GUIDELINES FOR
GOOD HYGIENE PRACTICES, GOOD MANUFACTURING PRACTICES AND HACCP IN MILK PRODUCTION, PROCESSING, STORAGE AND TRANSPORTATION

Funded by
the European Union

EU FOOD SAFETY
AB GIDA GÜVENLİĞİ

European Union Food Safety Project

Funded under the EU Aid Program for the Turkish Cypriot community (TCc), the "EU Food Safety Project" executed under the contract 2021/423-933 "Technical assistance to improve implementation of food safety standards and disease crisis preparedness", strives to support faster social and institutional development of the Turkish Cypriot community and higher economic growth of its agri-food chain sector. The aim is to achieve improved food safety, public health, animal health, and protection of the environment, and to mitigate the impact of potential exotic animal diseases, in particular those posing imminent threats. The project started in May 2021 and will be completed in April 2024.

For more information about the project, you can visit the project's website, follow its social media account and contact the project team through the following communication channels:

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1. BACKGROUND

The "EU Food Safety Project" executed under Contract 2021/423-933 "Technical assistance to improve implementation of food safety standards and disease crisis preparedness" strives to support a faster social and institutional development of the Turkish Cypriot community (TCc) and a higher economic growth of its agri-food chain sector.

The project aims to achieve improved food safety, public health, animal health and protection of the environment, and to mitigate the impact of an imminent threat of potential exotic animal diseases.

This document was produced within the following project activity:

Prepare guidelines for stakeholders to complement the input delivered in specific trainings, workshops and other capacity building activities.

2. INTENDED AUDIENCE

The intended audience of this guidance are food business operators in the dairy industry.

Milk is a perishable food product and easily falls prey to microbial contamination and increased pH levels. This causes dairy products to diminish in quality and taste if proper hygiene measures are not taken in manufacturing and storage conditions.

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

- Pasteurised milk,
- UHT milk, condensed milk, fermented milk and flavoured milk,
- Ghee, butter, cream,
- Curd, yoghurt, butter milk, paneer, cheese.

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 two main sections. The first section contains guidance for implementation of good manufacturing practices and good hygiene practices. The second section of this document is recommended because it 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 and two tables: Hazard Analysis and HACCP Plans. Tables of Hazard Analysis are expected to help the industry 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.

3. AIM OF THE GUIDELINES

It is to be noted that these guidelines do not replace any legal provision.

These guidelines are 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 milk and dairy products, 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 and complexity of operation. The use of these guidelines are voluntary and food business operators may comply with the requirement of the legal text according to other established best practices.

It is important that food handlers involved in whole supply chain of milk and dairy products are trained appropriately to implement the good manufacturing practices and good hygiene practices to ensure food safety.

The guidelines have been produced to assist the food business operators in the milk processing industry, to achieve the legal requirements for microbiological criteria of milk and dairy products and made verification and validation of implemented procedures based on the HACCP principles in milk processing industry and to ensure a high level of customer protection regarding food safety.

The goal of the food safety system based on the HACCP principles is to keep under control the certain factors that can lead to potential food poisoning.

Food business operators and relevant local bodies should cooperate in order to prevent foodborne illness.

The guidelines are also available to the public on the project's Food Safety Platform: http://tccfoodsafetyproject.eu/. All parties involved in the milk processing industry should find them a valuable tool in their day-to-day operations.

4. PRE-REQUISITE PROGRAMMES

I. ESTABLISHMENT – DESIGN AND FACILITIES

1. LOCATION AND SURROUNDINGS

- The milk and dairy 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 already exists, appropriate control measures shall be taken.

- 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.
- The manufacturing premise shall not have direct access to any residential area.
- The manufacturing premises shall be located away from flood prone areas. Where the premises are located in areas prone to flooding, it is recommended that the height of the manufacturing area should be suitably elevated to prevent the risk of flooding.
- 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.
- 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 AND LAYOUT

2.1 Building Design and Layout

- 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 environmental contamination.
- The layout of different sections shall be such as to facilitate smooth and orderly workflow and to prevent possible cross contamination and backtracking.
- There shall be adequate lighting and ventilation and light fixtures shall be protected with proper covering.
- The layout shall ensure sufficient space in different sections for machinery, equipment, personnel, etc. without congestion.
- 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.
- Non-operative areas inside the establishment shall be properly cordoned off to avoid possible cross-contamination.
- 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.
- Raw milk receiving section shall be sufficiently separated from processing area to prevent cross contamination.
- Signboards directing the employees to wash and sanitize hands before entering and after each absence shall be installed.
- Narrow windowsills are recommended with the slope of at least 45° to prevent buildup of dust as well as items being left there.
- Infrastructure for cleaning tanker from outside and milk contact surface of barrel after unloading milk.

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 smoothened 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

- 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 cause less crevices).
- Premises shall be free of flaking paint and plaster to prevent the accumulation of dust, minimise condensation, and shredding of particles.
- Wall floor joints should be curved in processing and packaging areas to facilitate cleaning.
- Wall and pillar guards (SS) should be used to avoid daily wear and tear of the surfaces.
- 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 to prevent water stagnation on the floor.
- Sealed to prevent the entry of dirt, dust and pests.
- The wall to floor and wall-to-wall junctions shall preferably be rounded off to facilitate easy cleaning.
- 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.
- All floor areas coming under plant and machineries shall be visible, accessible and cleanable as much as possible.
- 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.
- 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

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.

- *Overhead fixtures:*

  Shall be suitably protected so that they do not act as contaminants in case of breakage

2.2.3 FLOORS

- Shall be non-slippery, sloped appropriately, to allow adequate drainage. The drainage shall flow opposite to the flow of manufacturing process flow.
- Shall be maintained in good repair with no cracks and crevices.
- 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 as it causes slippering. Sweeping and mopping is more appropriate and cost effective.
- The floor and the walls should not be damp or moist.
- The floor of the processing areas shall be smooth, impermeable and easy to clean and disinfect.

2.2.4 DOORS

- Shall have smooth, non-absorbent surfaces. Wooden doors are not recommended as it promotes mould growth, termites with ageing.
- Shall be easy to clean.
- Shall be close-fitting and with suitable precautions to prevent entry of pests.
- Gaps if any between the door and the floor should be closed with suitable material like rubber strips, polyurethane, etc. to avoid pest entry.
- To ensure dust, insects, birds and animals are kept out of the premises entry/ exit points, they should be suitably protected with strips from PVC/air curtains/ doors with automatic self- closing devices, etc.
- External opening windows, roof vents or exhaust fan, where present, shall be adequately screened to avoid any external pest ingress.
- 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

3.1. 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 they permit 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. suitable 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.

3.2. Equipment, containers and piping should be clearly labelled and identifiable, especially equipment and containers for waste, by-products & inedible or dangerous substances.

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

3.4. Manufacturing vessels, pipework, and material handling equipment are well bonded and smooth to prevent material build up and promote sanitary conditions.

3.5. 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 hoppers.

3.6. All utensils/containers containing food products shall be covered with a properly fitted cover/lid or with clean gauze net or any other material. This helps to completely protect food from dust, dirt, flies and other insects.

3.7. All equipment should be placed and installed at a distance from the walls.

3.8. All relevant equipment shall be labelled with their SOPs.

3.9. 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.

3.10. 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.

3.11. 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.

3.12. Defective equipment shall, if possible, be removed from production and quality control areas. If the equipment is such that it cannot be removed, its status should be clearly indicated.

4. FACILITIES/UTILITIES

4.1 Boiler/Steam Generation/Hot Water Generation

- 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.
- Boiler system shall have calibrated and functional gauges to indicate and control temperature, pressure of the system.
- 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.
- 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.
- The water used for steam generation shall cater to requirements prescribed in IS 4251:1967
- 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.
- Boiler systems should be tested for pressure and structural integrity at prescribed intervals to ensure operational and safety aspects.
- Boilers shall be operated by trained/qualified manpower as stipulated in legal text.
- Boiler area shall be equipped with fire fighting mechanisms. Necessary precautions shall be taken to prevent fire/accidents in the boiler area.
- Exhausts gases from the boiler system shall be discharged as per the prescribed pollution control legal texts.
- Access to boiler area should be limited and restricted.

4.2 Refrigeration System

- The dairy processing unit shall have adequate mechanical refrigeration system to cater to processing and storage requirements.
- The refrigeration system shall be equipped with necessary temperature gauges, pressure gauges, strainers and filters to ensure smooth and efficient operations.
- The gauges and control devices shall be functioning and calibrated periodically.
- Necessary industrial safety precautions shall be taken to avoid mishaps occurring due to fire/refrigerant gas leakage.
- 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.
- Gas/liquid receiver tanks should be periodically tested for pressure and structural integrity.
- 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.

- The dairy processing unit shall have necessary capacity IBT to for chilling raw and processed milk.
- Water used in IBT shall adhere to quality of drinking water.
- IBT shall be equipped with calibrated temperature gauges for recording and marinating the necessary temperatures.
- IBT water shall be periodically inspected for its visual quality and drained/ replaced.

4.3 Water Treatment Plant

Dairy processing units shall have a functional water treatment plant. It may comprise of the 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 of drinking water.

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

4.4 Chillers and Cold Room

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

4.5 Water Supply

- Adequate supply of potable water shall be available to meet operational needs.
- Water including steam/Ice used as a product ingredient or in contact with food of food contact surfaces or used for equipment and plant cleaning shall be potable.
- 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.
- Where it is necessary to store water, storage facilities including the storage tanks and water pipes shall be adequately designed, made of material that is non-toxic, corrosion resistant material and periodically cleaned 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.
- Where water filters are used, they shall be regularly monitored or effectively maintained.
- 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.
- 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.
- The construction material of pumps, valves, storage and distribution skids shall be non-reactive, non-corrosive, non-leaching and sanitary in design.
- 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

- 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.
- The following should be available - hand washing, lavatories, changing facility, rest and refreshment room. Such facilities shall be suitably located and designated.

4.6.2 HAND WASHING FACILITIES

- Facility with hot and cold or suitable temperature controlled potable water as well as suitable hygienic means for hand drying can be available for employees in areas they must pass prior to entering the processing areas. This will automatically alert employees and help them not to miss hand washing.
- Where hot and cold water is available, mixing taps should be provided.
- Hand washing notices shall be posted on walls near hand wash stations.
- Non-perfumed liquid soap should be used in dispensers as soap bars are a potential source of cross contamination.
- 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

- Hand drier where installed should be in working condition at all times during working hours.
- 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.
- Generally, and preferably, hand driers are considered better than paper towels based on cost efficiency and effectiveness.
- 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.
- 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

- Lavatories shall be separate from other areas and shall not be directly connected to the storage and manufacturing areas.
- 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.
- 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.
- All toilet facilities should be clean and sanitized at all times during working hours.
- Toilets should be designed in such a way as to ensure hygienic removal of waste matter.
- Toilets should be well lit and ventilated and should not open directly into food handling areas.

4.6.5 CHANGING FACILITIES

- 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.
- 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).
- It is advisable to also have a separate room between the 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.
- It is also recommended that the entrance from the outside to the changing rooms and exit from there to the processing rooms are separated.
- Factory footwear should be cleaned periodically and not to be used for external purposes.

4.6.6 REST AND REFRESHMENT ROOM

- Rest and refreshment rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas.
- Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods.
- Employees' own food shall be stored and consumed only in designated areas away from process and storage areas. Tiffin's and personal belongings also shall not be keept 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 the employees 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:

- Provide protection from dust, condensation, waste, pest access and harbourage and other sources of contamination.
- Be dry, well ventilated and enable monitoring and control of temperature and humidity in storage areas where specified.
- 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

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

4.10 Waste Disposal and Drainage

- 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.
- 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.
- Waste shall be segregated into wet and dry garbage and shall be removed periodically.
- It shall be kept closed, preferably foot operated or arrangements for waste disposal at regular intervals shall be put in place.
- 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.
- Drainage shall be equipped with appropriate traps to effectively capture contaminants.
- 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.
- 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.
- Dairy processing facilities shall be equipped by suitable capacity Effluent treatment plant (ETP) to ensure effluent discharge conforming to local rules .
- ETP shall be separately located, away from the operational/processing area but within the premises.
- The drain connecting processing area and ETP sump tank shall ensure no backtracking/reverse flow.
- The hazardous waste from ETP shall be discharged.
- ETP area shall be free from pests/animals/over grown vegetation growth.
- Discharges from ETP should be regularly tested for quality and conformance to local legal texts.

4.11 Cleaning Facilities

- Adequate facilities, suitably designated shall be provided for cleaning food, utensils and equipment.
- 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.
- 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.

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

- Vendor Quality Development Programme laying down the criteria for selection, approval, review and on going approval should be implemented.
- All raw material, processing aids, ingredients consignments shall be procured from the vendors approved and registered or licensed from other local bodies. An approved vendor should be evaluated as per the quality supplied and other relevant factors.
- Raw materials received shall be according to the storage and processing capacity of the processing plant.
- All raw materials and ingredients, wherever applicable, shall conform to all standards laid down under the relevant legal texts.
- 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.
- 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.
- All bulk tankers/containers receipt if any shall be checked for seal integrity / previous cargo / inspection checklist at the time of receipt.
- All packaged raw materials shall be checked for 'expiry date'/'best before'/'use by date', packaging integrity and storage conditions.
- The incoming vehicles that bring the raw materials, shall be checked for cleanliness and hygiene.

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.

- 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.
- Surfaces of electrical wiring to filling machines and other lines equipment should be cleaned to avoid microbial growth.
- A routine program should be established to inspect all gaskets and seals in product line connections and should be manufacturing/packing plant specific.
- 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.

- 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.
- 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.
- 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.
- Adequate space should be maintained from walls and between pallets to ensure sufficient movement and air circulation.
- Periodic visual checks should be made of all pallets, racks and other storage infrastructure, w.r.t structural integrity and infestations.
- 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.
- All materials and product should be clearly marked with their relevant Identification/Lot Number, to maintain the traceability.
- The identification marking should be easily accessible/visible even when the material or product is stacked.
- 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

- Access to material and product storage areas should be restricted to authorised persons only.
- 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.
- Insectocutors shall be installed, appropriately, at the entrance of storage areas.

2.3 Damaged, Returned & Recalled Goods

- Damaged/returned goods should be placed in a designated area, labelled and physically segregated for appropriate disposal.
- Records for such returned or recalled materials, with action taken, shall be properly maintained.

2.4 Cleaning of Storage Area

- 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.
- Cleaning standard operating procedures (SOPs) shall be defined and records demonstrating compliance shall be maintained.
- Storage areas should be regularly inspected for cleanliness and good housekeeping.
- Cleaning materials should be stored in a separate location in order to avoid contamination

3. MILK PROCESSING

3.1 General

- 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, filing machines and filing machines nozzles, etc.
- 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.
- Critical food processing parameters like temperature / vacuum, etc. records shall be maintained and recorded appropriately.
- Intermediate in-process samples to be tested for critical parameters and their test results shall be maintained.
- Personnel shall put on clean protective clothing including footwear and wash their hands before entering.
- Cleaning schedule for equipment in the food processing sections shall be maintained to ensure entire operations are carried out in hygienic conditions.
- System shall be in place to screen/detect and prevent contamination of foods by foreign bodies such as glass, plastic, metal, etc.
- Access to processing areas by outsiders shall be restricted or controlled. Where risks are particularly high, access to processing areas shall be only via a changing facility.
- The presence of any allergens identified in food ingredients shall be informed to consumers appropriately.
- In case steam is used directly on food during processing, the steam to be prepared from potable water and of culinary grade.
- 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.
- Adequate space, preferably separated from processing areas, shall be provided for cleaning and storing mobile equipment and utensils including the storage of cleaning materials.
- Incoming materials and finished products shall be quarantined immediately, if required, after receipt or processing, until they have been released for use or distribution.
- Intermediate products purchased and used as raw material shall be handled as ingredient on receipt.
- 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

- Dairy processing establishments should have potable water available, which should meet the criteria specified by the local bodies having jurisdiction and should be regularly monitored.
- 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.
- 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.
- Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in dairy processing. These criteria depend on 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.
- 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.
- 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.
- 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

- 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:
  - Item identity / Serial No
  - Calibrated / Inspected Date
  - Calibration due / Inspection Due Date.
- Internal and external calibration schedule shall be maintained for all equipment.
- Calibration procedures shall have defined action plan if instrument fails during calibration.
- Calibration frequency should be documented in the list based on standards like BIS or end use.
- Calibration should be done over the full range of use of the equipment or device and during calibration measurement range has to be considered.

- Internal/External calibration should also be carried out using a reference material having traceability.
- When no reference material is available, a suitable consensus material must be used.
- Acceptance criteria should be mentioned and also corrective action if any instrument found out of specification.
- If the error is more than the acceptance criteria, then the equipment/ measuring device needs correction.

4. MILK AND MILK PRODUCT PACKAGING AND WAREHOUSING

4.1 Packaging and Wrapping

- 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 legal texts thereunder. Only food grade packaging materials shall be used as primary packaging material. Packaging materials like aluminium, tin and plastic shall conform to the standards as mentioned under the FSS legal texts from time to time.
- 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 and sanitised before reuse, while damaged or defective are discarded, repaired or replaced, as appropriate, before re-use.
- The packaging materials or gases where used, shall be non-toxic and shall not pose a threat to the safety and suitability of food under the specified conditions of storage and use.
- The wrapping and packaging of dairy products shall take place under satisfactory hygienic conditions and in rooms provided for that purpose.
- The manufacture of dairy products and packaging operations may take place in the same room provided it is equipped to ensure hygienic working conditions.
- 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.
- Packaging materials shall be prepared/assembled in hygienic conditions prior to use for batch/continuous systems.
- Packaging shall be done without delay followed by labelling. If it is not the case, appropriate procedures shall be applied to ensure that no mix-ups or mislabelling could occur. It shall be handled by a 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.
- Filling, bottling, wrapping, packaging, etc. shall be carried out hygienically.
- All weighing scale used in packaging section shall be checked regularly against certified standards and their records to be maintained.

- Packaging/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.
- 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.
- Packaging of milk and milk products shall be carried out 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.
- 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:

Receipt – 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 the product and package must be checked and the shipping vessel inspected for cleanliness prior to loading a shipment.

Personnel in charge of the warehouse shall ensure that good warehousing practices are followed by all personnel, visitors and contractors.

- 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.
- Broken, spilled/damaged products shall be stored in properly demarcated areas and be destroyed routinely after necessary authorization/approvals.
- Product spilled on the floor should not be used and rejected and stored as described above.
- Hand washing facilities shall be available for all persons operating at the warehouse to maintain hygiene.
- Properly maintained toilets away from the main go-down with proper hand washing facility should be available.
- The operator shall ensure that all employees receive appropriate training to allow them to perform their appropriate function.
- Incoming materials inspections requirements should be laid down.
- Hold and release programs should be available.
- Sufficient number of pallets should be available to accommodate all materials.
- Direct sunlight on product shall be avoided.
- For products that need to be stored at specified conditions and temperature, those conditions need to be verified and recorded.

4.3 Storage of Hazardous Substances

- Hazardous substances shall be stored in rooms or cabinets used only for that purpose and handled only by authorised and properly trained persons.
- Wet and dry chemicals shall be stored separately as per their compatibility to avoid accidental mixing due to leakage or spillage.
- 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.
- 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

- 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.
- 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.
- All traceability records for rework shall be maintained.
- Stored rework/non-conforming/market returned material shall be protected from exposure to microbiological, chemical or extraneous matter contamination.
- 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.
- 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.
- Standard operating procedure should be defined and documented for handling any rework or non-confirming products.
- Additional inspection of reworked/reprocessed in-process or finished product is required and documented.

6. TRANSPORTATION AND DISTRIBUTION

- 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.
- Transportation time for raw milk to dairy plant 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.
- Milk tankers, refrigerated vehicles and insulated vehicles transporting raw milk, processed milk and milk products should be registered 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.

- 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.
- 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.
- 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 degrees Celsius).
- Vehicles should be completely unloaded, cleaned and sprayed with appropriate insecticide/pesticide in all corners created between the floor and the wall of the vehicle. This exercise should be carried out at the pouch loading plant utilizing the services of pest control operator at the plant. These vehicles shall also have a proper working light arrangement inside the vehicle.

6.1. Storage and Transportation Guidelines for Finished Products

- Carriers used by the establishment must be designed, constructed, maintained, cleaned and utilized in a manner to prevent food contamination.
- 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.
- 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.
- 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.
- For establishments who do not wish to re-pasteurize already pasteurized products, food carriers, tanks, transport lines and transfer pumps must be dedicated to pasteurized products only.
- Ingredients and finished products 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.
- Transportation temperatures must be monitored and recorded to ensure proper temperatures for refrigeration and freezing. Finished products must be transported under conditions to prevent microbiological, physical and chemical contamination.

- 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.
- 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.
- 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.
- 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.
- Transportation equipment must be frequently washed; carts should have sanitary drain cocks to prevent accumulation of water in the carts.
- It is imperative that waste and scrap carts be clearly labelled to avoid adulteration of ingredients or products. 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

- Established and applied traceability system shall be in place.
- It shall enable identification of product lots and their relation to batches of raw materials, processing and delivery.
- 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.
- 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.
- The facility/ system shall identify incoming material from suppliers.
- It shall identify the initial distribution route for the end product.
- Records shall be maintained.

7.2 Recall Procedures

- Organisation shall develop & implement milk Recall Procedure in accordance with FSS (Food Recall Procedure) legal texts, 2017.
- There shall be a documented and effective product recall plan in place in accordance with the FSS (Food Recall Procedure) legal texts, 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.
- Where a product has been recalled because of an immediate health hazard, other products which are produced under similar conditions which may also present a hazard to public health shall be evaluated for safety and may need to be recalled.

- Recalled products shall be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed/reworked in a manner to ensure their safety.
- 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.
- 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.
- 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.
- 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.
- 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 AND 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:

- The first step in the hazard analysis is to identify all potential hazards before control measures are selected. 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 ensure 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.
- 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.

- 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.

8.2. Key Aspects of Hygiene Control Systems:

- 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.
- Incoming raw milk when arriving at the dairy plant, and provided that further processing does not allow otherwise, 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.
- 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.
- 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 micro- organisms.
- 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".
- 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 they are packaged until they are 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 on 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 assuremaintaining suitability. Reasonably anticipated temperature abuse should be taken into account in designing the normal patterns of distribution and handling.
- 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.

- 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.
- 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.
- Corrective action taken for non-compliance with incoming milk criteria should be commensurate with the potential risks presented by the non-compliance.
- Necessary microbiological criteria 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 products, intermediate products or finished products in order to verify that the more comprehensive set of control measures have been properly carried out.
- The flow of the products 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 do not contaminate the milk.
- 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.
- 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 in a way 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 meet the quality and safety standards should be verified periodically.

Quality control programme shall be in place to include inspection and testing of incoming raw materials and finished products.

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. In case of complaints or feedback on the product, the FBO shall carry out the testing either though their in-house/ external accredited labs/ lab to ensure product compliance to standards.

Incoming raw materials / Bulk chemicals / Ingredients test records or Certificate of Analysis shall be maintained.

Calibration of laboratory equipment shall be done periodically.

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 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.

- 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.
- 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.
- 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.

III. ESTABLISHMENT - MAINTENANCE AND SANITATION

1. CLEANING AND SANITATION

Cleaning and sanitizing programmes shall be established at the 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.

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.

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 .

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.

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.

Cleaning and 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
- A validation mechanism should be in place for all cleaning programmes.
- 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.

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;

- Quick acting,
- Easily and quickly applied,
- Relatively inexpensive,
- Relatively non-corrosive to hands and dairy utensils.

2. 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:

- 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.

- Cross contamination controls
  - There should be flow plate systems installed to physically separate active product lines from CIP lines for manual and semi auto dairy systems.
  - For automated dairy units, double seat mix proofs should be installed in all pneumatic valve clusters.
  - 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:

- Rinsing with warm water for about 10 minutes,
- Circulation of an alkaline detergent solution (0.5-1%) at 75°C,
- Rinsing out alkaline detergent with warm water for about 5 minutes,
- Circulation of nitric acid solution (0.5-1%) at 70°C,
- Post rinsing with cold water,
- 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:

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

3. PEST CONTROL

3.1 General Requirements

- The organization shall have a nominated pest control technician to manage pest control activities and/or deal with external pest management agency.
- Pest control program shall identify target pests and address plans, methods, schedules and control procedures.
- Program shall include a list of chemicals which are approved for use in specified areas.
- 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

- 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.
- Windows, doors and ventilation openings shall be designed to minimize pest entry.
- Compound walling should be of appropriate height to prevent the entry of animals into the premises.

IV. ESTABLISHMENT - PERSONAL HYGIENE AND EMPLOYEE FACILITIES

1. HEALTH STATUS, ILLNESS AND INJURY

- Milk and milk product handlers of the manufacturing facility shall undergo a medical examination by a registered medical practitioner before joining work and thereafter annually to ensure that they are free from any infectious or communicable diseases. A record of these examinations shall be maintained.
- The employees in manufacturing units shall be inoculated against the enteric group of diseases as per recommended schedule of the vaccine and records shall be maintained.
- 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 products, shall be prevented from handling milk and milk products or materials which come in contact with milk and milk products till the time he/she get the fit to work certificate from the registered medical practitioner.
- 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.
- 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

- 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.
- Where gloves are used for product contact, they shall be clean, food grade (like nitrile etc.) and in good condition.
- 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)
- The provision of clear information to all contractors of any hygiene requirements specific to the manufacturing area in which they will be working,
- The implementation of 'return to work' procedures following illness or foreign holidays, particularly in relation to diseases that may have been contracted while away.
- The implementation of a personal medication procedure to control personal medicines that could be a potential contamination risk to the product.
- Protective clothing mandated for use in manufacturing areas or hygiene purposes shall not be used for any other purposes.

- 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.
- Hand washing notices shall be posted at appropriate places.
- Fingernails shall be kept clean without nail polish and trimmed.

3. PERSONAL BEHAVIOUR

- 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.
- Any behaviour or unhygienic practices which could result in contamination of milk and milk products shall be prohibited in food processing, distribution, storage and handling areas. This includes smoking, chewing or eating, sneezing or coughing over unprotected food, spitting, etc.
- Personal effects such as jewellery, watches, pins, 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.
- 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

- Personnel who work in, or enter 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).
- Clothing mandated for milk and milk product protection or hygiene purposes shall not be used for any other purpose.
- Work wear shall not have buttons and outside pockets above waist level.
- Work wear shall be laundered at predefined intervals.
- Work wear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.
- Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints,
- Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

5. VISITOR CONTROL

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

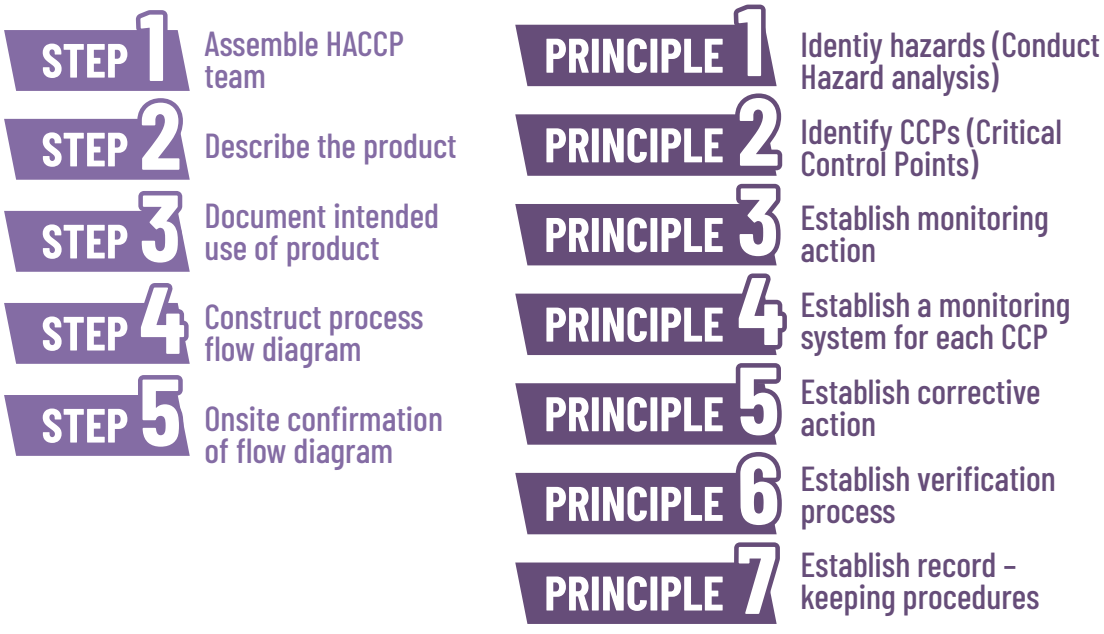
V. HACCP IMPLEMENTATION

1. 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 in identifying the critical points in the production line and suggesting critical limits in compliance with legal texts and therefore the preventive and corrective measures. Though HACCP system was designed to prevent the occurrence of foodborne hazards coming into the products, 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 Standard Sanitation Operating Procedures (SSOPs) along with Good Manufacturing Practices (GMPs) and 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.

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 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.

2. APPLICATION OF HACCP SYSTEM - HACCP IMPLEMENTATION STEPS

2.1 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 bodies. A 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).

2.2 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 products, for example, catering operations with similar characteristics or processing steps may be grouped for the purpose of development of the HACCP plan.

2.3 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, and elderly should be considered, as necessary.

2.4 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.

2.5 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.

2.6 List of all Potential Hazards (See Principle 1)

List of all Potential Hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards.

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 of 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.

2.7 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. 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.

2.8 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.

2.9 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:

- Measurements or observations that provide results within an adequate time frame;
- Monitoring device used;
- Applicable calibration method;
- Monitoring frequency;
- Responsibility and authority related to monitoring and evaluation of monitoring results; and
- 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.

2.10 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.

2.11 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.

2.12 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.

5. CONCLUSION

Hygiene is one of the key parameters ensuring quality and credibility of any dairy farm or production or processing facility. To comply with industry best practices and ensure highest levels of food safety to end consumers, it is imperative to maintain key hygiene standards and monitor performance.

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This publication was funded by the European Union. Its contents are the sole responsibility of the NSF Euro Consultants Consortium and do not necessarily reflect the views of the European Union.

EU FOOD SAFETY
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