. No substances which could contaminate food may be used or stored in food handling areas or be stored with any product, ingredients or product packaging materials.
- iv. The detergent/disinfectant in use inside the processing facility shall be located at a designated place and labelled legibly. The same shall not be stored in any food containers.

5. Rework & Control of Non-Conforming Product

- i. A non-conforming product can be detected through customer complaints, internal defect findings, internal audits, external audits, in coming material inspection or simply during normal testing and inspection activities.
- ii. All rework/non-conforming/market returned materials shall be segregated, identified, stored, handled, labelled and used in such a way that product safety, quality, traceability and regulatory compliance are maintained.
- iii. All Traceability records for rework shall be maintained.

- iv. Stored rework/non-conforming/market returned material shall be protected from exposure to microbiological, chemical or extraneous matter contamination.
- v. Where rework/non-conforming/market returned 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.
- vi. Where ever rework activities involves removal of product from filled packages adequate controls shall be put in place to ensure removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.
- vii. Standard operating procedure should be defined and documented for handling any rework or non-confirming products.
- viii. Additional inspection of reworked/reprocessed in-process or finished product is required and documented.

6. Transportation & distribution

- i. Conveyances and/or containers used for transporting foodstuffs shall be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and shall be designed and constructed to permit adequate cleaning and/or disinfection. Where direct contact with food may occur, materials used in carrier construction shall be suitable for food contact.
- ii. Transportation time for raw milk to dairy plant/MCC/BMC should be within 4 hours of milking. Food products in conveyances and/or containers are to be so placed and protected as to minimize the risk of contamination.
- iii. Milk tankers, refrigerated vehicles and insulated vehicles transporting raw milk, processed milk and milk products should be registered with FSSAI through the dairy unit which owns/hires these services. Transporting any commodity/food product along with milk and milk products shall not be permitted as it compromises the hygienic conditions.
- iv. Where conveyances and/or containers are used for transportation anything other than foodstuffs or for transporting different foods, there shall be effective cleaning between loads to avoid risk of contamination.
- v. Bulk foodstuffs in liquid, granules or powder form shall be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, to show that they are used for the transport of foodstuffs. Vans/vehicle/trucks carrying milk must be insulated, or shall have tarpaulins to cover/protect from summer winds, rain dust.
- vi. Wherever necessary, conveyances and/or containers used for transporting foodstuffs shall be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored. For example, Ingredients and products requiring refrigeration shall be transported and stored at 5°C or less but not frozen. Frozen ingredients and products shall be transported and stored at temperatures which do not permit thawing (for example, below zero degree Celsius).
- vii. Vehicle should be completely unloaded, cleaned and sprayed with appropriate insecticide/pesticide in all corners created between the floor and the wall of vehicle. This exercise to be carried out at the pouch loading plant utilizing the services of pest control operator at the plant, also these vehicles shall have a proper working light arrangement inside the vehicle.
- viii. Storage and Transportation guidelines for finished products

Step	Long shelf life products like Butter	Cultured/Fermented products like Dahi, Chach, Probiotic drink	Long shelf life products like Cheese	Ice creams	Pasteurized Milk	UHT products
At plant	-18 °C	4 to 8°C	4 to 8°C	Below -18 °C	<5°C	Ambient Temperature
Plant to Hub storage area	-18 °C (Storage /transporting vehicle)	4°C (Storage /transporting vehicle) not below 2 °C	4°C (Storage /transporting vehicle) not below 2 °C	-18 +/- 2 °C (Storage /transporting vehicle)	<5°C	Ambient Temperature
Transportation From Storage area to retail Shops/distributors	Refrigerated transport with temp not exceeding 4 degree C	Refrigerated transport with temp not exceeding 4 to 8 degree C	Refrigerated transport with temp not exceeding 4 to 8 degree C	Refrigerated vehicle with temperature of -18 +/- 2 °C	Refrigerated/insulated vehicle with temperature <5 °C	Ambient Temperature
Retail Storage	Not to exceed 4 °C	Not to exceed 4 °C	2 to 4 °C	Not to exceed -18 +/- 2 °C	<5 °C	Ambient Temperature

- i. Carriers used by the establishment must be designed, constructed, maintained, cleaned and utilized in a manner to prevent food contamination.
- ii. Carriers must be suitable for the transportation of food. This can be verified by visual inspection upon receipt by the manufacturer and prior to loading to ensure they are free from contamination and suitable for the transportation of food.
- iii. Carriers provide effective protection from contamination, including dust and fumes. The manufacturer shall have a program in place or assurances to demonstrate the adequacy of cleaning and sanitizing. The plant should have records that the carrier is properly cleaned and sanitized. Special attention should be given to carriers used to transport goat and sheep milk from the farm to the establishment to ensure that these meet the appropriate requirements.
- iv. The transportation of pasteurized dairy products in bulk multi-use containers without re-pasteurization is strongly discouraged as there is no guarantee that equipment is adequately cleaned. Re-useable plastic totes are not acceptable for the transporting of pasteurized product.
- v. For establishments who do not wish to re-pasteurize already pasteurized product, food carriers, tanks, transport lines and transfer pumps must be dedicated to pasteurized product only.
- vi. Ingredients and finished product requiring temperature controls must be transported in a manner to prevent temperature abuse that could result in deterioration affecting product safety. Dairy

products which require refrigeration are transported at a temperature of 4°C or less; frozen ingredients at temperature that does not permit thawing.

- vii. Transportation temperatures must be monitored and recorded to ensure proper temperatures for refrigeration and freezing. Finished product must be transported under conditions to prevent microbiological, physical and chemical contamination.
- viii. To assess this task, the written program must be examined to verify that the requirements for food carriers as outlined in the program are being followed, records are kept and acceptable deviation procedures occur when conditions are not met.
- ix. It is important that dairy products are not transported in carriers that do not meet the requirements of the program, thereby posing a contamination risk to the product. This can be verified with visual and organoleptic inspections of the carriers by the inspector and visual observations of personnel responsible for loading and unloading carriers.
- x. Carts used for transportation of ingredients and finished products within the processing operation as well as forklifts used in the warehouse are subject to abuse, so careful attention is required maintain these pieces of equipment.
- xi. Forklifts and carts tend to have painted surfaces so it is important that the exterior of these items be free of flaking material that may contaminate the products.
- xii. Transportation equipment must be frequently washed; carts should have sanitary drain cocks to prevent accumulation of water in the carts.
- xiii. It is imperative that waste and scrap carts be clearly labelled to avoid adulteration of ingredients or product. Also the type of forklift dictates the area where it may be used. Propane may contaminate some stored food so electric forklifts should be used in food processing areas.

7. Traceability and Recall

7.1 Traceability

- i. Established and applied traceability system shall be in place.
- ii. It shall enable identification of product lots and their relation to Batches of raw materials, Processing and delivery.
- iii. This system shall allow the operator to trace within 24 hours the history of a specific lot from receipt through all stages of storage and shipping.
- iv. All ingredients shall be identified by a lot number through which the source, date received and any special characteristics of the material can be determined. Coloured stickers/labels for Material Status Identification can be used to identify all ingredients and finished products in the plant like for example green can be used for released products, orange/yellow colour can be used for the products which are on hold, and red colour can be used for rejected products.
- v. The facility/ system shall identify incoming material from suppliers.
- vi. It shall identify the initial distribution route for the end product.
- vii. Records shall be maintained.

7.2 Recall procedures

- i. Organisation shall develop & implement milk Recall Procedure in accordance with FSS (Food Recall Procedure) Regulations, 2017.
- ii. There shall be a documented and effective product recall plan in place in accordance with the FSS (Food Recall Procedure) Regulations, 2017. Such a plan shall allow the organization to effectively locate all affected milk and milk 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.

- iii. 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.
- iv. 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.
- v. The effectiveness of the Product recall procedure should be internally tested and documented at least once in a year. A recommended good practice is a Mock Recall.
- vi. Recall can be classified as
 - Class 1 Recall – Could be for dangerous or defective food products that could cause serious health problems or even death.
 - Class 2 Recall – This is for the food products that are unlikely to cause any adverse health problems, but that violate the act, the rules and regulations made there under.
- vii. Manufacturing records systems, distribution records systems and the marking of outer cartons and of individual packs shall be designed in a way that will facilitate effective withdrawal or recall, if necessary.
- viii. Recall management team is important to have a team responsible for traceability and recall management. The team is responsible for co-ordinating all aspects of the product recall.
- ix. Recall decision process should be defined and the recall management team should immediately inform the recall program coordinator on duty of the issue. Recall information management and risk assessment should be in place.
- x. The Recall communication should be brief, specific, identifying clearly the food product size, lot no., code, serial no, and any other pertinent descriptive information to enable accurate and immediate identification of the product.

8. Quality Control & Testing

8.1 Control of food hazards - The combination of control measures should effectively control the identified hazards in milk and milk products. The combination of control measures should be designed in a systematic way, and the chosen combination should be adapted to the hygiene status of the milk and raw materials used with consideration given to the relevant microbiological, chemical and physical hazards of concern and to the establishment of Food Safety Objective(s) and/or related objectives and criteria. Where appropriate control measures and/or control measure combinations are chosen to control hazards that are reasonably likely to occur, the procedures should be implemented as such in order to minimize or prevent the likelihood of a health risk to the consumer. The following procedures are intended to enhance and supplement those aspects of the HACCP which are critical to the successful design of a system of food safety controls -

- a. All potential hazards should be identified and this should be done before control measures are selected and is the first step in the hazard analysis. The identification should be based on the initial descriptions developed during preliminary steps and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during processing and distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified. Each potential hazard should be evaluated to determine the severity of its adverse health effects and reasonable likelihood of

- occurrence. Potential hazards that are determined to have severe adverse health effects and/or are reasonably likely to occur should be subject to control by the system of control measures.
- b. Following hazard evaluation, control measures and control measure combinations should be selected that will prevent, eliminate, or reduce the hazards to acceptable levels. The next step in the hazard analysis process is to select control measures that will be effective in controlling those hazards.
 - c. Process criteria for control measures should be established in order for the process to be applied in a manner that will meet the performance required, i.e., assure the adequate delivery of the control measure. Process criteria should be established at such intensities that the control measures actually deliver the expected performance, taking into account normal process deviations.

8.1.1 Key aspects of hygiene control systems:

- i. From milk production through to finished products, products should be stored at appropriate temperatures and for appropriate times such that the growth or development of a food safety hazard will be minimized and the product's suitability will not be adversely affected. Because milk and many milk products have sufficient moisture content to support the growth of pathogens, temperature and time controls represent key microbiological control measures to control growth throughout the manufacturing process, from the handling of milk to the distribution and storage of perishable milk products (e.g., pasteurized drinking milk, desserts, and soft cheeses, depending on shelf life). For instance, for liquid milk, increased storage temperature will decrease the shelf life.
- ii. Incoming Raw milk when arriving at the dairy plant, and provided that further processing does not allow otherwise, the milk should be cooled and maintained at such temperatures as necessary to minimize any increase of the microbial load of the milk. The principle of "first arrived, first processed" should apply.
- iii. Intermediate products that are stored prior to further processing should, unless further processing does not allow it, be kept under such conditions that limit/prevent microbial growth or be further processed within a short time period.
- iv. The ultimate safety and suitability of milk and milk products, as well as the intensity of the control measures that need to be applied during processing, depends not only on the initial microbial load upon receipt at the dairy plant but also on preventing the growth of microorganisms.
- v. Application of proper storage temperatures and management of raw materials is an essential factor in minimizing microbial growth. The ability of a product to meet intended Food Safety Objectives and/or related objectives and criteria is dependent upon the proper application of the control measures, including time and temperature controls. There should be adequate stock rotation, based on the principle of "first in, first out".
- vi. It is essential that milk and milk products be kept at an appropriate temperature in order to maintain their safety and suitability from the time it is packaged until it is consumed or prepared for consumption. While the storage temperature should be sufficient to maintain the product's safety and suitability throughout the intended shelf life, the appropriate storage temperature will vary depending upon whether the product is perishable or non-perishable. For perishable products, the distribution system should be designed to maintain adequate low-temperature storage to ensure both safety and suitability. For non-perishable products designed to be shelf-stable at ambient temperature, extremes of temperature should be avoided, primarily to assure

maintaining suitability. Reasonably anticipated temperature abuse should be taken into account in designing the normal patterns of distribution and handling.

- vii. It is the responsibility of the manufacturer to determine the shelf life of the product and the conditions for storage. Limitation of shelf life is a control measure that, in many cases, is decisive for the safety and suitability of the product. The corresponding storage conditions are an integral aspect of product shelf life.
- viii. Microbiological criteria's and other specifications, including those used to verify the effective application of control measures within the framework of HACCP principles, should be developed including the use of a risk assessment approach.
- ix. Incoming milk manufacturers should establish incoming milk criteria that take into account the end use of the milk and the conditions under which the milk was produced. Depending upon the end use of the milk, particularly for milk used in the production of raw milk products, certain specific microbiological criteria may be appropriate to verify the microbiological quality of the milk used as raw material.
- x. Corrective action taken for non-compliance with incoming milk criteria should be commensurate with the potential risks presented by the non-compliance.
- xi. Microbiological criteria being necessary are to be established at different points in the process for carrying out the design of control measure combinations and for the verification that the control system has been implemented correctly. In some cases, for example where more comprehensive control measures are put into place to ensure the safety and suitability of milk (such as may be the case for raw milk intended to be used in the production of raw milk products), it may be necessary to establish criteria for in-process product, intermediate product or finished product in order to verify that the more comprehensive set of control measures have been properly carried out.
- xii. The flow of the product and of the ingredients within equipment and through the processing facility should maintain a forward progression from raw material receipt to finished product packaging so as to avoid cross contamination. The flow of the water, air, effluents, and milk should be carefully evaluated to ensure that the cross-contamination does not occur. Similarly, the flow of personnel should be evaluated to ensure that their actions couldn't contaminate milk.
- xiii. Preventive measures should be implemented to minimize risks of contamination of milk and milk products with physical and chemical hazards this requires the effective control of equipment maintenance, sanitation programmes, and personnel, monitoring of ingredients and processing operations. Preventive measures should include those that will minimize the potential for cross contamination of allergenic components and/or ingredients that may present in other products to a milk product in which these components and/or ingredients are not supposed to be present.
- xiv. Ingredients used for the processing of milk products should be purchased according to specifications and their compliance and these specifications should be verified.. Preferably, specifications for raw materials should be established such that their use will result in a safe and suitable product. No raw material should be accepted if it is known to contain chemical, physical or microbiological contaminants that would not be reduced to an acceptable level by normal sorting and/or during processing. Raw materials should, where appropriate, be inspected and sorted before processing. Any claims that raw materials meets the quality and safety standards should be verified periodically.
 - a. Quality control programme shall be in place to include inspection and testing of incoming raw materials and finished products.

- b. Laboratory facility with trained and competent personnel shall be available for food testing. If there is no in-house laboratory present, all the regular testing shall be done through an accredited external laboratory/laboratory notified by FSSAI. In case of complaints or feedback on the product, the FBO shall carry out the testing either through their in-house/ external accredited labs/ lab notified by FSSAI to ensure product compliance to standards.
- c. Incoming raw materials / Bulk chemicals / Ingredients test records or COA shall be maintained.
- d. Calibration of laboratory equipment shall be done periodically.

8.1.2 Specification and Test Methods

Authorized specifications for raw material, packaging materials, In-process material, Intermediate material, and finished products should be maintained. The specifications should include;

- A description of the materials,
- The designated name of the material / product and the code reference
- Directions for sampling and testing
- Qualitative and quantitative requirements with acceptance limits
- Storage conditions and any special handling precautions
- Shelf-life

Validated methods should be used for testing of material / product. Analytical method verification should be carried out for the compendia / pharmacopeia methods. Scientifically valid test methods published internationally (e.g. AOAC, BAM, USP, FCC etc.) can also be used for testing and the manufacturer should affirm that the tests are accurate, precise and specific for its intended purpose.

8.1.3 Laboratory Personnel

- i. Personnel shall be appropriate in number with desired skill set.
- ii. All personnel shall wear clean protective clothing appropriate to the tasks being carried out.

8.2 Laboratory Facility and Equipment

- i. All laboratory equipment and instrumentation shall be appropriate for the analysis required and shall be calibrated. Written standard operating procedures shall be available for each instrument or equipment. Analytical methods shall include a control step to verify instrument or piece of equipment is functioning accurately.
- ii. Quality Control laboratories should be designed and equipped to suit the operations required.
- iii. Sufficient space should be available for storage of chemicals, media, glassware, documents, samples and records,
- iv. Personnel operating the equipment shall be trained
- v. Records of each service and calibration must be maintained for each equipment,
- vi. Adequate colour coded waste bins shall be provided for the collection of laboratory waste material prior to disposal.

8.3 Sampling

- i. Sampling procedures shall be established and documented. The following shall be included as a part of sampling procedure:
 - a. The sampling equipment and type of sample container to be used
 - b. The method and frequency of sampling
 - c. Sample storage and handling requirements prior to testing, e.g. to minimise separation of mixed powders
 - d. The quantity of sample required

- e. Any special precautions to be taken to maintain homogeneity of sample
- f. Instructions for any subdivision of the sample
- g. The cleaning and storage of sampling equipment and reusable containers
- ii. Sample containers shall be clearly labelled with the contents, sample identification number, lot number and date sampled.
- iii. Tables or notes used for calculation of the sample requirements shall be documented.

8.4 Analysis and Validation

Written procedures shall be in place for the preparation of the reagents to be used in the analysis. Reagents and Reference standards shall be clearly labelled with the following information:

- date of receipt or preparation,
- their concentration,
- standardisation factor,
- shelf life
- storage conditions
- Reference standards and any secondary standards prepared from them should be stored, handled and used according to instructions.
- Samples shall be analysed according to written procedures, using test methods which are either legally required or are internationally accepted, or other methods that have been scientifically validated for the required sample matrix.

Validation studies shall be an essential part of Good Manufacturing Practices and shall be conducted as per the pre-defined protocols. These shall include validation of processing, testing and cleaning procedures.

Validation shall include the following parameters:

- Specificity / selectivity;
- Recovery;
- Precision;
- Linearity and range;
- Accuracy;
- Limit of Detection (LOD) / Limit of Quantitation (LOQ)

Validation details shall be recorded and retained. Results of any sample analysis should be within the validated range of the methods used.

Personnel, premises, utilities, support systems and equipment should be appropriately qualified before manufacturing processes are validated. Materials, environmental controls, measuring systems, apparatus and methods should be considered during process validation. Process validation should be done based on actual operational conditions. A written report summarizing recorded results and conclusions shall be prepared, documented and maintained.

1. Processes and procedures shall be established on the basis of validation study and undergo periodic revalidation to ensure that they remain capable of achieving the intended results. Critical processes shall be validated, prospectively for retrospectively.
2. When any new Master Formula or method of preparation is adopted, steps shall be taken to demonstrate its suitability for routine processing. The defined process, using the materials and equipment specified shall be demonstrated to yield a product consistently of the required quality.

3. Significant changes to the manufacturing process, including any changes in equipment or materials that may affect product quality and/or the reproducibility of the process, shall be validated.
4. Validation of process shall be based on protocol where The protocol should include or reference at least the following elements:
 - *The manufacturing conditions including operating parameters, processing limits and component (raw material) inputs.*
 - *Type of testing or monitoring to be performed (in-process, release, characterization) and acceptance criteria for each significant processing step.*
 - *Justified sampling plan, sampling points, sample size and the frequency of sampling for each unit operation and attribute.*
 - *Details of the equipment and/or facilities to be used, including measuring or recording equipment.*
 - *Acceptable limits with details of methods for recording and evaluating results, including statistical analysis.*

8.5 Laboratory Documentation

Procedures shall be in place so that the data for all sampling, analysis and calculations are correctly recorded.

- i. Records duly signed off shall be maintained for all tests and analysis performed in the laboratory.
- ii. Retention of samples both raw material and finished product and the records of laboratory documents shall be done for a time period that is consistent with the requirements for the manufacturing records.

8.6 Control of Retention Samples

- i. Retention samples of key raw materials and finished products should be stored in appropriate conditions and quantity.
- ii. Retention samples of finished products shall be stored in the same or simulated containers as per shelf life in which the finished products have been actually marketed.

8.7 External Laboratory

- i. There shall be clear defined scope, details of services and responsibilities with contracted external Laboratory.
- ii. Periodic testing as per Schedule 4 requirements may be done through an accredited external laboratory/ FSSAI notified laboratory.
- iii. Trend analysis shall be carried out periodically on all analysis carried out by external laboratories, to ensure that there are no major trends or variations developing.
- iv. Quality control programme shall be in place to include inspection and testing of incoming raw materials and finished products.

III. ESTABLISHMENT - MAINTENANCE AND SANITATION

1. Cleaning and Sanitation

- i. Cleaning and sanitizing programmes shall be established at facility to ensure that the food-processing equipment and environment are maintained in a hygienic condition to prevent contamination of food, such as from metal shards, flaking plaster, food debris and chemicals and records of the same shall be maintained. The programme should ensure that all areas of the establishment are appropriately clean, and shall include the cleaning of all equipment as well.
- ii. It must be kept in mind that food manufacturers are always obliged to maintain high hygienic standards. It is important to note that equipment should also be clean from bacteriological point of view. The equipment surfaces should therefore be first thoroughly cleaned with chemical detergents and then disinfected.
- iii. Cleaning agents and disinfectants shall be food grade quality and should be handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions, and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contamination .
- iv. Cleaning shall remove the food residues and dirt and it can be carried out separately or by using the combined methods, such as heat, scrubbing, turbulent flow and vacuum cleaning or other methods that avoid the use of water, and chemical methods using appropriate cleaning agents.
- v. These facilities should be constructed of corrosion resistant materials, be easy to clean and shall have adequate supply of hot and cold potable water, where appropriate.
- vi. Cleaning & Sanitation of milk processing unit should be done for all equipment and frequency should be based on the run time, nature of the product, CIP validation outcome.

The recommended frequency should be as follows:-

- ◆ Raw milk unloading system, silos, pipelines, leaky pouch handling tank and pipelines -Daily
- ◆ Process milk tankers - Every time before filling
- ◆ Pasteurizer, clarifiers & separators, standardiser, homogenisers - Every 5 to 7 hours of operation

- vii. A validation mechanism should be in place for all cleaning programme.

Sample Sanitation and Housekeeping Program for warehouses

S. No	Places to be cleaned	Suggestive Frequency of Cleaning	Type of cleaning
1.	Gangways (dry store and cold store)	Daily	Brooming
2.	Top of material stacks in dry store	Daily	Dry dusting
3.	Stairways	Daily	Wet Wiping
4.	Office area and equipment	Daily	Brooming & dusting
5.	Inside yard	Fortnightly	Dry mopping
6.	Fans and blowers	Monthly	Wet mopping
7.	Tube lights	Monthly	Dry mopping
8.	Electric switch board	Weekly	Dry mopping
9.	Walls and ceiling for presence of any cobwebs, dust	Weekly	Dry wiping
10.	Cold store /deep freeze Cold store	Monthly/quarterly/Yearly	Complete defrosting/cleaning of chamber and fumigation
11.	Product Transportation vehicle	Every time before loading	Brooming

Cleaning procedure should generally involve-

- Product recovery by scrapping, drainage and expulsion with water or compressed air
- Removing gross visible debris from surfaces
- Applying a detergent solution to loosen soil and bacterial film (cleaning)
- Rinsing with water (hot water where possible) to remove loosened soil and residues of detergent
- Dry cleaning or other appropriate methods for removing and collecting residues and debris
- Cleaning should be followed by disinfection with subsequent rinsing for all food contact surfaces

Cleaning In Place (CIP system)

CIP is a process that is used for washing and cleaning of technological elements (tanks, pasteurizers, pipelines) without dismantling them. CIP cleaning utilizes a combination of chemical and physical effects to remove the soil from produce-contact surfaces, by taking the solution to the equipment surface:

- i. Temperature and conductivity sensors are to be calibrated quarterly through NABL accreditation labs. Temperature sensor should not have error more than 2 °C. Rota meter can be placed at clean in place pump delivery line to ensure the turbulent velocity during every Cleaning in place operation.
- ii. **Cross contamination controls**
 - a. There should be flow plate systems installed to physically separate active product lines from CIP lines for **manual and semi auto dairy systems**.
 - b. For **automated dairy units**, double seat mix proofs should be installed in all pneumatic valve clusters.
 - c. Also, positive pressure mechanism should be in place in plate heat exchanges between products and cooling medium/heating medium/raw milk controls and monitoring devices for the same should be in place.

CIP PROGRAMMES

CIP programmes for circuits with plate and tubular heat exchangers, HTST pasteurizer , evaporators and other equipment with the heated surfaces. The recommended procedure is :

- i. Rinsing with the warm water for about 10 minutes
- ii. Circulation of an alkaline detergent solution (0.5-1%) at 75°C
- iii. Rinsing out alkaline detergent with warm water for about 5 minutes
- iv. Circulation of nitric acid solution (0.5-1%) at 70°C
- v. Post rinsing with cold water
- vi. Gradual cooling with cold water for about 8 minutes

CIP programmes for circuits with pipe systems, tanks and other process equipment with no heated surfaces. The recommended procedure is :-

- i. Rinsing with the warm water for about 3 minutes
- ii. Circulation of alkaline detergent solution (0.5-1%) at 75°C
- iii. Rinse with warm water for approx. 3 minutes
- iv. Disinfection with hot water preferably

The design of centralized CIP systems - In this system, there are sensors for measuring levels, temperature and concentration of certain fluids in each tank. All signals from the probes and pumps are forwarded to the central computer. All the relevant data for the system can be seen at the terminal, and it is possible to select washing program cycle, generate diagrams, etc. In practice, there are no restrictions in meeting individual requests for the size and complexity of the CIP system. CIP station in a dairy consists of the necessary equipment for the storage, tracking and distribution of cleaning liquid to the various CIP circuits. A centralized CIP system has found its place in many dairies, but in large dairies with a large processing capacity, the distance between the central CIP systems and peripheral CIP circuits becomes too long. CIP pipe systems contain large amounts of fluids, even if they are “pumped out”. The residual water in the pipes after flushing dilutes detergent solution, which means that large amounts of the concentrated detergent must be added in order to maintain the required concentration.

Decentralised CIP System: A decentralised CIP is an attractive alternative for large plants where the distance between a centrally located CIP station and peripheral CIP circuits would be extremely long. The large CIP station is replaced by a number of smaller units located close to the specific groups of process equipment in the dairy, but there is still a central station for storage of the alkaline and acid detergents which are distributed to the individual or satellite CIP units. The supply and heating of rinsing water (and acid detergent when required) should be arranged locally at the satellite stations. These stations operate on the principle that the various stages of the cleaning programme should be carried out with a carefully measured minimum volume of liquid – just enough to fill the circuit to be cleaned. A powerful circulation pump should be used to force the detergent through the circuit at a high flow rate. The solution should preferably be considered spent after having been used once. In some cases it may, however, be used for pre-rinsing in a subsequent programme.

Cleaning Agents

Depending on the purpose, a good washing material should have the following properties:

- i. Good alkalinity
- ii. Should be freely soluble in water.
- iii. Should not have corrosive action on metal surface.
- iv. Good wetting agent with the ability to make a contact with the surface to be cleaned.
- v. Should make emulsion with fat and remove the same from the surface.
- vi. Good dissolving power, or the ability to dissolve protein.
- vii. Good deflocculating power or the ability to break up dirt particles.
- viii. Germicidal power or effectiveness in killing micro-organisms.
- ix. Penetrating power or the ability to penetrate the milk equipment surfaces.

DETERGENTS

The detergents are a substance which functions to remove milk deposits and other foreign matter from the surface to be cleaned. Many detergents however, are used in combination with sterilizing action. Dairy detergents are broadly classified into four groups. **Alkali:** Sodium hydroxide, sodium carbonate, sodium phosphate, etc. **Acids:** Most acid cleaners may be combined with wetting agents to provide the greatest possible penetration of soil. Low corrosiveness on equipment or other contact surfaces is desirable. It should be relatively safe to handle and shall be harmless. For milk stone removal, mild acids have been found most satisfactory. They have a good buffering ability, so that they can be used to remove milk stone and hard water scale. They are only slightly irritating to human skin. Phosphoric, tartaric, citric acids, etc. are mild organic acids while strong acids like nitric acid is also used.

Chelating agents: Prevention of water hardness precipitation may be achieved by using sequestering/chelating agents. These are used together with acids or alkalies like tetraphosphate, hexametaphosphate. There are three main classes of chelating agents.

- i. Ethylene diamine tetra-acetic acid (EDTA) and its sodium salts: They are heat stable and are compatible with quarternary ammonium compounds (QACS).
- ii. Sodium salts of gluconic and heptonic acids are stronger chelating agents than EDTA for calcium and magnesium, but a high concentration of caustic soda solution (2-5%) is required for effectiveness.
- iii. Poly phosphates such as sodium tri polyphosphate and sodium pyrophosphate: They are not heat stable.

Wetting agents: Surface active or wetting agents in solution improve the wetting of particles and penetration of the solution into capillary pores and minute spaces between and under soil particles and equipment surfaces. These are either used alone or in conjunction with acids or alkalies e.g. teepol. Too high concentration, however, may tend to insulate these particles from chemical attack by the solution. There are three groups: anionic, non-ionic and cationic depending upon how they dissociate in aqueous solution. The most common group is the anionic one. These compounds ionize with the negative anion being the active species. They are excellent detergents but poor sanitizers. Examples are sulpho soaps-sulphated alcohols and alkyl aryl sulphonates.

- i. Non-ionic wetting agents are also in use and many of these are liquids. Foaming characteristics vary from low to high. Examples are condensation products between ethylene oxide and an alkyl phenol.
- ii. The cationic group includes the quarternary ammonium compounds. They possess poor detergent properties but are very good sanitizers.

A few typical formulations are given below:

Manual cleaning detergent

- i. Dodecyl benzene sodium sulphonate (LAS) 40% Active - 10%
- ii. Non ionic surfactant - 4%
- iii. Sodium tripolyphosphate - 25%
- iv. Sodium metasilicate 10%
- v. Filler: Borax or sodium sulphate - 51%

Pipeline cleaner

- i. Surfactant 3%
- ii. Sodium tripolyphosphate 25%
- iii. Sodium metasilicate 10%
- iv. Sodium carbonate 30%
- v. Sodium sulphate 32%

General purpose CIP detergent

- i. Caustic soda - 68%
- ii. Soda ash - 10%
- iii. Tetra Sodium pyrophosphate - 8%
- iv. Sodium metasilicate - 6%
- v. EDTA - 4%
- vi. Trisodium phosphate - 4%

CIP heavy duty detergent

- i. Caustic soda - 95%
- ii. Sodium gluconate - 5%

Acid descalent cleaner

- i. Non ionic surfactant - 0.3%
- ii. Phosphoric acid - 31%
- iii. Water - 68.78%

General purpose detergent-sanitizer

- i. Sodium or potassium di-chloroisocynurate - 10%
- ii. Sodium tripolyphosphate - 35%
- iii. Anhydrous sodium metasilicate - 15%
- iv. Anionic surfactant - 5%
- v. Sodium carbonate - 35%

SANITISATION

Sanitation is the reduction of microbial contamination of the food contact surfaces to a level considered safe, from public health points of view. Chemical substances which prevent growth of micro-organisms are known as antiseptics while those which cause death are called “disinfectant “,” germicide”, or “Sanitizer”. Sanitizers are the compounds or type of antimicrobial that kills or cause irreversible inactivation of at least 99.9% of all bacteria, fungi and viruses present on surface.

Sanitizers should have the following properties.

1. Quick acting.
2. Easily and quickly applied.
3. Relatively inexpensive.
4. Relatively non- corrosive to hands and dairy utensils.

Methods of sanitization:

- i. **Heat:** Most effective and reliable method when both temp. and time are controlled. It can be applied by steam, hot water and hot air.
 - a. Steam: Temperature-time combination of 15 psi/5min or 0 psi/15min, condensation temperature > 80°C is effectively used for sanitisation.
 - b. Hot Water: Higher the temperature, the less time that is needed to kill microorganisms. **Temperature should be minimum 85°C** (necessary).
- ii. **Radiation:** It should be used in dairy plants where heat-sensitive parts to be sanitized. It can be used to sanitize only the packaging materials, air required in the processing of ice cream and dairy products like peda, milk cake etc.
 - ◆ Contact time = 2 minutes, in the range of 250 nm.
- iii. **Chemicals:** Required properties for chemical sanitisers are non-toxic, quick acting, non-corrosive to hands and equipment, wide range of activity, destroy M/Os rapidly and should be stable under all type of conditions. Continue use of one sanitizer may develop resistivity in M/Os. So rotation of sanitizer is necessary. Chemicals used for sanitization can be classified as

- a. Halogens bearing compounds like Chlorine, iodine (Iodophores) and bromine compounds. (Solution must not contain more than 200 ppm available chlorine.)
- b. Quaternary ammonium compounds (QACs)
- c. Peroxyacetic acid (PAA)

CIP SYSTEMS

Single-use System: This simple system is intended for cleaning one process circuit at a time with all liquids discharged to drain after use. Usually single-use systems are small units which are normally placed close up to the equipment to be cleaned. In a variation of the system detergent and rinse water from a previous cycle are recovered and used for a pre-rinse cycle for the next circuit to be cleaned.

A typical cleaning programme for one tank cleaning covers a 20 minute programme sequence. Three pre-rinses of 20 seconds with intervals of about 40 seconds each to remove the gross soil contamination is followed by a CIP return pump discharge of the water to drain. Then the detergent solution is circulated for about 10-12 minutes, after which the spent chemicals are discharged to drain. This is followed by two intermediate rinses with cold water with an interval of 40 seconds each to leave the water to drain or to recovery tank. There is a further rinse and finally an organic acid solution of strength approx. 0.08 – 0.1 per cent is circulated for about 3 minutes and then discharged to drain.

The programme for plate heat exchanger includes a water rinse, 0.8% cent acid solution (e.g. phosphoric acid) circulation at 60° C, a caustic soda solution (pH 12-13) circulation and final water rinse.

The cleaning sequence of evaporators is rinsing with water for 1 minute, circulation cleaning with acid and antifoam agent (usually phosphoric acid solution strength of 0.8%) at 73° C for 30 minutes, circulation cleaning with caustic soda solution of 1.2 per cent concentration including additive at 78° C for 46 minutes, rinsing for 8 minutes and finally acid rinsing at pH 4-5.

Re-Use System: The system is based on the principle that the detergents shall be recovered and re-used as much as possible. Re-use system is equipped with a tank for each chemical. The essential components of a CIP plant are caustic and acid tanks, fresh water tank, return water tanks, a heating system and feed and return pumps. The piping system of a cleaning plant is fixed in the plant and equipped with remote controlled valves and measuring devices.

A typical cleaning sequence for pipelines is: Water rinse at 59° C for 3 minutes, caustic soda solution (strength 0.5 per cent) recirculation at 70 °C for 46 minutes and hot water sterilization at 90° C for 5 minutes. Once or twice a week acid treatment is done. In this case after detergent solution recirculation follows water rinse at 70° C for 3 minutes, and finally water is recirculated at 90° C for 5 minutes for sterilization. The same sequence is used for tank cleaning.

For heat exchangers, the normal sequence is: 50° C water rinse for 5 minutes, 1-1.5 per cent caustic soda solution recirculation at 70° C for 15 minutes, 70° C water rinse for 3 minutes, 1 per cent acid solution recirculation at 79° C for 10 minutes and finally 90° C water circulation for 10 minutes for sterilization.

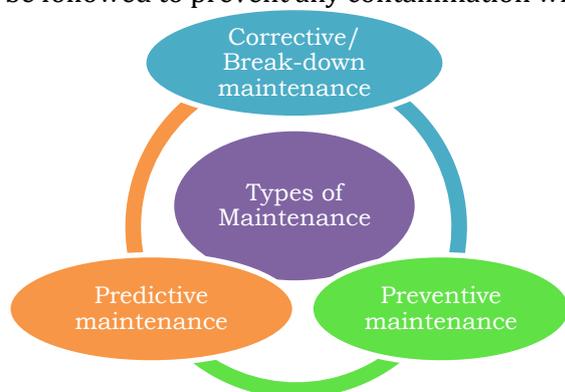
Multi-use System: In this system, local small standard units are placed closed to the equipment to be cleaned but they are fed with detergents from a centrally placed storage unit. After having used in the local unit, the detergent is sent back again to the storage unit. The system enables rinse product as well as cleaning media to be effectively recovered. These units are designed for cleaning-in-place of tanks and pipelines. They work with automatically controlled programmes.

2. Maintenance

- i. Maintenance workshops shall be separate and away from production areas. Whenever spares, changed parts and tools are stored in the production area, these shall be kept in dedicated rooms

or lockers. Tools and spare parts, for the manufacture of products which are susceptible to microbial contamination, shall be disinfected before these are carried inside the production areas.

- ii. Preventive maintenance of equipment and machinery shall be carried out regularly as per the instructions of the manufacturer.
- iii. The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards and cover the maintenance procedure, frequency and identification of the person (and/ or external agency) responsible for maintenance activity.
- iv. Internal & External calibration schedule for critical food safety equipment shall be maintained.
- v. Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination and post maintenance verification shall be done.
- vi. Temporary fixes that put product safety at risk shall be removed / permanently fixed in a timely manner.
- vii. Lubricants, heat transfer fluids or any other similar material shall be food grade where there is no risk of direct or indirect contact with the product.
- viii. Plant equipment's breakdown records shall be maintained.
- ix. Loose items control policy (Nut & bolts, Nails broken pieces or smaller parts of machines) shall be followed to prevent any contamination with product or packaging material.



Corrective/ Break-down maintenance	Preventive maintenance	Predictive maintenance
Maintenance of equipment after equipment break down or malfunction is often most Expensive	Maintenance performed with the intent of avoiding failures, safety violations, unnecessary production losses, and to conserve original materials of fabrication	Advances in sensing and computing technology have given rise to 'predictive maintenance'
The worn out equipment part can damage other parts and lead to multiple damage and increase repair/replacement costs.	The effectiveness of a preventive maintenance schedule depends on the Root Cause Analysis	It uses sensors to monitor key parameters within a machine or system and uses this data in conjunction with analysed historical trends to continuously evaluate the system health and predict a breakdown before it happens e.g. on-line monitoring of bowl speed, motor current, flow-rate etc. during operation of Clarifier / Cream separator / Bacteria removing clarifier.
Higher Machine downtime and Production loss	The history sheet maintained also helps in early detection of problems and increased equipment life.	The continuous temperature monitoring of say bearings or internal motor / transformer windings would enable the operator to take appropriate action even before the equipment is due for preventive maintenance.

3. Animal and Pest control

3.1 General Requirements

- i. The organization shall have a nominated pest control technician to manage pest control activities and/or deal with external pest management agency.
- ii. Pest control program shall identify target pests and address plans, methods, schedules and control procedures.
- iii. Program shall include a list of chemicals which are approved for use in specified areas.
- iv. Effective sanitation and Hygiene, inspection of incoming materials and monitoring can minimize pest infestation and thereby limit the need for pesticides

3.2 Preventing access

- i. Buildings shall be kept in good condition to minimize pest activity and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access shall be sealed.
- ii. Windows, doors and ventilation openings shall be designed to minimize pest entry.
- iii. Compound walling should be of appropriate height to prevent the entry of animals into the premise

3.3 Harbourage and Infestation

- i. Storage practices shall be designed to minimize the availability of food and water to pests.
- ii. Ingredients and materials shall be stored above the ground and away from walls. Where outside space is used for storage, stored items shall be protected from weather or pest damage (e.g. bird droppings).
- iii. Any Potential pest harbourage such as burrows, undergrowth, old & unused equipment shall be removed.
- iv. Materials found to be infested shall be handled in such a way so as to prevent contamination of other materials or products.

3.4 Monitoring and Detection

- i. The complete manufacturing plant and surrounding areas must be regularly examined for animals and pest activity
- ii. Pest-monitoring program shall include the placing of detectors and/ or traps in key locations to identify pest activity.
- iii. A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.

3.5 Eradication

- i. The pest control treatment shall be carried out by trained personnel without posing a threat to the safety or suitability of milk and milk products.
- ii. The pest control will be carried out with permissible chemical, physical or biological agents, within the appropriate limits. Records of pesticides/insecticides used shall be maintained to show the type, quantity and concentrations used; where, when and how applied, and the target pest.
- iii. Pest infestations shall be dealt with immediately by a competent person. The cause should be identified and corrective action taken to prevent reoccurrence.
- iv. In case of insect infestation area, appropriate fumigation should be done as per Plant quarantine Rules.

3.6 Pest control – 4 D method

<u>1D – Deny Entry- Preventing Entry</u>	<u>2D – Deny Shelter – Elimination of Harborage of Pests</u>	<u>3D – Deny Food- Eliminate food sources to pests</u>	<u>4D – Eradication of Pests</u>
<ul style="list-style-type: none"> • Seal all holes, crevices at ceilings, walls and floors • Threshold clearances of doors < 6mm, fix metal kicking plates • Double door / air curtains / strip curtains / mesh screens, self-closing doors at appropriate locations Missing / damaged gratings of drains installed / replaced 	<ul style="list-style-type: none"> • Avoid False sealing in processing and storage area • Repair defects on walls, floors, ceilings, woodwork & other structures • Remove disused / obsolete articles from food premises 	<ul style="list-style-type: none"> • Store all foods and condiments in sealed / covered containers • Floor free from food remnants • Prohibit preparing food and utensils cleaning at other places • Store refuse in dedicated closed container and discard periodically to prevent accumulation. • Surface channels and gratings clean and clear of food remnants 	<ul style="list-style-type: none"> • Clean & disinfect pest infested places, clothing and equipment • Use Insectocuter – Place 4.5 to 6 m away from food handling area • Use low wall mounted insectocutors • Clean insectocutor every week • Cover all foods during Pest control treatment • Use glue pads inside and rodent boxes outside the processing areas • Pest or chemical contaminated food be discarded.

3.7 An Integrated Pest Management system is not a one-time event and that relying solely on chemical controls when so many other tools are available is never the best solution. Likewise it can have following steps –

Step 1 Inspection - The cornerstone of an effective IPM program is a schedule of regular inspections. For food processors weekly inspections are common, and some plants inspect even more frequently. They should be focussed upon areas where pests are more likely to appear – receiving docks, storage areas, employee break rooms, sites of recent ingredients spills etc. and identify any potential entry points, food and water sources, or harbourage zones that might encourage pest problem.

Step 2 Preventive Action – As regular inspections reveal vulnerabilities in your pest management program, take steps to address them before it cause a real problem. Like exclusion by maintaining a structural program to close potential entry points revealed during inspection.

Step 3 Identification – Different pests have different behaviours by identifying the problematic species, pests can be eliminated more efficiently and with the least risk of harm to other organisms. Professional pest management always starts with the correct identification of the pest in question.

Step 4 Analysis – Once the pest is identified, we need to figure out why pests are in our facility. Is there food debris or moisture accumulation that may attract it? What are the reasons for finding their way in, perhaps through the floors or walls, could incoming shipments be infested. The answers to these questions will lead to the best choice of control techniques.

Step 5 Treatment Selection – IPM stresses the use of non chemical control methods, such as exclusion or trapping, before chemical options. When other control methods have failed or are in appropriate for the situation, chemicals may be used in least violation formulations in targeted areas to treat the specific pest. Right treatment should be done in right places, and only a much as you need to get the process complete.

Step 6 Monitoring – Sine pest management system is an ongoing process, constantly monitoring facility for pest activity and facility and operational changes can protect against infestation and help eliminate existing ones.

Step 7 Documentation – Since pest control can account for up to 20% of your total food safety audit score, it's imperative that IPM program should be ready to showcase come audit time. Important documents include scope of services, pest activity reports, service reports, corrective action reports, and trap layout maps, lists of approved pesticides, pesticides usage reports and applicator license.

4. Drainage and Waste Disposal

- i. All milk and milk product waste and other waste materials shall be removed regularly from the places where milk and milk products are handled, or processed or packed.
- ii. A refuse bin shall be placed in all appropriate places with a proper cover and shall be emptied regularly. The design of the refuse bin shall be such that no hand touch is required to avoid cross contamination chances. The waste bins shall be washed daily with a disinfectant and dried before next use.
- iii. Adequate drainage and waste disposal systems and facilities shall be designed and constructed so that the risk of contaminating milk/milk products or potable water supply is avoided.
- iv. Drains shall be designed to meet expected flow loads, constructed so as to prevent accumulation or back flow of waste water. Drains should be located so that they can be easily and effectively cleaned and inspected.
- v. Drains shall be equipped with appropriate traps.
- vi. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and free from animals and pests.
- vii. Segregation of non-biodegradable waste like plastics /metals / glass materials, bags, containers should be done, before disposal.
- viii. Waste disposal shall be done in accordance with local rules and regulations in a hygienic manner.
- ix. The disposal of sewage and effluents (solid, liquid and gas) shall be as per the Factory/Environment Pollution Control Board requirements.

IV. ESTABLISHMENT - PERSONAL HYGIENE AND EMPLOYEE FACILITIES

1. Health Status and Illness & Injury

- i. Milk and milk product handlers of the manufacturing facility shall undergo a medical examination by a registered medical practitioner before joining for work and thereafter annually to ensure that they are free from any infectious or communicable diseases. A record of these examinations shall be maintained.
- ii. The employees in manufacturing units shall be inoculated against the enteric group of diseases as per recommended schedule of the vaccine and a records shall be maintained.
- iii. Personnel known, or, suspected to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through Milk and milk product, shall be prevented from handling Milk and milk product or materials which come in contact with Milk and milk product till the time he /she get the fit to work certificate from the registered medical practitioner.
- iv. Food handlers shall report the following conditions to the management for possible exclusion from Milk and milk product handling areas – jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected lesions, (boils, cuts or sores) and discharges from ear, eye or nose. Medical examination of a Milk and milk product handler shall be carried out apart from the periodic medical examination, if clinically or epidemiologically indicated.
- v. In the manufacturing 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. Personal Cleanliness

- i. Food handlers shall maintain a high degree of personal cleanliness and shall wear work clothing, head covering, and footwear that are fit for purpose, clean and in good condition. Work wear shall provide adequate coverage to ensure that hair, beards, moustaches, perspiration, etc. cannot contaminate the product.
- ii. Where gloves are used for product contact, they shall be clean, food grade (like nitrile etc.) and in good condition.
- iii. Food handlers must wear clean and washable or disposable overclothing (including headgear, nose mask, shoe cover and where appropriate, neck-covering and/or beard snood)
- iv. The provision of clear information to all contractors of any hygiene requirements specific to the manufacturing area in which they will be working,
 - v. The implementation of 'return to work' procedures following illness or foreign holidays, particularly in relation to diseases that may have been contracted while away.
 - vi. The implementation of a personal medication procedure to control personal medicines that could be a potential contamination risk to the product,
- vii. Protective clothing mandated for use in manufacturing areas or hygiene purposes shall not be used for any other purposes.
- viii. All people entering food processing, storage, distribution and handling areas shall wash their hands with soap and potable water, followed by drying and sanitizing, where required such as:
 - before starting work;
 - after handling chemicals;
 - after handling incompatible food products (for example, raw versus cooked or ready-to eat) or contaminated materials;
 - after breaks;
 - after coughing or sneezing or blowing their nose; and
 - after using toilet facilities.
 - after using telephone / cell phones,
 - after smoking in designated areas etc.
- ix. Hand washing notices shall be posted at appropriate places.

- x. Fingernails shall be kept clean without nail polish and trimmed.

3. Personal Behaviour

- i. The Milk and milk product manufacturer shall implement an effective personal hygiene programme that identifies hygienic behaviour and habits to be followed by personnel to prevent contamination of food.
- ii. Any behaviour or unhygienic practices which could result in contamination of Milk and milk product shall be prohibited in food processing, distribution, storage and handling areas. This includes smoking, chewing or eating, sneezing or coughing over unprotected food, spitting etc.
- iii. Personal effects such as jewellery, watches, pins, perfumes or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.
- iv. The organization should provide separate lockers/place for personnel working in manufacturing areas to keep their personal belongings, tiffin etc. Food contact tools and equipment shall not be kept in personal lockers.

4. Work wear and Grooming

- i. Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears or fraying material).
- ii. Clothing mandated for Milk and milk product protection or hygiene purposes shall not be used for any other purpose.
- iii. Work wear shall not have buttons and outside pockets above waist level.
- iv. Work wear shall be laundered at predefined intervals.
- v. Work wear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.
- vi. Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints,
- vii. Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

5. Visitor Control

- i. Organisations should implement and display visitor control policy.
- ii. The Food Business shall ensure that visitors to its food manufacturing, processing or handling areas must wear protective clothing, footwear and adhere to all the personal hygiene provisions required for personnel required in the food business.
- iii. Visitor identity cards provisions should be in place to maintain control on visitor's access into restricted areas.

V. ESTABLISHMENT - PRODUCT INFORMATION AND CONSUMER AWARENESS

1. Product information and Labelling

- i. All packaged food products shall carry a label and requisite information as per provisions of Food Safety and Standards Act, 2006 and Regulations made there under so as to ensure that adequate and accessible information is available to each person in the food chain to enable them to handle, store, process, prepare and display the food products safely and correctly and the lot or batch can be easily traced and recalled if necessary. This should also include information that identifies food allergens in the product as ingredients or where cross contamination cannot be excluded as per FSS (Packaging & Labelling) Regulations, 2011, if applicable.
- ii. All incoming, in-process and finished products shall be suitably identified for product identification, stage of processing, inspection and test status etc. so as to avoid their inadvertent use. Lot identification shall be done to facilitate traceability, product recall, effective stock rotation etc.

2. Consumer Awareness and complaint Handling

- i. 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.
- ii. 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 Documented procedures and trained personnel shall exist for customer complaint and AE (Adverse Event) investigation and response.
- iii. Verification of customer satisfaction can be recorded after appropriate actions implemented.
- iv. Regular complaint data analysis can be utilized to reduce future customer complaints.

VI. ESTABLISHMENT - TRAINING AND MANAGEMENT

1. Awareness and Responsibilities

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

2. Training Program

- i. 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.
- ii. These training programmes shall be delivered by qualified and trained personnel.
- iii. Training for each employee can cover the following:
 - Skill Matrix of the employee, Gap analysis for training needs
 - particular tasks relevant to the employee's specific role;
 - general good manufacturing practice;
 - Importance of, and factors involved in, personal hygiene.
- iv. Each new employee should receive training upon employment. This training should be repeated, modified or extended as required.
- v. A Training Program should exist for all levels of the organization (i.e. part-time, full-time, temporary staff, management, visitors, contract personnel).
- vi. Training procedures define short and long-term training requirements, retraining, refresher training, as well as the qualification steps (and experience level needed) for Trainers. When consultants are used for training, retained records demonstrate that they possess the necessary qualifications/training/experience.
- vii. Training and qualification records shall be maintained for all personnel with relevant details like: Date, Topic, Name of Instructor, appropriate duration, Employee Signatures etc.

3. Instruction and supervision

- i. Managers and supervisors of food processes shall have 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.
- ii. 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.

4. Refresher Training

Training programmes shall be routinely reviewed and updated wherever necessary. Systems shall be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of Milk and milk products.

5. Management and Supervision

- i. Persons engaged in manufacturing, packaging, labelling, holding, or in performing any quality control operations shall have the education, training, or experience to perform the assigned functions.

- ii. The organisation management shall ensure providing necessary trainings & resources to their employees to develop food safety culture at plant site.
- iii. Employees performing specialized job functions should be certified to a recognized industry standard or governmental organization. Certification records shall be verified.
- iv. Standard operating procedure for GMP systems compliance should be maintained and its compliance shall be verified through records /checklists on routine basis.

VII ESTABLISHMENT – AUDIT, DOCUMENTATION AND RECORD KEEPING

1. Self-evaluation and review

- 1.1 The FBO shall conduct a self-evaluation of the process to verify the effectiveness of the implemented food safety system at periodic intervals through internal and external audits at least twice in a year. Necessary corrective actions based on self-evaluation results shall be taken. Records to be maintained.
- 1.2 FBO shall also undertake a complete review of the systems including self- evaluation results, customer feedback, complaints, new technologies and regulatory updates at periodic intervals, but atleast once in a year for continual improvement.

2. Documentation and records

- 2.1 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.
- 2.2 The important records that shall be maintained include:
 - A. Legal
 - i. FSSAI License and Registration of Manufacturer/Supplier/Dealers/Retailers
 - ii. Pollution Control Board Certificate of plant/manufacturing unit
 - iii. Record of Discharge Effluent & its Compliance with statutory requirements - ETP Compliance
 - B. Procurement/Quality
 1. Raw material receiving and traceability records (including records for milk being received from Milk Collection Centres, BMCs, Chilling Centres).
 2. Receiving records for raw materials and additives (other than milk)
 3. Quality Control / Lab test reports records/Compositional analysis/Microbial test records – raw milk, processed milk and milk products.
 4. External testing reports - Microbiological / chemical test reports pertaining to milk and milk products, water, other food ingredients, additives etc
 5. Certificates of Analysis/COA
 6. Internal and external audit records/ Corrective action (CAPA).
 7. Records for receipt of packaging materials and COA/Supplier certification.
 8. Certificate for Virgin / food grade Packing material
 9. Certificate of Ink approved for use for milk and milk products packet.
 10. Testing record of Packaging materials.
 11. Records of samples picked up FSSAI/State FDA authorities.
 - C. Production/Processing
 1. Daily production records
 2. Raw material consumption/utilisation records
 3. Process monitoring records – CCP's/OPRP's
 4. Temperature records of cold room (s)/ storage tanks/silos (when in operation), pasteurizer, chillers, driers etc.
 5. Consolidated daily production records.
 6. Packing/Packaging records
 7. Despatch records
 - D. Cleaning, Sanitation and Pest Control

1. Cleaning, plant hygiene and sanitation records.
2. Pest Control and routine treatment records.
3. CIP Record - Processing Level
4. Record of Equipment Swabs for Monitoring Effectiveness of Cleaning
5. Record - Periodic Review of Residual Chemical after Cleaning
6. Records of Cleaning and Disinfection for Cold Stores/ Freezers
7. Cleaning and sanitation records – milk tankers
8. Vehicle inspection record – milk tankers, trucks – raw milk handling and material dispatch

E. HR/Manpower related

1. Training record of Food handlers.
2. Health record of the employees (involved in milk handling operations)
3. Record of system to prevent entry of Person from other Department suffering from diseases/Visitor entry records
4. Record of Hygiene monitoring of operators/ Workers
5. Training Records of Officer's (new Joinees/ OJT or Identified Trainings)

F. Marketing

1. Consumer complaint records
2. Product Traceability Record - Mock Recall Simulation
3. Product recall and Traceability records pertaining of milk and milk products supplied/distributed.

G. Common

1. Calibration records – Processing equipment's & accessories, Lab equipment's & accessories, Cold stores & Freezers, Engineering & Utilities – to be maintained by concerned departments.

H. Engineering/Utility

1. Maintenance records – Breakdown and Preventive

C. SUBCONTRACTING OPERATIONS

1. Terms of Agreement/ Contract

- i. The contract acceptor shall ensure that the terms of the contract are clearly stated in writing. This shall include a Technical Agreement between the two parties.
- ii. Raw Materials, Intermediates & Finished Products shall be covered by detailed specifications. Any specific GMP requirements shall be clearly emphasized, and quality control, record transfer, coding rejection, dispute, and complaint procedures shall be identified & agreed.
- iii. Contractual conditions shall cover the following aspects to ensure quality standards and good manufacturing practice:
 - Milk and Milk products shall be produced safely within the manufacturing environment,
 - To agree on a detailed product specification that covers all aspects of product, process, pack and delivery; this shall include the parameters to be used for acceptance or rejection, and any legal requirements,
 - To agree on levels of sampling of finished products and sample plans to be used in case of dispute,
 - To agree on the methods for determination of dates of expiration and the confirmatory documents,
 - To evaluate the adequacy of the control resources, systems, methods and records of the manufacturer,
 - To agree, wherever possible, objective methods of examination; subjective measurements should conform to recognised and accepted standards if possible,
 - To agree the period for record keeping.

Any amendments or improvements shall be well documented and confirmation of acceptance of the completed work shall be recorded.

2. Technical Agreement

- i. A technical agreement is a useful method of clearly defining the responsibilities of each party.
- ii. Attention shall especially be given to clarifying the responsibilities of each party in relation to key/critical activities, such as:
- iii. The scope of the instructions given by the Contract Giver to the Contract Acceptor,
 - Approval and release of raw materials,
 - Changes to the formulation and processes,
 - Release specification,
 - Release of the finished product and its transportation,
 - The complaints and withdrawal and recall procedures,
 - The procedure for notifying the Contract Giver of any abnormality during the contracted process.
- iv. Any agreement may also include a section on the ownership of intellectual material (e.g. formulae, specific processing techniques), together with any restrictions on the transfer of information to third parties. Items of possible confidentiality should be identified and any appropriate safeguards be mutually agreed.

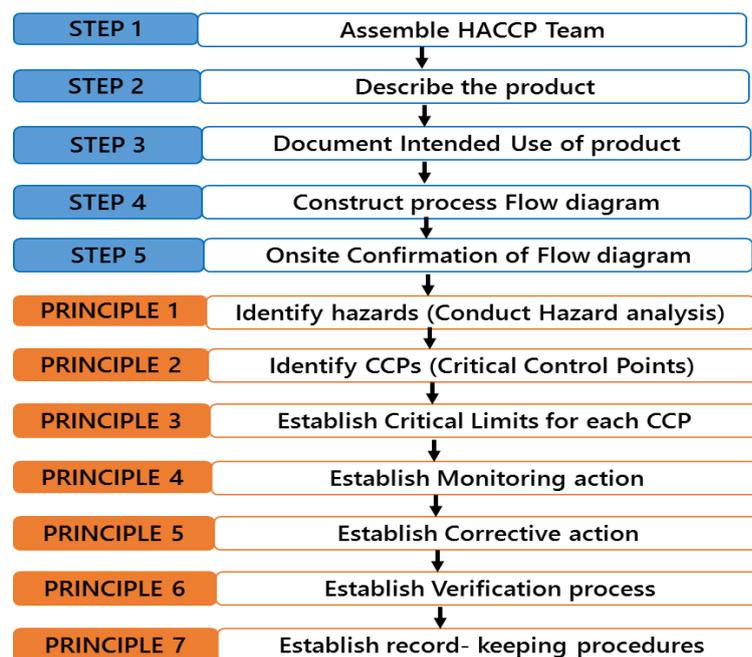
D. HACCP IMPLEMENTATION

I. INTRODUCTION TO HACCP

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.

Hazard Analysis Critical Control Point (HACCP) is essential to carry out to identify the critical points in 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 prevent the occurrence of foodborne hazards coming into the products, yet it is not possible to achieve zero risk and does not eliminate the possibility of hazards in the 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 which are critical and are likely to pose safety problems (physical, chemical and microbiological). 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) & Good Hygiene Practices should be considered as Pre-Requisite for HACCP.

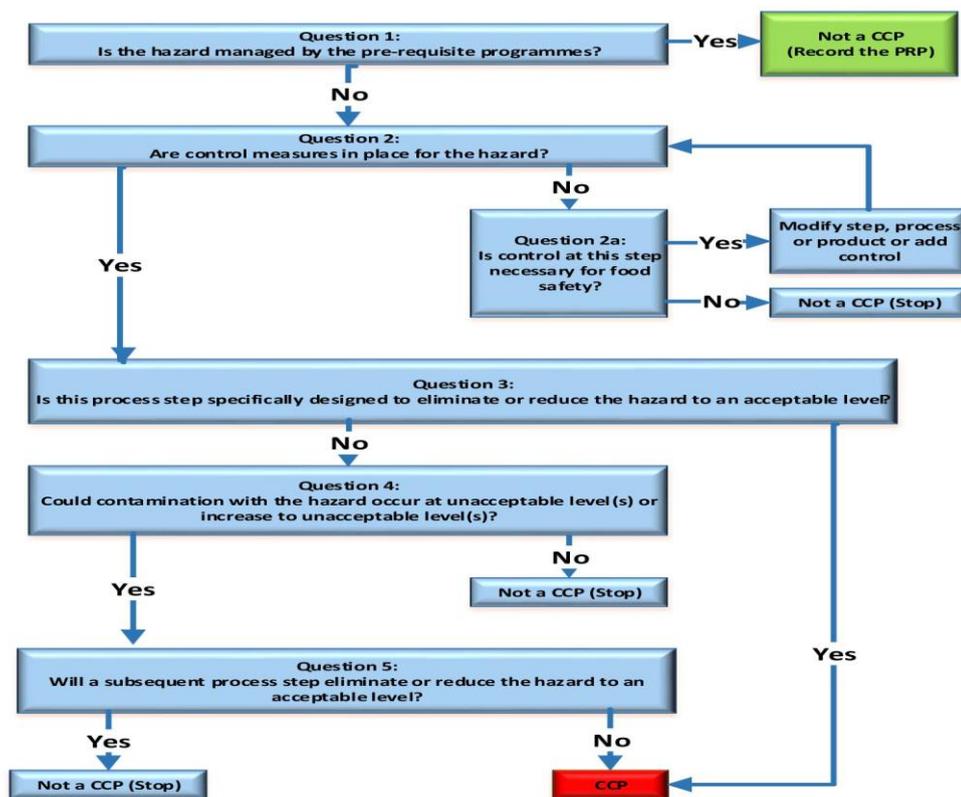
Risk assessment is a critical step in a HACCP plan. Below is a template to determine what severity and probability a processing step is involved with and therefore what level of criticality is holds in the processing line.

		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?	Frequent	Extreme	Extreme	Very High	High	Medium
	Likely	Extreme	Very High	High	Medium	Medium	
	Occasional	Very High	High	Medium	Medium	Low	
	Seldom	High	Medium	Medium	Low	Very Low	
	Unlikely	Medium	Medium	Low	Very Low	Very Low	

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



II. APPLICATION OF HACCP SYSTEM

1. HACCP Implementation steps

1.1 Assemble HACCP team

The food operation shall ensure that the appropriate product specific knowledge and expertise is available for the development and implementation of an effective HACCP plan. A multidisciplinary team shall be assembled either in-house or if such expertise is not available on-site , expert advice shall be obtained from other sources, such as trade and industry associations, independent experts, regulatory authorities, HACCP plan shall be identified and shall describe which segment of the food chain is involved and the general classes of hazards to be addressed (all or selected classes).

1.2 Describe product

A full description of the product shall be drawn up, including relevant safety information such as composition (including raw materials ingredients, allergens), origin, physical/chemical properties that impact food safety (including Aw, pH, etc.),microbial/static treatments (heat treatment, freezing, brining, smoking etc.), packing, labelling, durability and storage conditions and method of distribution. Within businesses with multiple product for example, catering operations with similar characteristics or processing steps may be grouped for the purpose of development of the HACCP plan.

1.3 Identify intended use

The intended use of the product shall be defined based on the expected uses of the product by the end user or customer. The suitability of the product for vulnerable groups of the population such as pregnant women, infants, elderly should be considered, as necessary.

1.4 Construct flow diagram

The flow diagram shall be prepared to cover all steps in the operation for each specific product or product category. When applying HACCP to a given operation, consideration shall be given to steps preceding and following the specified operation.

1.5 On-site confirmation of flow diagram

Steps shall be taken to confirm the proceeding operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a competent person or persons. On-site verification activities shall be carried out whenever there are any changes in the process.

1.6 List of all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (SEE PRNCILPLE 1)

The HACCP team should list all potential hazards (physical, chemical, biological) that may be reasonably expected to occur at each step according to the scope. It should then conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food.

In conducting the hazard analysis, the following should be included as appropriate:

- The likely occurrence of hazard and severity of their adverse health effects;
- The qualitative and/ or quantitative evaluation of the presence of hazards;
- Survival or multiplication of micro-organisms of concern;
- Production or persistence of foods of toxins, chemicals or physical agents; and
- Conditions leading to the above.

For selection of control measures, consideration shall be given to what control measures, if any, can be applied to each hazard.

More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control, measure. Where elimination of hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.

1.7 Determine Critical Control Points (SEE PRINCIPLE 2)

For each hazard that requires control, control measures shall be identified. The control measures shall be reviewed to identify those that need to be addressed through the HACCP plan and for which CCPs shall be identified. There may be more than one CCP at which control is applied to address the same hazard or there may be cases where there is no CCP identified. The CCP in the HACCP system shall be determined and this may be facilitated by a logic reasoning approach such as the application of a decision tree (see dia 2). The application of a decision tree should be flexible. This example of a decision tree may not be applicable to all situations and alternative approaches may be used.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

1.8 Establish Critical Limits for each CCP (SEE PRINCIPLE 3)

Critical Limits shall be specified and validated for each CCP. In some cases more than one critical limit may be elaborated at a particular step.

These critical limits shall be measurable, Critical Limits based on subjective data (such as visual inspection of product, process, handling) shall be supported by instructions or specifications and / or education and training.

1.9 Establish a monitoring system for each CCP (SEE PRINCIPLE 4)

A monitoring system shall be established for each CCP to demonstrate that the CCP is under control. The monitoring shall be able to detect loss of control at the CCP and in time to make adjustments to regain control of the process and prevent violation of the critical limits. Where possible, process adjustments should be made when the results of monitoring indicate a trend towards loss of control at a CCP. The adjustment should be taken before a deviation occurs.

Data derived from monitoring shall be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring shall be sufficient to ensure that the CCP is under control. The monitoring system shall cover the following:

- a) Measurements or observations that provide results within an adequate time frame;
- b) Monitoring device used;
- c) Applicable calibration method;
- d) Monitoring frequency;
- e) Responsibility and authority related to monitoring and evaluation of monitoring results; and
- f) Records.

All records and documents associated with monitoring CCPs shall be signed by the person(s) doing the monitoring and by the responsible reviewing official(s) of the company.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

1.10 Establish corrective actions (SEE PRINCIPLE 5)

Specific planned corrective actions shall be developed for each CCP in the HACCP system in order to deal with deviations when they occur and to prevent their recurrence. This may require identification of the causes of deviation.

The action shall ensure that the CCP has been brought under control. Actions taken shall also include proper disposition of the affected product. Deviation and product disposition procedures shall be documented. Records of deviations and disposition shall be maintained.

1.11 Establish Verification Procedures (SEE PRINCIPLE 6)

The verification procedures consist of two activities, verification activities and validation activities.

The food business operator shall have in place a system to verify the HACCP plan at a set frequency. Procedures for verification shall be established. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in-house, verification should be performed on behalf of the business by external experts or qualified third parties.

The HACCP system, including the HACCP plan, shall be reviewed (at least once in a year) and necessary changes made when any modification is made in the product, process, or any step.

Verification activities shall include:

- Self-evaluation;
- Review of the HACCP system and plan and its records;
- Review of deviation and product dispositions; and
- Confirmation that CCPs are kept under control.

The results of verification shall be maintained and communicated to the HACCP team/ relevant staff.

The food business operator shall periodically validate the HACCP plan and necessarily before its implementation and after any changes are made. The objective of the validation process is to ensure that identified hazards are complete, correct and effectively controlled under the HACCP plan. Validation activities should include actions to confirm the efficacy of the HACCP system. Records of validation shall be maintained. An annual review of the complete HACCP system shall be carried out.

Verification and validation activities are also important for maintenance of the system as well as continual improvements.

1.12 Establish Documentation and Record Keeping (SEE PRINCIPLE 7)

HACCP procedures shall be documented. Documentation and record keeping shall be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

Documentation shall include (as a minimum) the following:

- HACCP team composition;
- Product description;
- Intended use;
- Flow chart;
- Hazard analysis;
- CCP determination;
- Critical limit determination;
- Validation process; and
- HACCP plan

The HACCP plan shall include the following information for each identified CCP:

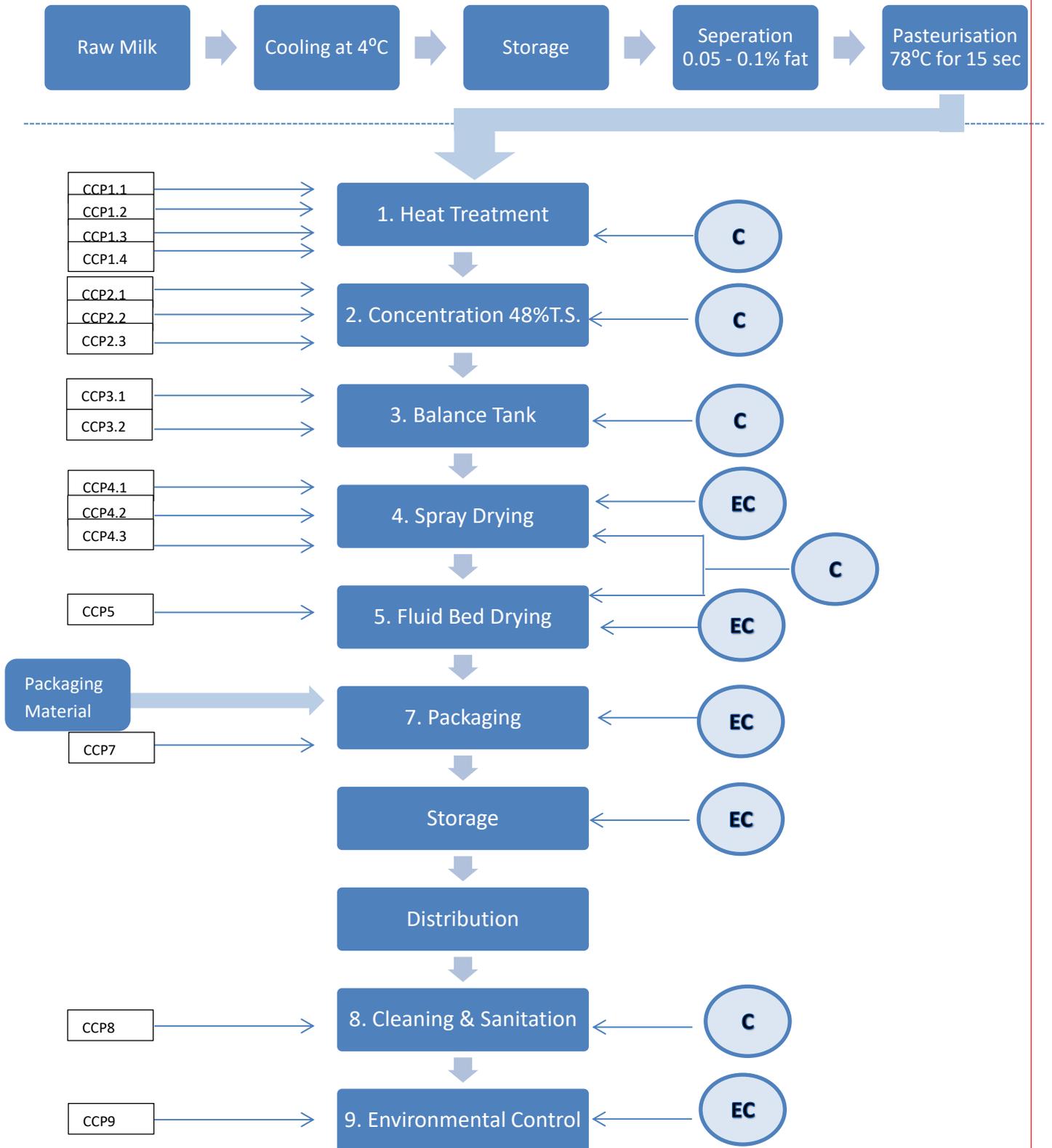
- Food safety hazard(s) to be controlled at the CCP;
- Control measure(s);
- Critical limit(s);
- Monitoring procedure(s);
- Corrections and corrective action(s) to be taken if critical limits are exceeded;
- Responsibilities and authorities for monitoring, corrective action and verification;
- Record(s) of monitoring.

Records to include

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Disposition of non-conforming products;
- Verification procedures performed;
- Modifications to the HACCP plan;
- Validation record;
- Product release records; and
- Testing records.

2. HACCP Plan

2.1 Skimmed Milk Powder



Process Step	Potential Hazard	Preventive Measure	CCP No.	Critical Control Point	Critical Limits	Monitoring Procedure & Frequency	Responsibility	Corrective Action	Record	Verification
Preheat treatment	Pathogens & saprophytic M/Os survival growth	Proper temperature and time control	1.1	Temperature & time	Not less than 90°C and 1 min	High heat temperature chart visually every hour	Evaporator Operator	Check steam pressure	High heater temperature chart	Examination of plant records by section in charge
		Flow control assurance	1.2	Temperature device calibration	Temperature device to be within $\pm 0.5^{\circ}\text{C}$	Flow rate	Calibrating the temperature instruments every 6 months	Maintenance supervisor	Temperature instrument to be repaired or replaced and recalibrated before use	Calibration record
	Restricting running to 20 h	Ensure no mixing with untreated milk takes place								
	Microbiological contamination	Ensure proper cleaning of the equipment	1.3	Cleaning & Sanitisation	As per conformed cleaning & sanitization procedures	Ensure that the preheaters and associated lines have been cleaned and sanitized before use	Evaporator Operator	Reclean and sanitise as necessary	Cleaning & sanitization records	Examination of cleaning records by section in charge daily QA manager periodically
Enzyme lipase	Proper time temperature control	1.4	Temperature & time	Not less than 90°C and 1 min	High heat temperature chart visually every hour	Evaporator Operator	Check steam pressure	High heater temperature chart	Examination of plant records by section in charge	
Concentration	Microbial contamination build up	Proper sanitization & GMPs. Evaporator operation under optimal conditions.	2.1	Cleaning & sanitization of evaporator, pumps, pipelines & other system components	As per conformed cleaning & sanitization procedures. Cleaning once in 20 hours	Where long runs are necessary, operate evaporator at temperatures above max. growth temperature of thermophillic M/Os	Evaporator Operator	Reclean	Cleaning & sanitization records	Inspection of plant weekly by incharge to ensure cleaning. Periodic specialist examination & maintenance of plant by manufacturers

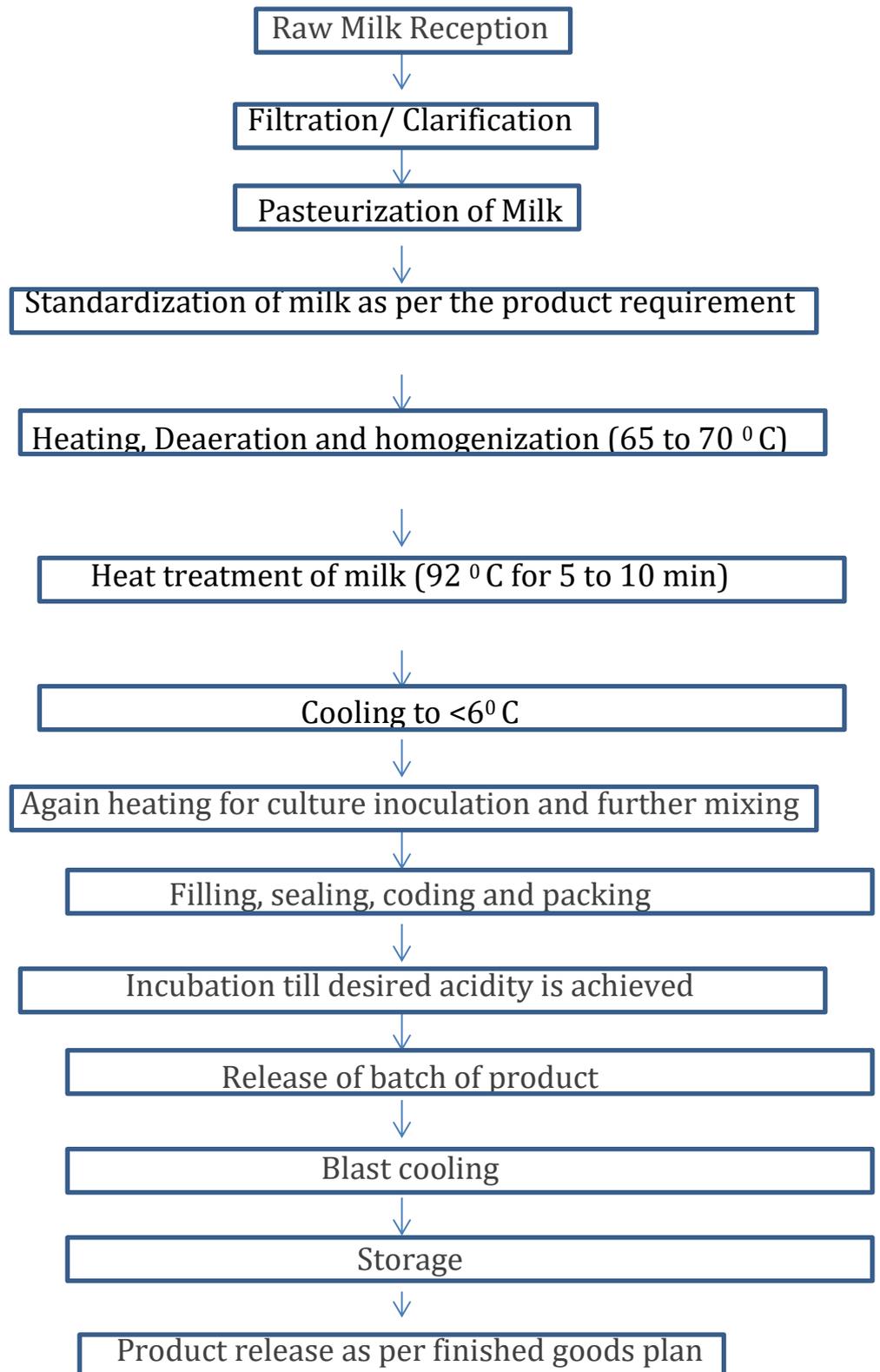
		Evaporator equipped with appropriate instruments (for temp. vacuum), instruments properly maintained	2.2	Proper operation of the evaporator	All operating parameters as approved	Cleaning routines to be correctly implemented. Trained staff to be employed at all times. Visual inspection of tubes, valves, gaskets, jets, sprays after each cleaning for blockage & wear. Visuals on temperature, pressure, gauges, plant operation records	Evaporator Operator	Check operating parameters and adjust as required. Recycle till okay	Evaporator operation record	Examination of plant records by in charge daily & by QA Manager weekly.
	Contamination with cleaning residues	Proper maintenance of pump of pump seal, flash vapor ducts, gaskets	2.3	Instrumentation calibration	Temperature device calibration	Calibrating the temperature instruments every 6 months	Maintenance supervisor	Temperature instrument to be repaired or replaced and recalibrated before use	Calibration record	Examination of calibration records by QA Manager every 6 months
Balance tank, dual	Environmental contamination of concentrate with bacteria	Good manufacturing practices Tanks are kept with covers in place during operation	3.1	Balance tank condition	Cover in place during operation	Visual during operation	Evaporator Operator	Replace cover	Evaporator operation record, GMP records	Examination of plant records & GMP records by the section incharge
	Excessive build up of bacteria (S. aureus) & toxin production, incase of extended plant run	Ensure continuous and regular flow of concentrate to allow shortest residence time Use of dual balance tank regularly cleaned during run	3.2	Shortest residence time	Continuous flow- each balance tank to be cleaned every 6 hours	Plant records, visual during operation	Evaporator Operator	Examine the cause and take action in consultation with the in charge	Plant operation records	Examination of plant records weekly by the section incharge

Spray dryer operation	Microbiological Contamination	<p>Precaution against contamination from raw milk to heated milk, concentrate or powder.</p> <p>Precautions against cross contamination between the wet side of the plant & the powder site, like locating air inlet away from exhaust air outlet.</p> <p>Dryer equipped with suitable instruments (inlet air temperature, outlet air temperature).</p> <p>Instruments maintained properly.</p> <p>Precaution against inward leaking of air, regular inspection of dryer chambers for stress cracks & appropriate repair & maintenance schedules. To ensure no sudden increase in feed rate. Exhaust stack covered when not in use.</p> <p>Cleaning according to conformed procedures.</p> <p>Trained staff at all times</p>	4.1	Feed control	No mixing of raw milk	Precautions against contamination from raw milk to heated milk, concentrate or powder to be monitored on a continuous basis. GMP records	Evaporator Operator	Re pasteurized the mixed milk	Evaporator operation record	<p>Examination of process records daily by section incharge.</p> <p>Dust samples from dryer fluid bed, cyclone and silo to give early warning of plant contamination by QA Manager</p> <p>Periodic specialist examination & maintenance of plant by manufacturer to detect cracks in dryer inner wall</p>
			4.2	Cleaning & sanitization	<p>Refer to cleaning & sanitization procedures.</p> <p>Camber & cyclones are wetcleaned once a week.</p> <p>Atomizer manually cleaned twice in a production run.</p> <p>Dry cleaning after each run, of chamber, ducts, cyclones, rotary valves etc.</p> <p>Dry exhaust wet cleaned daily</p>					

	Physical contamination (dust etc.)	Cleaning & changing filters of main drying air & fines return air as appropriately specified	4.3	Air filters	Cleaning/ replacing filters when pressure drop across it reaches at pre-set values	Visual inspection at startup & shut down daily	Dryer operator	Reclean or replace filter as necessary	Dryer (air heater and fines return) operation record	Examination of plant records & visual inspection weekly by plant incharge
Fluid bed dryer operation	Microbial contamination through air	Air filters cleaned & changed as per conformed schedules & procedures. Exhaust stack to be covered when not in use. GMPs.	5	Air quality	Intact filter in place	Visual inspection at startup & shut down daily	Dryer operator	Reclean or replace air filters, as replaced	Dryer Operation records	Examination of plant records & visual inspection by plant incharge.
	Physical contamination (dust etc.) through air	Proper cleaning of duct work, cyclones, rotary valves. Ensure no cracked rubber ware. Air filters changed as required.								
Packaging Materials	Physical/ microbial contamination source	As per specification, storage and handling of packaging materials according to conformed procedures	6	Storage & handling	Areas to be cleaned & tidy. Each batch inspected for damage etc. before use.	Ensure clean storage environment. Ensure dirty material is rejected. Audit supplier's QA	QA & Purchase Managers	Reject suspected packaging material, change supplier	Packaging records	Examination of packaging records by QA Manager regularly
Packaging	Environmental contamination	Same as those of step 5	7.1	Clean environment	As per CCP9	As per CCP9	As per CCP9	As per CCP9	As per CCP9	As per CCP9
		Good housekeeping and GMPs.								
	Small piece of component falling into pack	Regular PM of equipment	7.2	Proper operation & PM of equipment	All component always properly lightened	Check equipment condition at startup	Operator	Tighten equipment in machines properly	Packaging Record	Examination of packaging records & PM records regularly by the section incharge
All process steps involving product	Microbial / toxin contamination	Effective cleaning procedures	8	Cleaning parameters	Approved cleaning	Visual inspection,	Evaporator & dryer operators	Reclean	Cleaning records	Examination of cleaning & plant

in contact with production equipment (preheater, evaporator, balance tanks, tanks, dryers, pipework, cyclones) cleaning	due to poor cleaning				procedures, no residues	temp, solution concentration, time frequency etc. as approved. Before startup of every batch				operation records by QA Manager & plant incharge daily
Environment control in powder manufacturing, packaging and surrounding areas	Environmental contamination with microorganisms through air and deposits of powder	Bacterial hygiene to avoid contamination of areas producing/handling powder. Minimization of dust and powder deposits in dryer & other areas with application of dry cleaning techniques. Proper maintenance of the building to prevent contamination from external sources such as rain water, pest infestation etc.	9	Clean environment	Clean air, no cracks in dryer insulation, & wall; No powder deposits on powder installation, building walls, roof etc.	Microbial tests (Standard Plate Count, Coliform tests & Salmonella tests). Visual inspection of dryer installation, walls, etc. regularly	Plant incharge, sanitization incharge	Repair dryer insulation, clean dryer wall, building of powder deposits & other dirt	Sanitation records, GMP records	

2.2 Plain curd



S. No.	List of Manufacturing/ Process Steps / (sequential)	Possible Hazard Type:	Possible Hazards	Source	Hazard Adverse Impact	Control Measures
1.	Raw milk Reception	P	Extraneous materials (Debris, chaffs, Dust)	Improper covering of vehicles and milk handling	Can cause choking	Physical inspection of each consignment. Vehicle suitability monitoring prior to unloading. De-dusting of unloaded material.
		C	Animal Drug residues	Animal fed with drugs to increase milk production	Adverse health effects	Meeting schedule 4 requirements
		B	Vegetative pathogen (contamination and/or growth)	Improper handling of milk	Adverse health impacts	Procurement from approved firm. Maintenance of proper temperature Tanker sanitation prior to milk pick up. Effective microbiological testing
2.	Raw milk solids, water & microbial culture for inoculation	P	Improper covering of the vehicle covering while transporting. Raw material storage bag spilling or bursting Packing integrity	Adverse health effects		Physical inspection of each consignment & reject if not satisfactory use approved lot only. Vehicle suitability monitoring prior to

			compromised			un loading. De-dusting of unloaded material
		C	Transport vehicle when used for carrying chemicals. Chemical spillage.	Adverse health impacts like poisoning		Vehicle suitability monitoring prior to unloading Ensuring quality testing of water and culture. Also temperature of mixing and storage.
		B	<i>High moisture content due to improper covering of vehicle</i>	Acute and chronic GI infections		Vehicle suitability monitoring prior to unloading Microbiology of RM/PM on receipt.
3.	Filtration and Clarification	P	Debris and Extraneous material	Improper cleaning and washing of filters and clarifier	Contamination of milk	Ensuring proper filter conditions like cleanliness, integrity and chilling temperature also. Efficiency of clarification verification can be done by checking sedimentation tests
		C	NA	NA	-	-

		B	NA	NA	-	-
4.	Standardization	P	Extraneous material	Machine and Equipment	Contamination of milk	Proper washing of machinery before standardization procedure
		C	NA	NA	-	-
		B	NA	NA	-	-
5.	Pasteurization and homogenization	P	Extraneous material	Machines and equipment	Contamination of milk	Ensure proper CIP process, proper functioning of deaerator
		C	Chemical Residues	Improper rinsing of health tanks and pipes	Adverse health effects	Ensuring effective cleaning in place
		B	Pathogen (survival and/growth)	Fluctuation in Pasteurization temperature and time	Contaminated milk	Appropriate time-temperature combination should be followed, and pressure of homogenization process
6.	Heat treatment of milk and Cooling	P	NA	NA	-	-
		C	NA	NA	-	-
		B	NA	NA	-	-

7.	Inoculation & Mixing	P	Extraneous material	Mixing machines	Adverse health impact	Proper cleaning of agitator spindles. Agitator speed and mixing time
		C	NA	NA	-	-
		B	Poor quality culture	Inoculation Culture		Procurement from approved firm. Effective incubation temperature & time
8.	Filling, sealing and packing	P	Extraneous material	Leak in Packaging material Contaminated Filling machines	Contamination of Curd	Packaging material should be checked for its rigidity and stability.
		C	Chemicals	Primary packaging material Ink leakage	Adverse health effect	Use of food grade primary packaging material and ink
		B	Microbial growth	Filling issue and package leaks	-	Package material should be checked for its rigidity and stability.
9.	Incubation	P	NA	NA	-	-
		C	NA	NA	-	-
		B	Growth of undesirable micro organisms	1.Cross contamination 2.Microbially infected Packaging material	Contamination of curd	Incubation at controlled temperature

10.	Blast cooling			3.Fluctuation from controlled incubation temperature		
		P	NA	NA	-	-
		C	NA	NA	-	-
11.	Storage	B	NA	NA	-	-
		P	Damage to Packaged product due to insects/pests	Insects and rodents	Adverse health effect	Effective pest management program Packs of curd should be stacked above the ground level.
		C	NA	NA	-	-
12.	Dispatch	B	Growth of microbes	Uncontrolled temp. and fluctuation in temperature	Makes curd unfit for consumption	Stored at cold temperature as per the process.
		P	NA	NA	-	-
		C	NA	NA	-	-
		B	Growth of microbes	Pest infestation, Temperature may rise and lead to growth of micro organism	Adverse health effect	Controlled temperature

E. INSPECTION CHECKLIST

MILK & MILK PRODUCT PROCESSING

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

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

S. No.	Audit Question	Scoring
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2
I	Design & facilities	
2	Design of food premises provide adequate working space; permit maintenance, cleaning & prevent 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 at all ends 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 (preferably SS 316 for equipment& SS 304 for tanks/tankers).	2
9	Premise has sufficient lighting.	2
10	Adequate ventilation is provided within the premises.	2
11	An adequate storage facility for food, packaging materials, chemicals, personnel items etc is 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 product ingredient or in contact with food or food contact surface. Tested for quality semi annually. Check for records.</i>	4
14	Raw Milk Reception Dock (RMRD) facility is sufficiently raised with sides & top to prevent contamination while unloading of raw material.	2
15	Separate processing facilities available for heat treated milk & milk products to avoid cross contamination.	2
16	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2
II	Control of operation	
17	Incoming material is procured as per internally laid down specification & from approved vendors. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2
18	Milk & other raw material are inspected at the time of receiving for food safety hazards.	2
19	Raw milk received through bulk chilling centres, the temperature of milk is maintained at 5°C or lower.	2
20	Raw milk when brought to dairy plant by farmers, should reach the plant within 4 hours from milking & is cooled to 5°C or lower as quickly as possible.	2
21	Incoming material, semi or final products are stored according to their temperature and humidity requirement, in a hygienic environment. FIFO & FEFO is practised.	2

MILK & MILK PRODUCT PROCESSING

22	Milk is brought to the collection centre within 4 hours and immediately chilled to a temperature of 4°C or lower.	2	
23	Pasteurization temperature & holding time (Ideally 72°C for 15 seconds for HTST) are properly maintained. (Batch pasteurization (63°C for 30 minutes, UHT (135°C for 1-2 sec))	2	
24	Post pasteurisation process, milk is cooled immediately to a temperature of 4°C or lower.	2	
25*	<i>Requisite time and temperature is being achieved, maintained, monitored & recorded while manufacturing/processing.</i>	2	
26	Packing or filling of heat treated milk and milk products are carried out hygienically.	2	
27	Packaging materials is food grade & in sound condition.	2	
28	Cleaning chemicals & other hazardous substance are clearly identified & stored separately from food.	2	
29	Transporting vehicle for food use are kept clean and maintained in good repair.	4	
30	Transporting vehicles for carrying milk are capable of meeting requisite temperature (where applicable).	2	
31	Recalled products are held under supervision & are destroyed or reprocessed/reworked in a manner to ensure their safety. Check for records.	2	
III	Maintenance & sanitation		
32	Cleaning of equipment (preferably CIP), food premises is done as per cleaning schedule & cleaning programme. Proper arrangements available for cleaning, sanitizing of road milk tankers, cans etc.	2	
33	Preventive maintenance of equipment and machinery is carried out regularly as per the instructions of the manufacturer.	2	
34	Measuring & monitoring devices are calibrated periodically.	2	
35*	<i>Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.</i>	4	
36	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2	
37	Drains are designed to meet expected flow loads and equipped with traps to capture contaminants.	2	
38	Food waste and other refuse are removed periodically from food handling areas to avoid accumulation.	2	
39	Effluent Treatment Plant (ETP) is in place.	2	
40	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	2	
IV	Personal Hygiene		
41	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	
42	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	
43*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage etc) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc).</i>	4	
46	Food handlers are equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2	
V	Training & records keeping		

MILK & MILK PRODUCT PROCESSING

47	Internal / External audit of the system is done periodically. Check for records.	2	
48	Food Business has an effective consumer complaints redressal mechanism.	2	
49	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2	
50*	<i>Appropriate documentation & records are available and retained for a period of one year or the shelf-life of the product, whichever is more.</i>	4	

Total points/110

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"/>	A⁺	100 - 110	Compliance – Exemplar
<input type="checkbox"/>	A	88 - 99	Compliance – Satisfactory
<input type="checkbox"/>	B	55 - 87	Needs Improvement
<input type="checkbox"/>	No grade	<55	Non Compliance

F. PROFORMAS/TEMPLATES

1. Mandatory Proforma

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. _____

Place: _____

From: _____

Date: _____

To: _____

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 Proforma

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 Signature		

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

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

2.6 Non-conforming Material/Product

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

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			Remarks
	Date	Time	Person responsible	

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 Correction & Corrective Action Report

Location:

Date:

Time:

Audited By:

Processing area in charge:

Schedule IV (Hygienic And Sanitary Practices)	Observation (Non Conformance)	Correction/Corrective action	Root Cause Analysis	Preventive measures

2.15 Pest Management Plan

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

2.16 Pest monitoring record

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

2.17 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

2.18 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.

2.20 Visitor Record

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

ANNEXURE 1: GMP and GHP to be followed at the level of village collection, MCC and BMC level

MILK COLLECTION LEVEL

As Raw Milk is highly perishable in nature; care shall be taken during milk collection, storage and transportation to the processing unit so that the quality and food safety of milk are not compromised.

i. At village level collection (VLC)

- a. Proper location, building layout so as to prevent cross contamination from chemicals, insect/pest, biological and other hazardous substances.
- b. Use of proper milk collection equipment – preferably from SS.
- c. Ensure use of clean milk storage cans/containers.
- d. Proper personal hygiene and cleaning /sanitation protocol at the centre.
- e. Adequate weighing and testing facilities for Fat, SNF and organoleptic evaluation.
- f. Cans / Containers made up of mild steel, GI and plastics shall not be used.

ii. Bulk Milk Collection/ Milk Collection Centre (BMC/MCC)

- a. Proper location, building layout so as to prevent cross contamination from , objectionable odours, chemicals, insect/pest, biological and other hazardous substances. It shall be away from slaughter house/ meat cold stores, sewage treatment plants or any other possible threats to food safety.
- b. Use of proper milk collection equipment– preferably from SS.
- c. Appropriate facilities for cleaning and sanitation of milk storage cans ,tanks, pipelines and equipment.
- d. Arrangements for cooling the milk including use of suitable technologies (BMCs/MCCs) for chilling milk to 5 °C or below
- e. Proper personal hygiene and cleaning, sanitation and waste disposal protocol at the centre.
- f. Adequate weighing and testing facilities for Fat, SNF, organoleptic evaluation and check for adulterants.
- g. Ensure clean milk tankers for dispatching of milk.

iii. Transportation of milk from collection centre to milk processing unit

- a. Raw Milk shall be transported from VLC to MCC/BMC/ processing unit as applicable within 4 hours of milking and it shall be cooled as soon as practicable to a temperature of 5 degree Celsius or below.
- b. The transportation of raw chilled milk to processing unit shall be done in clean, insulated container/milk tanker (SS) to avoid any chemical/biological contamination of the raw milk.
- c. Adequate precautions also need to be taken to ensure that integrity and temperature of milk is maintained.

ANNEXURE 2: Sample design and layout of milk processing plant

The following aspects are considered while installing/designing a facility for processing of milk and milk products.

- i. **Process design:** This determines how the intended products in a plant are actually made. Facility design is determined from material flow, people movement patterns, utility requirements, environmental conditions and legal and regulatory requirements.
- ii. **Process Simulation:** Mathematical and Physical simulation of process may be conducted to understand and investigate parameters and determine operating conditions. This helps in understanding constraints and considerations which are likely to occur during actual operating conditions/ during process.
- iii. **Process Instrumentation and Control:** Food processes are to under careful control and well documented for efficiency and fulfilling the legal and regulatory requirements. Use computer automation to support Hazard Analysis and Critical Control Point (HACCP) programs and to integrate manufacturing with marketing, shipping, and logistics and its extent determines the space requirements and in-turn the design of the facility.
- iv. **Plant Sanitation:** Sanitary design is an underlying principle of food plant design. Maintaining sanitary conditions is a constant challenge in operations, due to production requirements, low skill and motivation level of available labor and inherent characteristics of foods and processing conditions.
- v. **Waste materials (Food & Packaging):** Food processing produces waste materials, which are bio degradable and non-biodegradable in relatively high quantities. Access to a convenient and economical means of disposal for liquid and solid food waste can be a factor in plant location.

These 4 principles determine the layout of milk and milk product processing facility

A. Site geometry, location and premises.

The premises, location and geometric aspects of the site needs to be considered while installing/commissioning/modifying a milk and milk product processing facility. The site/location should facilitate food safety and hygienic operations.

B. Sanitary Design

Foods are subject to many hazards, primarily contamination by microbes, foreign matter, and spoilage. Most aspects of sanitary design are architectural details aimed at making plants easy to clean and less inclined to contaminate foods. This requires novel design of heating, ventilation, and air conditioning (HVAC) equipment, as well as careful specifications for all other equipment, which might be subjected to such conditions. Specifically, the HVAC system must be capable of reaching the required temperatures in a reasonable length of time (several hours), maintaining the temperature, and then cooling the facility. In a wet facility, the issues involve drainage, corrosion resistance, and avoidance of areas where soil can accumulate. All of these are directed at making it easy to clean the soil that could harbour microbes or become contaminants to foods. The architectural aspects to ensure and facilitate sanitation are irrelevant if the plant is not cleaned properly and frequently.

C. Design for people

Dairy processing facilities can be unpleasant places to work owing to its high humidity conditions, hot or cold environments and noise levels. The design of the processing facility should enable healthy and comfortable working environments which can facilitate the efficiency and loyalty of manpower involved in the operations. This would entail robust HVAC systems, insulation for noise/heat/cold, material handling arrangement's viz lifts, forklifts and adequate space for movements i.e congestion free working spaces.

D. Material flow

The governing concept is to minimize the distance over which material is moved and to have some logic as to the direction and sequence of operations. There are three classic choices in overall plant layout:

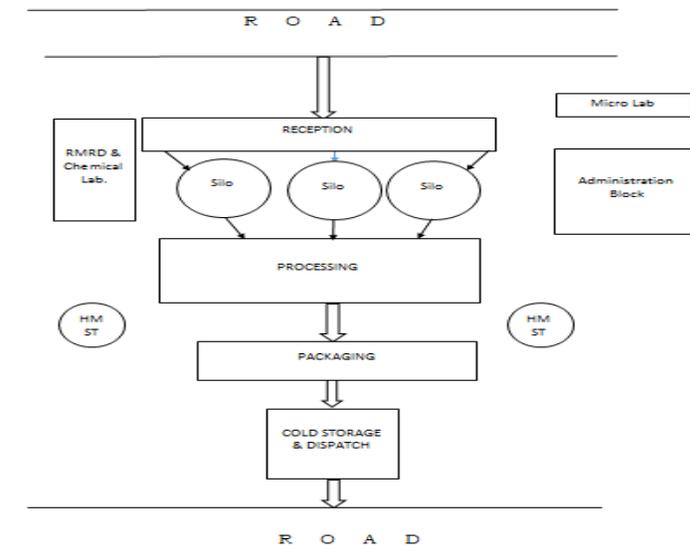
- Straight-through
- "U" shaped (180°)
- "L" shaped (90°)

The **straight-through pattern** is the simplest and has the advantage of relatively simple expansion, by adding lines in parallel. In this design reception and dispatch of milk happens in opposite sides. Road access on both sides is required in this design.

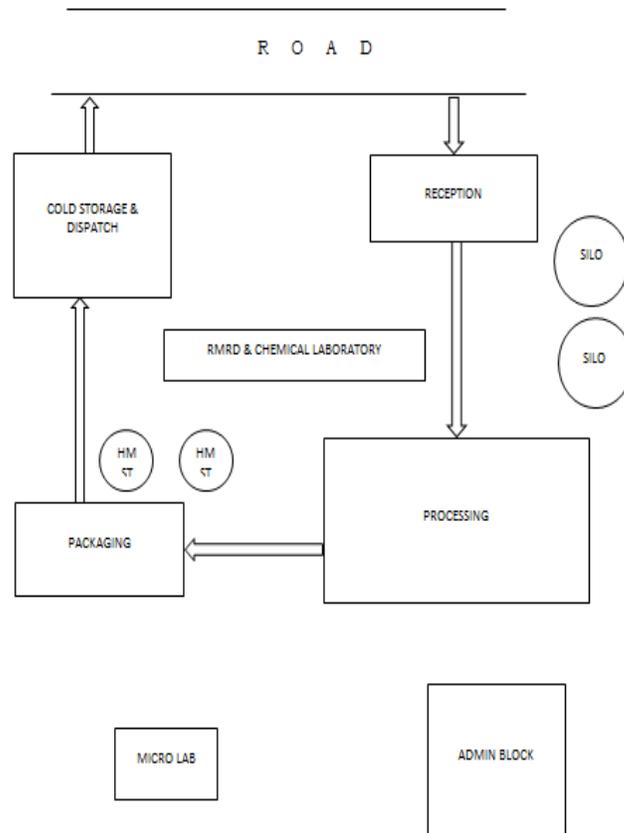
The **"U" shaped facility** can have reception and dispatch on one side. Expansion of such facilities is complex, but can be overcome by prudent planning.

The **"L" shaped facility** can adapt well to a less than ideal plot of land and can realize some of the benefits (as well as deficiencies) of the other pattern.

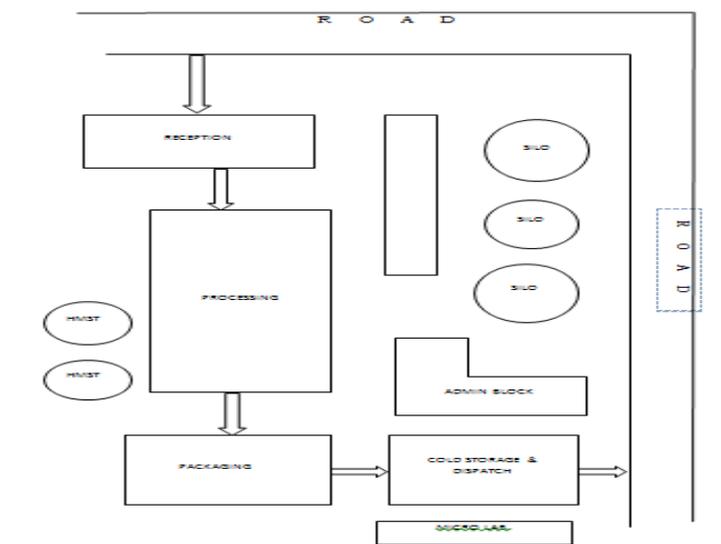
Straight-through Design ***



"U" shaped (180°) ***



L" shaped (90°) ***



*** The layouts are indicated for illustrative purpose only. Any suitable layout which ensures food safety and offers adequate protection from hazards may be adopted for dairy processing establishments.

ANNEXURE 3: Floors for dairy manufacturing facilities

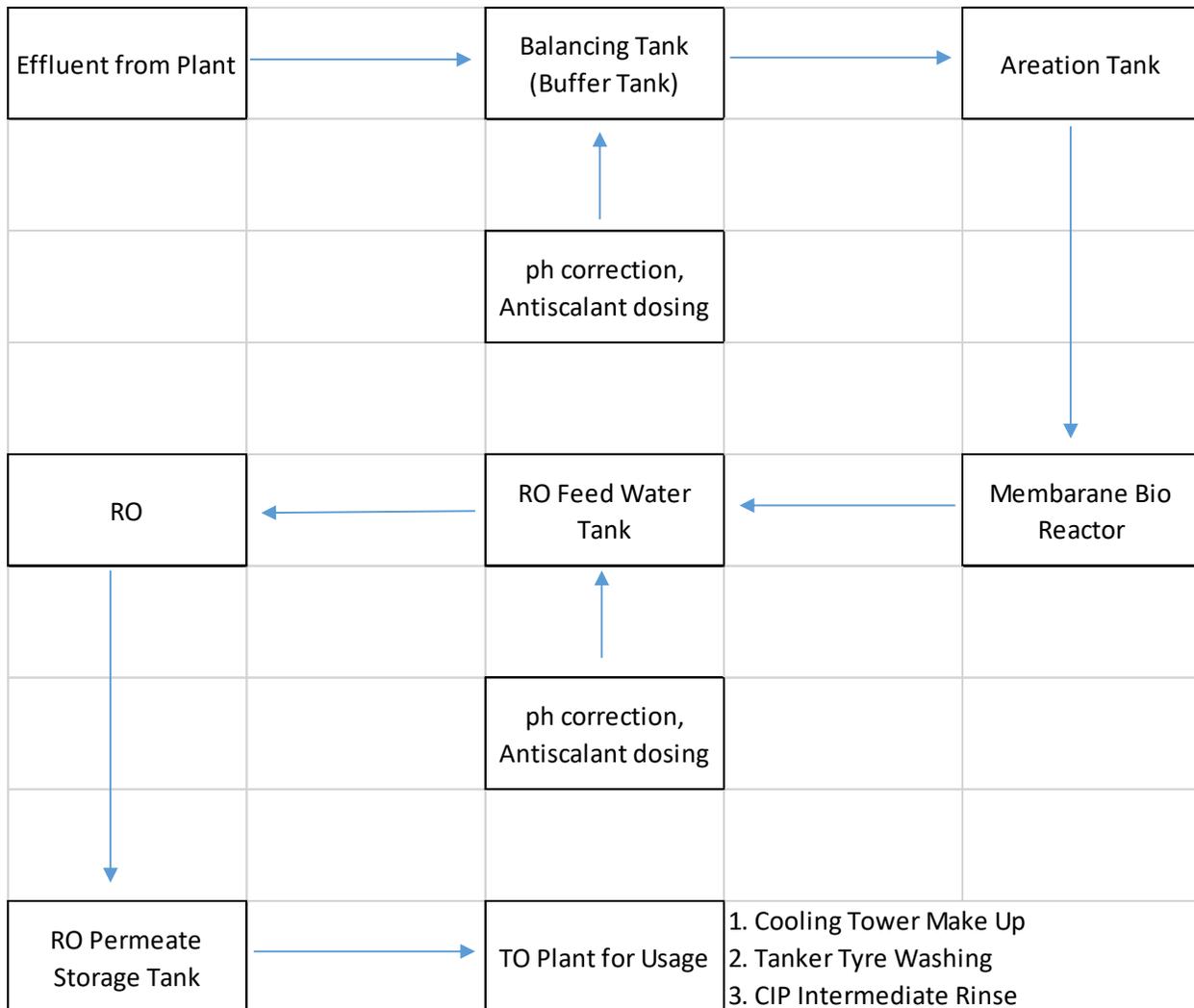
Floor finish	Features	Considerations	Dairy processing	Wet areas	Chillers Freezers	Dry stores
Ceramic tiles*	<ul style="list-style-type: none"> Highly durable and excellent for high traffic loads Relatively expensive and require long duration for installation Grout that is permeable makes cleaning and sanitising difficult 	<p>Epoxy grout finished flush with tiles</p> <p>Grout lines need to be maintained so they don't harbour microbes, dirt, and grease</p> <p>Impact resistance</p>	✓	✓	✓	✓
Quarry tiles	<ul style="list-style-type: none"> Machine-made clay or earthenware paving is usually unglazed, highly durable and excellent for high traffic loads Relatively expensive and require long duration for installation Grout that is permeable makes cleaning and sanitising difficult 	<p>Epoxy grout finished flush with tiles</p> <p>Grout lines need to be maintained – can harbour microbes, dirt, and grease</p> <p>Sealed with a water-based penetrating sealer</p> <p>Impact resistance</p>	✓	✓	✓	✓
Steel trowelled casehardened concrete	<ul style="list-style-type: none"> Smooth finishing treatment results in reduced surface absorbency Not suitable for wet applications unless properly sealed <i>e.g.</i> heavy duty polymer screed 	<p>Unsuitable for use in wet areas – porous nature results in absorption of spillages</p> <p>Pressure washing can damage the surface</p>				✓
Stainless steel – slip resistant	<ul style="list-style-type: none"> Often used on stairs, raised platforms and decks, and for the construction of drains/drain covers Durable and good for high traffic loads 	<p>Requires welded joints</p> <p>Slip resistance is a challenge for metal surfaces, especially in wet areas</p>	✓	✓	✓	✓
Epoxy resin	<ul style="list-style-type: none"> High solids epoxies provide good protection against acids and alkalis – but not against lactic acid Good adhesion Fast drying Withstands abrasive cleaning Compatible with textured, anti-slip additives Don't handle cold or thermal shock conditions Bonds well to prepared concrete 	<p>Must be durable and thick enough to create a protective barrier and prevent contaminants permeating to the concrete substrate</p> <p>Epoxy floors are harder, more durable and have a much higher compression strength than polyurethanes</p>	✓	✓	✓	✓
Polyurethanes	<ul style="list-style-type: none"> Long service life Good resistance to thermal cycling Excellent chemical resistance especially to lactic acid Low odour, seamless, and easy to clean Fast drying but not recommended for sloped floors UV stable Doesn't bond as well to concrete 	<p>Must be durable and thick enough to create a protective barrier and prevent contaminants permeating to the concrete substrate</p> <p>Polyurethane is softer and more elastic than epoxy resin, making it more resistant to scratching</p> <p>The elasticity makes it suitable for freezers where storage temperatures may reach -30°C</p>	✓	✓	✓	✓
Poly vinyl sheet	<ul style="list-style-type: none"> Long lasting, durable, hygienic, easy to clean and often recyclable Lightweight Economical 	<p>Requires heat welded joints</p> <p>Easily damaged by impact</p> <p>Not suited to heavy traffic</p> <p>Can be slippery when wet</p>	✓		✓	✓
Laminated thermosetting plastic sheeting	<ul style="list-style-type: none"> Cures when heated into durable and heat resistant materials Long lasting, hygienic, easy to clean Lightweight Economical 	<p>Requires heat welded joints</p> <p>Easily damaged by impact</p> <p>Not suited to heavy traffic</p> <p>Can be slippery when wet</p>	✓		✓	✓

ANNEXURE 4: General guide to packaging material

Food Products	Thermoplastics that may be used in contact with foods	Most common form of usage	Normal combination, if any
Liquid Milk	LLDPE, LDPE, HDPE, PP	Bags and Pouches	As such and in laminated form
	PC	Bottles	None
	LLDPE, LDPE, HDPE, PP, PET	Containers	
	PW, EVA	Cartoons	Coated on board
Whole Milk Powder	LLDPE, LDPE, HDPE, EAA, PET, Ionomer, Tin	Bags, Pouches, Containers	Laminated to paper, cellophane foil, BOPP, Polyester
Skim Milk Powder	LLDPE, LDPE, HDPE, PP, PET, Tin	Bags, Containers	None
Yoghurt/ Dahi	HDPE, ABS, HIPS, PP, PVC, Cellulose Acetate, PET	Containers	None
Cheese	NC, PVC, HDPE, LLDPE, LDPE, Ionomer, EAA, Nylon, PET	Wrappers, Pouches, Containers	Laminated to cellophane, BOPP, Polyester, Foil
	HDPE, HIPS, PP, ABS, Tin	Containers	None
Ice cream	PS, ABS, HDPE, PET, PP	Containers	Laminated to cellophane, BOPP, Polyester, Foil
	LLDPE, LDPE, HDPE, Pp, Cellophane, PET	Cartoon	Laminated to paper or board
Butter	NC, PVC, EVA, Nylon, EAA, Ionomer, Tin	Pouches, Containers	Coatings on board, Cellophane, foils, metallised BOPP, Polyester
Ghee	Tin, LLDPE, LDPE, HDPE, Ionomer, EAA, Nylon	Containers, Pouches, Liners	Coated/ laminated to polyester, nylon, foils and metallised BOPP
Shrikhand	ABS, HIPS, HDPE, LDPE, LLDPE, PP, PET	Containers	None
Milk based sweets	LLDPE, LDPE, HDPE, Ionomer, EAA, PP	Pouches	None
	ABS, HIPS, HDPE, LDPE, LLDPE, PET, Modified PPO	Containers	None
Rasogulla/ Gulab Jamun	LLDPE, LDPE, HDPE	Filling	None
	LLDPE, LDPE, HDPE	Pouches	None
	ABS, HIPS, HDPE, LDPE, LLDPE, PET, PP, Tin	Containers	None

ANNEXURE 5: Milk Condensate Recovery

Process Flow Chart for Waste Water Recovery RO



- Membrane Bio Reactor (MBR) reduces COD, BOD and suspended solids in treated water thus making it ideal for further treatment through RO.
- Permeate from MBR outlet shall be chlorinated up to 0.2 ppm to avoid any microbiological contamination.
- RO permeate monitors for conductivity, TOC (Total Organic Carbon) and TSS (Total Suspended Solids). If any of the parameter is out of norm the system, dumps water automatically through 3-way valve installed in transfer line.
- Water shall be chlorinated in storage tank upto 0.2 – 0.5 ppm to ensure that there is no microbiological contamination in water feed to plant.
- RO water permeate shall meet the requirement of IS: 4251 and IS 10500 drinking water standards.

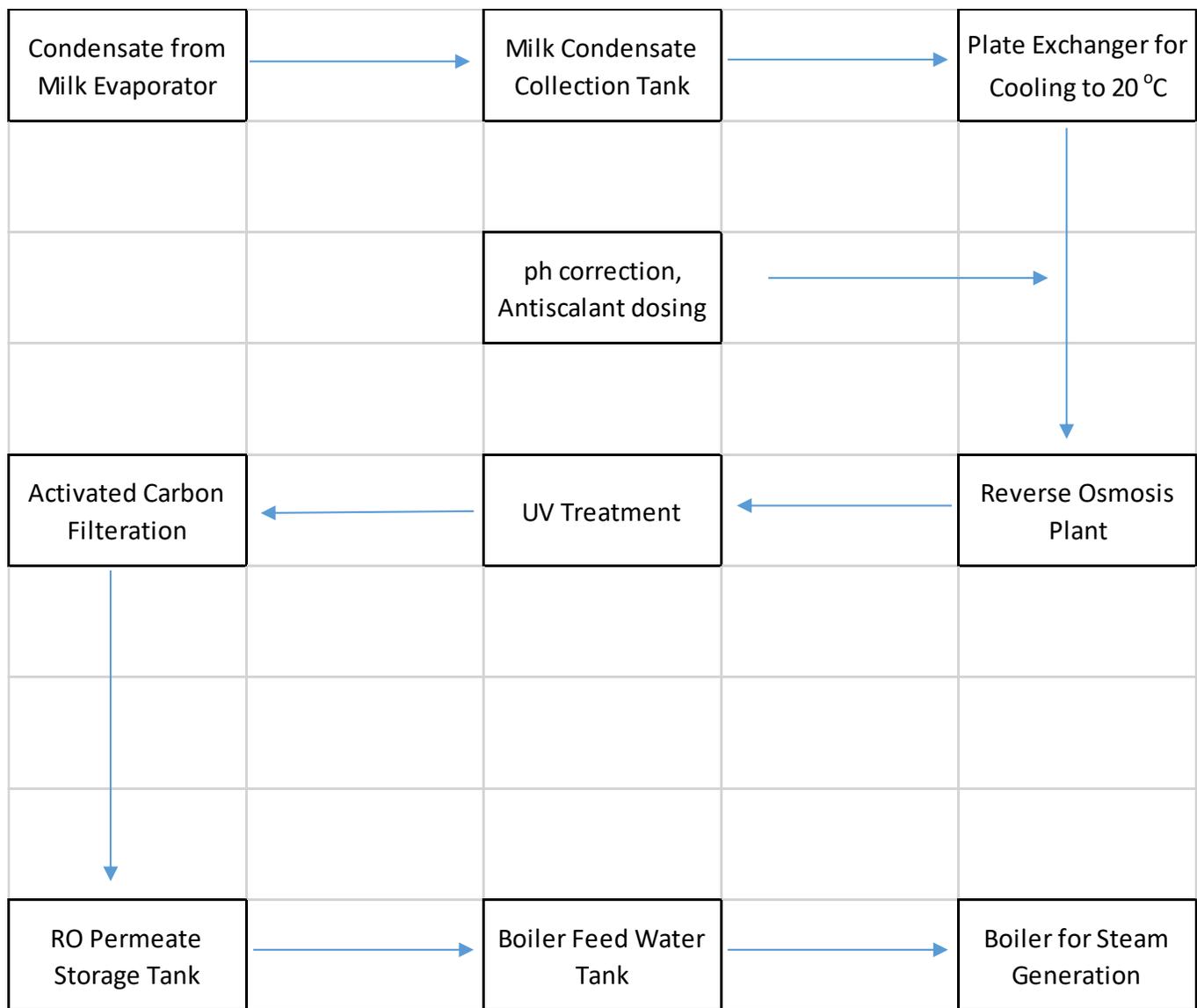
ANNEXURE 6: Recommended MILK CONDENSATE RECOVERY (CoW Water RO Plant)

Introduction

The milk contains 80% of water which is separated from milk in evaporator during processing. During the process of milk drying, water is released as by-product in different stages, this water contains the traces of milk. Condensate water from evaporator is not utilized and end up in waste water treatment plant contributing to hydraulic load of ETP.

Milk condensate recovery RO plant is used for steam generation thus reducing water with drawl from bore wells.

Process Flow Chart for Milk RO



- The milk condensate from plant shall not be stored for more than 4 hours to avoid contamination.
- RO permeate at outlet of RO plant and Activated Carbon Filtration (ACF) shall be monitored online for total organic carbon (TOC) to keep continuous tab on water quality. TOC shall be at outlet of RO plant maximum 1 ppm .If any point of time TOC value is high the system will automatically dump condensate to avoid carry over.
- All the equipment installed shall be preferably made of SS-316L MOC to avoid contamination and microbe generation.
- RO water permeate shall meet the requirement of IS: 4251 and IS: 10500 drinking water standards.
- Water conductivity at inlet to RO plant shall be less than 200 μS and at outlet of RO plant is below 50 μS .
- RO membranes shall be compatible to high temperature CIP and plant should undergoes CIP after every 24 hrs.
- Waste water generated from the plant is biological and can be treated in factory waste water treatment plant



(MILK CONDENSATE RECOVERY)

ANNEXURE 7: Relevant BIS Standards adopted in FSSAI

1. IS 10171:1999 – Guide on suitability of plastics for food packaging (Second Revision).
2. IS 2508:1998 – Specifications for low density polyethylene films (Second revision), reaffirmed in 2003
3. IS 11805:2007- Polyethylene pouches for packaging liquid milk (Second revision)
4. IS 15495:2004 – Printing Ink for food packaging – Code of Practise
5. IS 11584:1986 – Specification for High Density Polyethylene (HDPE) crates for milk sachets, reaffirmed in 2002
6. IS 7161:1973 – Specification for Vegetable parchment/Grease proof/Aluminium laminate for wrapping butter reaffirmed in 1999.
7. IS 9845:1998 – Determination of overall migration of constituents of plastic materials and articles intended to come in contact with food stuffs – methods of analysis (Second revision)
8. IS 2798: 1998 – Methods of test for plastic containers (First revision)
9. IS 13360: 1997 – Plastics – Methods of Testing
10. IS 1060 – Part I: 1960 - Methods of sampling and test for paper and allied products: Part I reaffirmed in 2004
11. IS 1060 – Part II: 1960 - Methods of sampling and test for paper and allied products: Part II reaffirmed in 1997
12. IS 1060 – III: 1969 – Methods of sampling and test for paper and allied products: Part III reaffirmed in 2004
13. IS 4006 –I, II &III :1985 – Methods of test for paper and pulp based packaging materials