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1 Good Manufacturing Practice (GMP)

GMP 1	Site Location
General Requirement	
<ul style="list-style-type: none"> Food factories shall be located in areas that are not likely to cause contamination and minimize the risk of contamination of raw materials, semi-finished products, rework, and finished products during inspection and acceptance, storage, production, and shipment. 	
Technical Guideline	
<ol style="list-style-type: none"> Food factories shall be located in areas that are not likely to cause contamination or shall employ strict food control measures to prevent contamination. The designation and construction of external environment around the premises shall prevent infestation from outer source. The roads near and within the factory shall be kept clean to prevent dust contamination. 	

GMP 2	Management of Local Environment
General Requirement	
<ul style="list-style-type: none"> Food factories shall establish, implement and maintain food safety standards for the factory premises and its environment to ensure they are maintained in good condition, prevent cross contamination, and minimize the risk of contamination of raw materials, semi-finished products, rework, and finished products. 	
Technical Guideline	
<ol style="list-style-type: none"> The environment around food premises shall be kept clear and free from waste at all times. The floor shall be adequately drained to prevent puddles and mud. The space in and around premises shall be kept clean and dust free. Facilities which create bad odors, harmful (toxic) gas, soot, or other unsanitary matter shall not be installed. Poultry, livestock, and domestic pets shall be prohibited from processing sites. Guard dogs kept on the premises shall be managed, contained, and excluded from areas where they could contaminate food processes. The drainage system within the premises shall be properly constructed and maintained. Drains shall be regularly cleaned, kept clear of debris, with no bad odors, damage, pooling of water, or pest infestation. 	

GMP 3	Site Design, Construction, Layout, and Maintenance of Factory Premises
General Requirement	
<ul style="list-style-type: none"> Food factories shall ensure that the interior and exterior of the factory and facilities (e.g., warehousing, raw material and product handling, temporary storage, and packaging zones) are designed, constructed, and maintained in a manner sufficient to prevent or minimize food safety risk. The layout of production equipment and staff movement, raw material intake and storage, and processing operations shall satisfy the intended purpose and prevent food safety risk. 	
Technical Guideline	
Site design and layout	
<ol style="list-style-type: none"> The site and equipment shall be designed and arranged to optimize process flow, maintain sanitary requirements and prevent product cross-contamination. The site shall have sufficient space for installation of facilities to maintain food safety and hygiene, including sanitary facilities, material storage, storage of food utensils and equipment and staff amenities etc. Sites that process vegetarian, vegan, ovo-vegetarian, lacto-vegetarian, ovo-lacto-vegetarian products, or products that include pungent spices shall be effectively separated from meat 	

processing sites, equipment, and utensils. Methods of preventing cross contamination and cleaning validation shall be implemented.

4. Production facilities shall be arranged to allow sufficient workspace for efficient processing and prevent product cross-contamination. Each facility shall operate within its production capacity.
5. Adequate employee access shall be established between and within the processing site. The work area shall enable staff to conduct their tasks (including cleaning and sanitation) without risk of contaminating food, food contact surface or inner packaging material through clothing or body contact.
6. If staff dormitories, cafeteria, restrooms, offices, and laboratories are present on the premises, they shall be isolated from preparation, processing, packing, food storage, food and additives storage areas, and have good ventilation and lighting. They shall be kept clean with adequate pest and harmful microorganisms prevention and a person nominated to supervise and check the condition.
7. Laboratories shall have sufficient space to conduct required tests. Microbiological testing laboratories shall be isolated from other areas, be subject to laws and regulations governing laboratories testing for pathogenic bacteria, and strictly follow the requirements of a laboratory biosafety manual.

Isolation of site

1. Sites with different functional areas (e.g., raw material warehouse, packaging material warehouse, processing area, etc.) shall be individually identified or effectively separated.
2. Areas of the site that require different cleaning protocols (e.g., clean processing area, semi-clean processing area, general processing area) shall be effectively isolated.

Construction of site

1. All buildings on the site shall be strong and durable, easy for maintenance, kept clean, and designed to prevent contamination of food, food contact surfaces and inner packaging material from contamination (invasion, resting and reproduction, etc.).

Security facilities

1. Power distribution on site shall be waterproof.
2. Power supply shall include a ground wire and earth leakage circuit breaker.
3. Power sockets and switches in high humidity work areas shall be waterproof.
4. Power sockets with different voltage shall be clearly labeled.

Floors and drainage

1. Floors shall be flat and non-slip, kept clean with no waste materials, erosion, cracking, standing wastewater etc. Floors in high-risk processing areas shall be constructed of non-absorbent and impermeable materials.
2. Wastewater shall be treated in a wastewater treatment system or other appropriate method.
3. Drainage systems in processing areas shall be unimpeded and clean, without bad odors. Waste traps shall be installed at the exit of each drain to intercept solid waste.
4. Other services shall not be installed in or near drains.
5. Drain exits shall include measures to prevent pest ingress.
6. The flow direction of drains within processing areas shall not be from low clean zones to high clean zones. Drains shall be designed to prevent counterflow.

Roof and Ceiling

1. The ceiling of processing, packaging, and storage areas shall be easy to clean and prevent accumulation of dust, dew, mold, and peeling. If the ceiling of high-risk processing and food exposure areas (except for raw materials storage areas) is susceptible to dust accumulation, a flat and easily cleaned ceiling shall be added. The ceiling shall be smooth with no gaps if constructed of reinforced concrete.
2. Platform roofs or ceilings shall be constructed of white or light-colored waterproof material, and paint shall be mold-proof, unlikely to peel and easily cleaned.
3. Pipes and services for steam, water and electricity shall not be installed above exposed food or food contact surfaces. Where this is not possible, methods shall be implemented to prevent

condensation and dust accumulation, and the services shall be waterproof and periodically cleaned.

4. Stairs and catwalks across production lines shall be designed and constructed to prevent contamination of food and food contact surfaces.

Wall and Windows

1. Walls in processing areas shall be constructed of non-absorbent, flat, easily cleaned, and impermeable light color material (with the exception of closed fermenter etc. which operate outdoors). Wall-to-floor junctions shall be designed for easy cleaning and to prevent the accumulation of debris.
2. Windows that need to be opened during processing shall be protected by stainless steel mesh. The mesh shall be easy to disassemble and protect against food contamination by dust and pests. Windows must not be opened in high-clean operating areas during processing.
3. External doors in processing areas shall be constructed of durable materials, flat and smooth impermeable, and easily cleaned. They shall remain closed during processing.

Lighting Equipment

1. Light fixtures of sufficient intensity shall be installed in all parts of the factory and kept clean to prevent food contamination. Light fixtures in product exposed areas shall be shatterproof, or not installed directly over exposed food or food contact surfaces, to avoid food contamination.

Ventilation Facilities

1. Sites for processing, packaging, and storing of food products shall have good ventilation, and ventilation systems shall be kept clean. Air regeneration facilities shall be installed to control indoor temperature, condensation of water vapor, bad odors, and prevent airborne contamination.
2. Odors and gas (include vapor and toxic gas) or dust which may accumulate and contaminate food shall be excluded, collected, and controlled by appropriate means.
3. Exhaust vents in processing areas shall include measures to prevent pest access, The air intake shall be equipped with air filtration devices which are easy to disassemble, clean and change.
4. Air direction within processing sites shall not flow from low clean zones to high clean zones to prevent contamination of foods, food contact surfaces and inner packaging materials.

GMP 4 Design and Maintenance of Equipment

General Requirement

- The equipment and utensils in the food factory shall be designed and selected for their intended purpose and to minimize food safety risk.
- A maintenance plan shall be established and implemented to maintain the equipment and utensils in good condition. It shall include a complete list of equipment and utensils, the maintenance frequency, and scope of maintenance.
- The equipment and utensils shall be used, maintained, and stored in a manner to mitigate the food safety risk.

Technical Guideline

Design

1. The design and construction of all food processing equipment shall be to avoid food sanitary hazards, be easy to disassemble, clean and sanitize, and be easy to inspect. Equipment shall be designed to prevent lubricating oil, metal scraps, wastewater or other substances causing food contamination.
2. Food contact surface shall be flat and smooth with no hollows or cracks which would enable the accumulation of food crumbs, dust and organic matter, and minimize the growth of microorganisms.
3. The design shall be simple, easy to drain and remain dry.
4. The design and construction of storage, transportation, and manufacturing systems (including gravity, pneumatic, hermetic, and automatic systems) shall enable them to be maintained and

<p>sanitary.</p> <ol style="list-style-type: none"> The design of non-contact equipment and utensils in food processing sites shall be such that they can be kept clean. Surface treatment of equipment, utensils, and pipes (such as plating and painting etc.) shall minimize the risk of contamination of food and food contact surfaces. <p>Material</p> <ol style="list-style-type: none"> All equipment and utensils used in food processing sites that may be in contact with food shall be non-toxic, odorless, non-absorbent, corrosion resistant, and can tolerate repeated cleaning and sanitizing. Inappropriate material that may cause corrosion shall not be used. Food contact surface shall not be made of wood, except for utensils in processes where there is no substitute material e.g., fermentation and wine aging. <p>Maintenance</p> <ol style="list-style-type: none"> A maintenance plan, operating procedure and maintenance standard for all machinery, equipment and utensils used in processing, packaging and storage shall be established. The machinery maintenance plan shall be implemented and reviewed periodically to minimize food safety risks caused by equipment malfunction. The machinery, equipment, utensils, and premises used for food manufacturing shall not be used for applications other than food manufacturing. <p>Quality Control Equipment</p> <ol style="list-style-type: none"> Sufficient inspection equipment shall be available on-site to carry out routine quality control testing of the quality and safety of raw materials, semi-finished products, rework, and finished products. Testing that cannot be conducted on-site shall be attributed to credible external research or inspection institutions.
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GMP 5 Facilities for Employees
General Requirement
<ul style="list-style-type: none"> Food factories shall make utilities available to employees including, at a minimum, handwashing facilities, locker rooms, and rest rooms. The utilities shall be designed, constructed, and used in a manner to mitigate food safety risk.
Technical Guideline
<p>Handwashing and sanitizing facilities</p> <ol style="list-style-type: none"> Handwashing facilities shall be installed at appropriate and convenient locations (entrance of processing areas, restrooms, processing site), with sufficient numbers of hand sanitizer and hand dryers. Water at an appropriate temperature for handwashing shall be provided. Facilities with adjustable cold and hot water can be installed if required. Handwashing stations shall be constructed of stainless steel or other non-porous material which avoids the build-up of dirt and is easy to clean and sanitize. Handwash stations shall be pedal, elbow, or proximity operated, to avoid re-contaminating cleaned hands. Liquid hand cleaner and hand sanitizer shall be installed. Hand drying shall be by hot air dryer or paper towel. Used paper towels shall be discarded into pedal or motion sensor trash cans while hand dryers shall be cleaned and sanitized periodically to avoid contamination. Drainage from handwashing facilities shall include devices to avoid counterflow, pest access and bad odors. Simple hand washing instruction shall be posted at obvious spots near the handwashing facilities. Shoe cleaning facilities or shoe changing procedures shall be applied to prevent high-risk processing sites from external contamination. <p>Change room</p> <ol style="list-style-type: none"> Change rooms shall be at appropriate and convenient locations near processing sites, with sufficient individual spaces for employees and separate areas for male and female. The change rooms shall have appropriate lighting and good ventilation.

2. The change rooms shall have sufficient space for employees to dress, with a full-length mirror, dust cleaning equipment and personal lockers and shoe racks etc.

Restrooms

1. Restrooms shall be deployed at appropriate and convenient locations throughout the premises and in sufficient quantity for the number of employees. Restroom drainage shall not be connected to other drains within the premises.
2. Restrooms shall have flush toilets, constructed of material which is impermeable and easy to clean and sanitize, and does not accumulate dust.
3. Handwashing facilities that meet regulations shall be installed inside all restrooms.
4. The outer door of restrooms shall be kept closed at all times and shall not open directly to processing areas unless there is an airlock for effective air flow control to prevent contamination.
5. Restrooms shall have appropriate lighting and good ventilation to avoid bad odors and pest infestation.
6. Signage “Please wash your hand” shall be placed in obvious areas within restrooms.

GMP 6 Sanitation and Hygiene Management Plan

General Requirement

- Food factories shall establish, implement, and maintain procedures for sanitation and hygiene management. The procedures shall include sanitation and hygiene management of the environment, facilities, and equipment at the factory premises, and to confirm that the environment and equipment at the factory premises are kept in an adequate and safe condition that is not likely to cause food safety hazards.

Technical Guideline

Sanitation and Hygiene Management Plan

1. A sanitation and hygiene review plan shall be implemented which stipulates the items for review and their frequency and appoints sanitation and hygiene personnel to conduct, confirm and record the review according to the plan.

Sanitation and Hygiene Management of Premises Environment

1. The roads and yards near and within premises shall be kept clean at all times. Floors in the premises shall be maintained with no cracks, water pooling, or dust.
2. Vegetation within the premises shall be pruned and trimmed periodically. The area shall be kept clear of unused equipment or debris so as not to attract pest infestation.
3. All equipment and facilities on-site shall be kept in good sanitary condition with appropriate maintenance to prevent food contamination.
4. Drains shall be kept clear with no accumulated mud or waste material.

Sanitation and Hygiene Management of On-site Facilities

1. Facilities on-site shall be kept clean and well maintained. Roofs, ceilings, and walls shall be repaired immediately if damaged, and floors and the drains shall immediately be repaired if damaged and not allowed to accumulate water.
2. Production areas shall be cleaned and sanitized when required (including floors and drains, etc.).
3. Vapors produced during processing shall be exhausted outside the premises.
4. The external surfaces of light fixtures and pipes shall be kept clean.
5. Cold (frozen) storage rooms shall be designed and located to allow for effective storage of frozen products. They shall be regularly defrosted and cleaned to prevent mold growth and maintain hygiene.
6. Effective measures (e.g., screening of windows, air curtains, fences, or bug traps) shall be implemented in manufacturing areas and storage facilities to prevent or eliminate pest infestation.
7. Raw materials and inner packaging materials not for immediate use, and other unnecessary items shall not be accumulated in food manufacturing areas.
8. Manufacturing areas shall not place or store substances in manufacturing areas that risk food

<p>safety.</p> <p>Sanitation and Hygiene Management of Machinery and Equipment</p> <ol style="list-style-type: none"> 1. Equipment and utensils used for manufacturing, packaging, and storage shall be cleaned and sanitized periodically. 2. Equipment, where applicable, shall be designed to drain directly to the drainage system to avoid contamination. 3. The cleaning and sanitizing of equipment and utensils shall avoid contamination of food, food contact surface and inner packaging material caused by detergents and sanitizers. All food contact surface shall be rinsed thoroughly if a sanitizer is applied that may leave a residue. 4. Equipment and utensils shall be cleaned immediately after use, and sanitized again before use, taking care to avoid chemical residues.

GMP 7 Environmental Management, Cleaning, and Sanitizing of Factory Premises
General Requirement
<ul style="list-style-type: none"> • The sanitation and hygiene management plan for the food factory shall include procedures for the use and storage of cleaning and sanitation equipment, chemicals, and supplies, and shall be designed to minimize food safety risk. • The cleaning and sanitation operations shall be designed and implemented to prevent cleaning agents and sanitizers from contaminating food and food contact surfaces. • Periodic verification of the effectiveness of cleaning and sanitation procedures shall be conducted.
Technical Guideline
<ol style="list-style-type: none"> 1. The detergents, sanitizers and chemical substances used in cleaning and sanitation shall meet applicable local laws and regulations, and shall be labeled clearly to demonstrate the toxicity, instructions for their safe use, and emergency treatment. They shall be locked in a specific location with appropriate signage, and personnel allocated as responsible for recording storage and usage. 2. Detergents shall not be stored in food manufacturing premises except as required for cleaning operations. 3. Utensils used for sweeping, cleaning, and sanitizing shall be kept in a specific location and not used for any other purpose.

GMP 8 Personnel Hygiene Management
General Requirement
<ul style="list-style-type: none"> • The food factory shall establish, implement, and maintain personnel hygiene procedures, including personal hygiene standards, work uniforms, and medical checks. • The food factory shall provide adequate protective clothing to everyone entering the site. • Medical checks shall include a regular medical checkup with feedback, follow-up, and treatment of any symptoms for personnel who are found to be unwell or may cause a food safety hazard, such as fever, cough, or open wounds. • The procedures shall be applicable to all personnel entering the work site.
Technical Guideline
<p>Personal hygiene standard</p> <ol style="list-style-type: none"> 1. Hands shall be kept clean and washed with hand cleanser before work. Long fingernails, nail polish and similar accessories are not permitted for personnel in contact with food products. 2. Either clean and sanitized impermeable gloves shall be worn, or both hands shall be thoroughly cleaned and sanitized before handling ready-to-eat foods that don't require heating before eating. Both hands shall be washed and clean before wearing gloves. 3. Smoking, chewing areca nuts or gums, eating, and drinking or other behavior that may contaminate food shall be prohibited in food processing areas. Sweat, saliva or cosmetics and drugs applied to the skin shall not be in contact with food, food contact surfaces or inner

packaging materials.

4. Hands shall be washed and sanitized according to the correct handwashing instructions before entering food processing areas (including when changing jobs), after going to the toilet, or when spitting or blowing the nose may cause hands to be contaminated.
5. Entry and exit of off-site staff shall be properly coordinated. If it is necessary for off-site staff to enter the food operation site, they shall be required to adhere to the same hygiene requirements as on-site staff.

Personal Apparel

1. Operators shall wear clean work clothes, including shoes and hair caps or nets to prevent hair and foreign matter from falling onto food, food contact surface or inner packaging material. Masks shall be worn if necessary.
2. Personal clothing shall be stored in change rooms and not permitted in the food operation site.

Medical Examination

1. Newly recruited employees shall be required to pass a medical examination from a health care institute before working in a food protection area. After employment, the employee shall be required to undertake a medical examination once a year, and the results shall comply with the provisions of food-related laws and regulations.
2. The staff person in charge on-site shall be informed if an employee presents during the infection or carrier period for hepatitis A, hand skin disease, rashes, abscesses, injuries, tuberculosis, typhoid fever, or other ailments including fever or cough that may pose a public health risk. The affected employee shall not be permitted to work in direct contact with food while symptomatic or a carrier of a contagious illness.
3. Hygiene requirement for visitors shall be documented and implemented.

GMP 9 Waste Management

General Requirement

- The food factory shall establish, implement, and maintain waste management procedures which include the collection, storage, and treatment of waste material (including treatment of discharged water and wastewater).
- Waste shall be removed from process lines as quickly as possible to prevent cross contamination of food and food contact surfaces.

Technical Guideline

1. Waste shall be classified, stored, and disposed of and by its characteristics in accordance with the Waste Disposal Act and related laws and regulations. Perishable waste shall be removed at least once per day, and the waste container shall be cleaned and sanitized after waste disposal.
2. Waste storage location shall not create bad odors or harmful (poisonous) gases, and shall prevent the contamination of food, food contact surfaces, water sources and the surrounding environment by disease breeding vectors.
3. Waste shall not be allowed to accumulate on food operation sites, and waste containers shall also not be stored arbitrarily around the premises to breed disease vectors.
4. In sites with raw materials handling, processing, packaging, and storage, waste shall be stored in impermeable, easy-to-clean and sanitize, airtight (sealable) containers and removed from the factory regularly (at least once per day). Reusable containers shall be cleaned and sanitized after waste disposal. If a large amount of waste is created, the waste shall be removed from the factory regularly to prevent disease vectors and contamination of water sources and the environment. The facilities for waste disposal shall be cleaned and sanitized immediately after waste removal.
5. Any chemicals, radioactive substances, harmful microorganisms, or other spoilage wastes that may cause a health or food product risk shall be subject to special storage facilities and disposal procedures.
6. toxic gases, wastewater, waste, and noise shall be handled properly in accordance with related

laws and regulations for public nuisance prevention.

GMP 10 Pest Control
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain a pest management procedure to prevent or remove harmful animals or insects that could cause a food safety risk in the factory premises, surrounding areas, and facilities.
Technical Guideline
<ol style="list-style-type: none"> The pest management program shall contain at a minimum: <ol style="list-style-type: none"> The responsible personnel for pest control; A pest control implementation plan; A record of pest types and pest activity analysis to confirm the use of effective chemicals; The chemicals used for pest control shall comply with the Environmental Agents Control Act and related laws and regulations, with Safety Data Sheets (SDS), and warnings and related handling instructions including procedures for accidental contact and ingestion; Description of pest control methods and frequency of application and inspection; Qualifications of pest control operators; Plant distribution map of pest control monitoring equipment (e.g., rodent stations, fly trap and sticky trap). No pests or their traces are permitted in factory sites. If found, the sources of pests shall be traced and eliminated, ensuring that the elimination methods do not contaminate food, food contact surfaces and inner packaging materials. All pest control operations and inspection records shall be kept.

GMP 11 Training
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain training programs for new and existing employees. Appropriate food safety training shall apply to all employees who impact food safety to enable them to apply food safety practices in their work environment.
Technical Guideline
<ol style="list-style-type: none"> The person in charge of each department shall be competent to carry out their duties, shall lead by example, supervise, and educate employees to follow established operating procedures or regulations at all times. Newly recruited employees shall receive appropriate training to meet the requirements of production, hygiene, and quality control. An annual training plan shall be established, conducted, and recorded for current employees. The annual training plan shall at least include internal and external training courses for food hygiene and Hazard Analysis Critical Control Point (HACCP) to improve the employee's professional ability and understanding of food safety. Personnel engaged in food safety management, hygiene and quality shall receive professional training and lectures. Food safety management training courses related to allergen management, food defense and food fraud shall be organized regularly to ensure the operators clearly understand allergen management procedures, food defense plans, food fraud management plans and their operational procedures. The planning and operation of training courses shall include assessments to ensure the effectiveness of training. Personnel in charge of each department shall participate in professional pre-employment or employment training organized by government sectors, research institutions or business management training units.

GMP 12 Management of Air and Water Quality
General Requirement
<ul style="list-style-type: none"> The food factory shall establish management standards for air, compressed air and other gases, and water (including ice and steam where appropriate) used in the processing of food products and monitor and record their condition periodically to mitigate any food safety risk. When non-potable water is used within the food factory, appropriate management shall be documented and implemented.
Technical Guideline
<ol style="list-style-type: none"> Sufficient water shall be available to meet the needs of the factory at the required pressure, temperature, and quality. Reservoirs (towers, tanks) shall be constructed from non-toxic materials that will not pollute water quality. Pollution prevention steps shall be in place and reservoirs shall be cleaned at least once per year, kept clean and the cleaning is recorded. Water used in food manufacturing (including water, ice, and steam in direct contact with food, and water used for cleaning food equipment and utensils) shall meet the requirements of the Drinking Water Quality Standards and be monitored regularly for water quality. Non-tap water usage shall require equipment for purification or sanitation, shall have available residual chlorine and pH value measured regularly by designated personnel, and shall be inspected at least once per year by a government recognized inspection body. The plumbing system for non-potable water that does not contact food (such as cooling water, sewage, or wastewater etc.) shall be differentiated from water used in food manufacturing by different colored and completely separate pipes, and counterflow prevention. Any underground water source and potential pollution sources such as septic tanks, waste sites, shall be separated by a distance of at least fifteen (15) meters. Water storage facilities shall be separated from potential pollution sources by at least three (3) meters. Compressed air or other gases used in food processing or cleaning of food contact surfaces or equipment shall be handled properly to avoid direct or indirect contamination.

GMP 13 Product Contamination Risk and Segregation
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain process control procedures. All manufacturing operations (including inspection and acceptance, manufacturing, rework, packaging, and storage) shall satisfy the food safety and sanitation regulations and be conducted to prevent the risk of food contamination and cross contamination.
Technical Guideline
<p>Manufacturing Operation Control Procedure</p> <ol style="list-style-type: none"> Manufacturing operational control procedures shall detail the formula, manufacturing operating standard, rework standard, procedure control standard (at least including the manufacturing procedure, control target, control item, control standard value, precautions etc.) and equipment operating standard. Employees shall be trained to follow manufacturing operational control procedures to meet the requirements of production, hygiene, and quality management. <p>Raw Material Handling</p> <ol style="list-style-type: none"> Raw materials shall be subjected to sensory evaluation and inspection for foreign matter before use and rejected if found to be unsatisfactory. When water used for cleaning of raw materials is recycled, appropriate methods shall be carried out to avoid secondary pollution of the raw material. Qualified and unqualified raw materials shall be stored separately and labelled correctly. Raw material shall be stored to avoid pollution, damage, and minimize quality deterioration. If temperature and humidity need to be controlled, control standards shall be established. Frozen material shall be kept under -18°C, and chilled materials kept under 7°C and above freezing point.

5. Frozen raw materials should be thawed under conditions that able to prevent quality deterioration.

Manufacturing Operations

1. All food manufacturing operations (including packaging and storage) shall meet safety and hygiene principles and be carried out at a rate designed to minimize the growth of pathogenic and food spoilage microorganisms and food contamination.
2. Relevant control methods and standards shall be established if temperature, humidity, pH value, water activity, pressure, flow rate, and time in food manufacturing process need to be controlled in the food manufacturing process. Data shall be recorded to ensure food is not spoiled or contaminated due to mechanical failure, time delay, temperature changes or other factors.
3. Appropriate methods shall be applied to prevent the growth of harmful microorganisms and deterioration during manufacture, storage, and transportation, including irradiation, high or low temperature sterilization, freezing, chilling, pH or water activity adjustment.
4. Effective methods shall be applied during processing or storage to ensure raw materials, semi-finished products, rework products and final products are not contaminated.
5. Equipment, containers and utensils for transport, storage, and loading and unloading of raw materials, semi-finished products and finished products shall be operated, used, and maintained to prevent product contamination. Equipment, containers, and utensils in contact with raw materials or contaminants shall be cleaned and sanitized thoroughly prior to use for finished products. Containers with processed food shall not be placed directly on the floor to prevent water splash contamination or indirect contamination from the outer or bottom of the container. Equipment, containers and utensils entering from a general operations area to a high-risk processing area shall follow appropriate cleaning and sanitizing protocols to prevent food contamination.
6. Effective steps shall be taken to prevent metal or other foreign substances contaminating the food. These steps may include the use of sieves, magnets, electronic metal detectors or other effective methods.
7. Inner packaging material shall be selected to provide appropriate protection during normal storage, transportation, and sales, prevent contamination by harmful substances and meeting hygiene requirements. Inner packaging shall not be reused, except for glass bottles, stainless steel containers, barrel containers (such as packaging water or sugar syrup etc.) that must be cleaned and sterilized with appropriate verified methods before reuse.
8. Food additives shall only be used according to regulations and agreed specifications. Checking systems for weighing and feeding shall be developed, implemented and records are kept.
9. Ready-to-eat products shall be strictly controlled to prevent microbial contamination.

GMP 14 Rework

General Requirement

- The food factory shall establish, implement, and maintain operating procedures for rework of raw materials and ingredients, semi-finished products, finished product, and packaging, to mitigate the risk to food safety. All rework information shall be accurately recorded. Reworked goods shall be traceable.

Technical Guideline

1. Raw materials that need to be reworked shall be reprocessed within the expiration date and shall prevent contamination, cross-contact and potential food safety risk.
2. The rework process shall conform to the factory's food safety plan and consider the possibility of cross-contamination and cross-contact.
3. Finished reworked products shall complete safety and quality confirmation before shipment.
4. Finished reworked products shall be identifiable and traceable.

GMP 15 Reception of Purchased Materials
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain procedures for the receipt of raw materials, ingredients, and food packaging materials. Each batch of raw materials shall be received into the factory only following a successful inspection. A raw material management policy shall be in place to trace the source of all materials. Any materials found to be defective shall be marked clearly, segregated, and appropriately disposed of.
Technical Guideline
<ol style="list-style-type: none"> Raw materials with unacceptable levels of microorganisms or toxic substances that cannot be removed or reduced during processing (e.g., cyanic acid in cassava) cannot be used. If raw materials are exposed to pesticides, heavy metals, or other toxic substances, the safety and quality shall be verified before use in accordance with relevant laws and regulations. The receipt of purchased packaging material shall include verification of source, applications, and storage methods to prevent product contamination.

GMP 16 Warehousing and Transportation Management
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain a warehouse management procedure which includes separation of storage areas, storage conditions, stock-in/stock-out management, and warehouse management. Warehouse management shall be recorded. The food factory shall establish, implement, and maintain a transport management procedure which includes requirements for the forms and condition of transport, intended use, and sanitation and hygiene management. Raw materials shall be used in order of production date, and within the expiry date. This shall also apply to the order in which finished goods are shipped.
Technical Guideline
<p>Warehouse management</p> <ol style="list-style-type: none"> Raw materials, ingredients, packaging materials, rework, semi-finished products, and finished products shall be stored separately and with sufficient space for storage and transport access. Warehousing of raw materials and finished products shall be separate or isolated. Materials and products with different characteristics stored in the same warehouse shall be stored separately. Warehouses shall be designed and constructed to minimize quality deterioration and prevent contamination of raw materials, ingredients, packaging materials, rework, semi-finished products, and finished products during storage. The structure and size of warehouses shall enable efficient storage and transport operations and including cleaning, maintenance, and pest prevention. Materials and products in warehouses shall be stored on pallets and storage racks, or alternatively effective steps taken to maintain cleanliness and hygiene. Stored items shall be placed at least 5cm away from the wall or floor to maintain good ventilation. Food additives shall be stored in dedicated cabinets and managed by specific personnel to confirm the use of food additives and their expiry date. The type, permit number, purchase amount and use of food additives shall be specifically recorded. Cold (frozen) storage of food that is prone to microbial growth shall be in cold storage rooms with a thermometer, temperature detector or automatic temperature recorder that can accurately indicate the product temperature and include automatic controllers or warnings for abnormal temperature changes. Cold (frozen) storage rooms shall be equipped with an alarm switch that can be used to contact a monitoring department for assistance in the case of emergency if the storage door fails or is locked in error. The temperature (and humidity if necessary) of warehouses shall be recorded and stored

products checked regularly. Any abnormalities shall be dealt with as soon as possible.

9. Warehouse management shall maintain inventory records and shipping records for finished products, including batch numbers, shipping times, locations, destinations, and quantities, to allow for rapid recall if problems occur.
10. The storage of materials provided by Clients shall be controlled. If there is any loss, damage, or failure, it shall be recorded, and the approved supplier notified for proper disposal.

Transportation Control

1. Transportation and environment of materials and products shall avoid direct sunlight, rain, severe temperature or humidity changes, impact and ponding of water to prevent damage to food packaging, or detrimental impact on the content, amount, quality, and purity of the food product.
2. Contamination prevention steps shall be established for raw materials, ingredients, rework, or products that potentially cause contamination of other materials or products. If prevention steps are not able to be established, raw materials, semi-finished products, rework and finished products shall not be transported with potentially contaminated items.
3. The containers and vehicles used for purchase of raw materials and ingredients shall be inspected to prevent contamination of the raw materials and the factory site. The containers and vehicles used for shipment of finished products shall be inspected before loading to confirm cleanliness and prevent contamination of finished products.
4. The logistics operation shall follow the temperature requirements of finished products. If temperature control is required during transportation, effective thermal insulation storage and transportation equipment shall be used, and temperature records shall be kept.

2 Hazard Analysis and Critical Control Point (HACCP)

HACCP 1 Establishment of HACCP Plan
General Requirement
<ul style="list-style-type: none"> • The food factory shall document and implement HACCP plans based on the Hazard Analysis and Critical Control Points (HACCP) guidelines published by the Codex Alimentarius Commission and risk management principles. • Prerequisite Programs shall be implemented before establishment of the HACCP plans. • The HACCP plans shall be managed systematically and consider all applicable food safety laws.
Technical Guideline
<p>Prerequisite Programs</p> <ol style="list-style-type: none"> 1. Prerequisite Programs refer to the essential fundamental conditions and activities for maintaining the sanitation of the whole food supply chain to minimize the possibility of product contamination or food safety risk in food processing and produce safe food for human consumption. 2. Prerequisite Programs in the TQF Program refer to the requirements of the chapter on Good Manufacturing Practices (GMP) in this certification standard (technical guideline).

HACCP 2 Establishment of HACCP team
General Requirement
<ul style="list-style-type: none"> • The food factory shall establish a food safety management (HACCP) team consisting of competent technical personnel including senior management or their proxies.
Technical Guideline
<p>Composition and ability of food safety management team personnel</p> <ol style="list-style-type: none"> 1. The food safety management team shall comprise of personnel with professional skills, with a leader who has professional knowledge and skill related to food products, and moderate communication skills to integrate other views and opinions. 2. The food safety management team shall include at least one (1) food technology graduate (or similar) and possess a certificate of competence from a HACCP training course. <p>Duties of the food safety management team</p> <ol style="list-style-type: none"> 1. The food safety management team shall document and implement HACCP plans which identify and control food safety hazards in material inspection and acceptance, processing, packaging, and storage of materials and products. The team shall conduct hazard analyses, determine critical control points, critical limits and their validation, determine monitoring, corrective action procedures, preventative measures, and verification procedures, and establish document and record keeping. 2. Senior management or their proxies shall achieve their food safety goals by supervising and supporting the food safety management system, supplying, and maintaining sufficient human resources to accomplish the operation, and maintenance and improvement of food safety management system.

HACCP 3 Product Description, Establishment of Flow Diagram and Hazard Analysis
General Requirement
<ul style="list-style-type: none"> The hazard analyses shall identify the biological, physical, and chemical hazards (including allergens) that could occur at each process step and the potential frequency and severity. The hazard analyses shall be based on the product descriptions, intended use, and the flow diagram for the target processes. The HACCP plans shall be defined by product type, processing lines, and production site.
Technical Guideline
<ol style="list-style-type: none"> Product description <ol style="list-style-type: none"> The product description shall include the product name, product features, source raw materials and ingredients, additive and the terms of use, package type, unit and weight, packaging material, expiration date and storage conditions. The product description shall include allergen content (intentional and potential cross-contact). The directions in the product description shall include: <ol style="list-style-type: none"> Storage temperature Expecting use Preparation method etc. Target audience <ol style="list-style-type: none"> The product description shall include the target consumer group. It shall identify potential vulnerable consumer groups (e.g., infants, elderly, and patients etc.). The flowchart shall apply to the particular production site and include all operating steps in the production process. <ol style="list-style-type: none"> All steps in the process flow diagram shall be examined and confirmed on the production site to ensure correctness and completeness. The production process shall be corrected when it does not agree with the flow diagram. The flowchart shall include all subsidiary processes including rework. Process steps and CCPs shall be marked individually on the flowchart. The flowchart shall be clearly labelled. HACCP plans may be combined if the food safety hazard analysis, critical control points and critical limits are identical.

HACCP 4 Critical Control Points (CCPs)
General Requirement
<ul style="list-style-type: none"> Critical Control Points (CCPs) shall be documented and implemented at each process step where control is necessary to eliminate a food safety hazard or reduce it to an acceptable level.
Technical Guideline
<ol style="list-style-type: none"> CCPs shall be determined if the hazard analysis identifies a significant hazard at a process step. The CCP decision tree or other risk assessment tool shall be used to determine if the step is a CCP or not.

HACCP 5 Critical Limits
General Requirement
<ul style="list-style-type: none"> Critical limits shall be established and scientifically validated at each CCP to demonstrate food safety control.
Technical Guideline
<ol style="list-style-type: none"> Critical limits shall be determined for every critical control point and shall be scientifically validated as capable of controlling a hazard within an acceptable range when appropriately applied. The food factory shall determine validation of critical limits internally or through credible

external sources. Critical limits may reference food law or scientific evidence from a competent authority for third party research. Critical limits shall apply specifically to the actual on-site process.

3. Several preventative measures may be implemented to control specific hazards and meet critical limits. Several hazard may be control by a specific measure.

HACCP 6 Monitoring Method
General Requirement
<ul style="list-style-type: none"> • The methods by which the critical limits are monitored, including methods, frequency, and responsible personnel, shall be documented and effectively implemented to ensure the process remains within the established critical limits.
Technical Guideline
<ol style="list-style-type: none"> 1. The monitoring procedure shall relate to the critical limits established for a given CCP. 2. Monitoring principles: <ol style="list-style-type: none"> (1) The monitoring methods shall conform to established critical limits. (2) The monitoring methods shall be able to provide indicative results of the safety of the process step rapidly (3) Monitoring frequency shall be continuous or shall ensure the CCP is under control if critical limits are monitored by batch. If a deviation happens at a CCP detected by continuous monitoring, any product processed at that time may be unsafe food and subject to corrective action. If deviation detected by batch, affected range is decided by food factory. (4) Established critical limit parameters shall be monitored in direct method. (5) Specific personnel shall be trained and appointed for monitoring and the implementation of the monitoring shall be confirmed by the person in charge. (6) Critical limit monitoring records shall be examined and reviewed regularly to confirm the outcome and correct disposition of product.

HACCP 7 Corrective Actions
General Requirement
<ul style="list-style-type: none"> • The corrective actions to be taken when monitoring indicates a deviation from the established critical limits shall be documented and implemented. The cause of any identified deviation shall be identified and corrected.
Technical Guideline
<ol style="list-style-type: none"> 1. The food factory shall establish procedures to correct the process status to prevent recurrence of the food safety hazard, restart the production process, and determine the disposition of affected product in HACCP plan. 2. The operator responsible for corrective action shall have full technical knowledge of the CCP, fully understand the corrective action procedure, and have the ability to differentiate and reach decisions rapidly. <p>Corrective actions documented in HACCP plans:</p> <ol style="list-style-type: none"> 1. Shall establish permanent solutions in written form for each CCP in the HACCP plan. 2. Shall ensure monitoring parameters can return the process step to meeting critical limits. 3. Shall ensure products that deviate from the established critical limits are quarantined and their disposition evaluated so that it is not shipped to customers. <p>Application documents for corrective actions shall include:</p> <ol style="list-style-type: none"> 1. Record of deviation, process, site, date, and time when the event occurred. 2. Identity, batch number, and quantity of affected product. 3. The result of investigation into the deviation. 4. Authorized corrective and preventative action for the recovery of the process step. 5. Authorized disposition and related content of the affected product.

6. Date and signature of personnel examining and authorizing corrective actions.

HACCP 8 Verification Procedure

General Requirement

- HACCP verification procedures shall be implemented periodically. HACCP plans shall be re-verified in the event of any changes in the inspection and acceptance, processing, rework, packaging, and storage of materials or finished products that can affect product safety.

Technical Guideline

Verification procedures shall contain at a minimum:

1. Calibration of measuring instruments.
2. Review of processing procedures.
3. Review of CCP monitoring and corrective actions records.
4. Investigation of operator compliance with HACCP plan requirements.

Verification of HACCP plan

1. Verification of HACCP plans shall be conducted regularly.
2. Verification shall also be conducted when suppliers, materials, equipment, processes, and legal requirements change.
3. Results of verification procedures shall be recorded.

HACCP 9 Documents and Records

General Requirement

- Documents and records related to the development and maintenance of HACCP plans shall be retained.

Technical Guideline

1. All documents shall be established and retained according to the internal document control system in the food factory.
2. The following content shall be retained as an important reference in maintaining and revising HACCP plans:
 - (1) Hazard analyses summary, including hazard confirmation and the principle of the control method.
 - (2) Current HACCP plans.
 - (3) Related supporting documents including validation records.
 - (4) All documents created in the preparation of HACCP plans.

3 Food Safety Management (FSM)

FSM 1	Organization and Personnel
General Requirement	
<ul style="list-style-type: none"> The senior management of the food factory shall determine the organizational structure and functions related to food safety and quality activities, including the duties and responsibilities in manufacturing, quality control, sanitation and hygiene management, and food safety management. 	
Technical Guideline	
Organization and Duty	
<ol style="list-style-type: none"> The Quality Control department shall have sufficient authority to operate all quality control functions, and the leader shall have authority to stop producing or shipping if justified. The food factory shall employ food inspectors to oversee inspection and analysis of general food and sanitation quality. The leader of production and quality control shall not be the same person. 	
Personal Qualifications	
<ol style="list-style-type: none"> Leaders in production, quality control, sanitation and food safety shall hold a college in a related discipline or high school (vocational) degree and have food production experience. Food inspectors shall hold a college degree in a related discipline or be qualified as food inspectors and technicians through a government license system. Personnel who have graduated from high school (vocational) or come from an unrelated department shall attend a government professional food inspection training course and obtain a certificate of completion. Professional and technical personnel shall comply with relevant laws and regulations. 	

FSM 2	Management Commitment and Food Safety Culture
General Requirement	
<ul style="list-style-type: none"> The senior management shall establish, implement, maintain, and continually improve the food safety commitment and culture, and practice the food safety culture within the factory. A review mechanism shall be in place with respect to management commitment. The food safety culture practices shall include at a minimum communication, training, employee feedback, and performance evaluation related to food safety. 	
Technical Guideline	
<ol style="list-style-type: none"> The senior management shall commit to implementing systems to produce safe food and practice a food safety culture within the factory that recognizes the needs and business activities of customers. Senior management shall establish a food safety performance review mechanism to maintain the food safety performance. Senior management shall be responsible for establishing, implementing, and maintaining the food safety system by: <ol style="list-style-type: none"> Establishing and communicating the food safety policy. Conveying the importance of compliance with food safety laws and regulations, standards, and social norms to employees within the food factory in a timely manner. Establishing pathways for food safety personnel to offer suggestions and opinions on food safety matters. Implementing, and maintaining other essential requirements of the food safety management system. 	

FSM 3 Food Safety Policy and Objective
General Requirement
<ul style="list-style-type: none"> The food factory shall document and implement a food safety policy and objectives, set performance indicators for the policy and objectives, and conduct regular performance evaluations.
Technical Guideline
<ol style="list-style-type: none"> The senior management shall establish a food safety policy which includes: <ol style="list-style-type: none"> Benchmarking customers' needs to improve safety, reliability performance. Implementing activities related to food safety based on compliance with food laws and accepted social norms. The senior management shall utilize food-safety related feedback from employees to raise food safety consciousness in the food factory. The food safety policy shall be participated by senior management directly or indirectly. All employees shall understand the intent and direction of the food safety policy. Translated versions of the food safety policy shall be published as necessary to ensure all employees understand the factory's food safety policy and objectives. <ol style="list-style-type: none"> Senior management shall confirm the appropriateness of the food safety policy regularly and amend the objectives as required. Senior management or their proxies shall confirm that the policy and objectives are achievable.

FSM 4 Management Review
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain management review procedures. Senior management shall review the food safety management system (including the HACCP plans) at a minimum annually, identify any changes that may impact food safety, correct any anomalies in a timely manner, and confirm the validity of the food safety management system.
Technical Guideline
<ol style="list-style-type: none"> The food safety management team within the food factory shall gather food safety management system information and records, and report to senior management regularly after analysis. Information for management review shall include the following: <ol style="list-style-type: none"> Non-conformities and corrective actions Process monitoring results Supplier management results Factory environmental inspections Internal audit results and other verification procedures Results of improvement activities The following information may additionally be included: <ol style="list-style-type: none"> Tracking agreed outcomes from previous management reviews Extraordinary events and product recalls (if necessary) Review of feedback and communication from customers The food safety management team shall review the development and implementation of HACCP plans and the results shall be reported to senior management. The HACCP review shall be carried out regularly or when changes occur due to new materials or products, modifications to the production line, or an update to food laws and regulations. The result of management review shall be recorded and used to improve the food safety management system.

FSM 5 Food Safety Legislation
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain procedures to ensure that food safety laws and regulations applicable in the territories of manufacture and sale are effectively implemented.

Technical Guideline
<ol style="list-style-type: none"> 1. The food factory shall be aware of related and essential food safety laws, regulations and requirements and establish management methods to comply with food safety laws and regulations applicable in the territories of manufacture and sale. When modifications to related laws or establishment of new laws occur, the food safety management team shall be advised and shall inform the factory of any necessary procedural changes.

FSM 6 Food Safety Management System
General Requirement
<ul style="list-style-type: none"> • The food factory shall establish, implement, and maintain the food safety management system. Its design and management shall be integrated and adjustable to incorporate customers’ requirements and the scope of business activities. • Information that might impact food safety and enable improvement of the food safety management system shall be collected, analyzed, and implemented if applicable.
Technical Guideline
<ol style="list-style-type: none"> 1. The food factory shall clearly specify the scope of the food safety management system, including all relevant areas and activities, premises, warehouses (including internal and external warehouses for storage of raw materials, semi-finished products, rework, and finished product.) and co-manufacturers (where appropriate).

FSM 7 Food Defense Management
General Requirement
<ul style="list-style-type: none"> • The food factory shall establish and conduct a food defense risk assessment. • A food defense plan shall be established, implemented, and maintained based on the food defense risk assessment, including the analysis of threats and vulnerabilities posed by incoming materials and services, and food manufacturing equipment and facilities. • The food factory shall be supported by food safety management system and shall document and develop the food defense system by identifying the known food defense risk factors that might cause public health risk, and implementing preventive measures that mitigate or remove the identified hazards.
Technical Guideline
Definition of Food Defense
<ol style="list-style-type: none"> 1. Food defense refers to the procedures applied to ensure the security of food materials and food products from all forms of malicious attack intended to contaminate and cause harm.
Principle of the Food Defense Plan
<ol style="list-style-type: none"> 1. The Threat Assessment Critical Control Point (TACCP) principle shall be applied to identify potential vulnerability within the food supply chain and processing operations which could be violated or attacked intentionally. Intentional attack may include malicious poisoning to support blackmail, espionage, or cybercrime with the intent of destroying corporate image, extorting money, stealing company intellectual property, or endangering public safety. Threats may be conducted by groups within the factory, external groups, or individuals. 2. Risk mitigation strategies and procedures shall be implemented for identified vulnerabilities to prevent or minimize the risk of the food factory and products from being exposed to malicious attack. 3. Food defense threat assessments, procedures and mitigation strategies shall be reviewed frequently and audited for effectiveness. 4. Corrective actions shall be immediately implemented where it is established by threat assessment that existing vulnerability mitigation strategies are not working as expected. 5. All related food defense activities shall be recorded and reviewed regularly to ensure actions are operated effectively.

FSM 8 Food Fraud Management
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain a food fraud vulnerability analysis procedure and food fraud prevention plan based on the fraud vulnerability analysis results. The food factory shall document and implement the food fraud prevention plan within the food safety management system by identifying the known food fraud risk factors and implementing preventive measures that mitigate or remove the identified hazard.
Technical Guideline
<p>Definition of Food Fraud</p> <ol style="list-style-type: none"> Food fraud is a common term for economically motivated adulteration (EMA), which is aimed at obtaining financial profit by adulteration, fabrication, dilution, material substitution, or false and misleading labelling or product claims. <p>Principle of Food Fraud Prevention Plan</p> <ol style="list-style-type: none"> The Vulnerability Assessment and Critical Control Point (VACCP) process shall be applied to identify potential food fraud vulnerability points in the food supply chain. A food fraud prevention plan shall be established to mitigate the fraud risk at the identified vulnerability points in the supply chain. The food fraud prevention plan shall consider, and include as appropriate, testing for ingredient content and purity, the application of anti-counterfeiting techniques, confirmation of supplier information, verification of manufacturing location and label and supplier audits. The established food fraud prevention procedures, frequencies and responsibilities shall be listed and reviewed frequently to confirm the effectiveness of the prevention plan. A review and analysis of the food fraud mitigation plan shall be implemented annually along with the procedure for verifying traceability.

FSM 9 Document Management Procedure
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain a procedure to manage documents and data in electronic and paper form, and confirm that food safety management system documents are current, in use, and controlled effectively. All related records shall be stored safely for the time period required by law in the applicable territories of manufacture and sale. Records shall at least be maintained until the expiration of the life cycle of the applicable products, and the relevant data shall be available at any time, if required.
Technical Guideline
<p>Document management</p> <ol style="list-style-type: none"> A procedure shall be implemented for publishing, amendment, and abolition of documents and must be approved and signed before implementation and recorded by the person in charge or the proxies. Only valid and current versions of documents shall be available and in use. Employees shall have easy access to current versions and changes to documents. <p>Record management</p> <ol style="list-style-type: none"> Records that are required by regulation shall be maintained. Writing instruments (e.g., pencil) which are easily erased must not be used for writing records. All records shall be signed by the operator and the supervising or authorized review person. The original record must not be edited beyond recognition, and the editor must sign near the changed record after editing. The application of a seal shall be managed correctly. All records shall be stored securely. Electronic files shall require authorization before being accessed. This requirement shall apply to local and remote backup systems. For paper records, designated personnel shall apply appropriate methods to maintain their safety and security.

FSM 10 Food Safety Management Procedures
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain effective procedures and operating standards for the processes and activities that affect food safety. The procedures and operating standards shall be documented and available in languages and in a form understood by all relevant personnel.
Technical Guideline
<ol style="list-style-type: none"> The food factory shall establish effective processing procedures for Good Manufacturing Practices (GMP), HACCP. All processes and operational steps that affect food safety shall be documented.

FSM 11 Resources Management
General Requirement
<ul style="list-style-type: none"> The senior management or their proxies shall supervise the application and maintenance of food safety activities, provide sufficient personnel and resources to achieve food safety management objectives, and ensure the continued supply of effective resources to satisfy the needs of operations, maintenance, review, and improvement of the food safety management system.
Technical Guideline
<ol style="list-style-type: none"> The senior management shall establish, implement, maintain, and update the food safety management system, provide the necessary resources including manpower, facilities, equipment, appliances, services (e.g., transportation, communication) and public facilities (e.g., electricity, gasoline, water) as required.

FSM 12 Purchasing and Supplier Management
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain purchasing and supplier assessment procedures to ensure that raw materials and services from external sources satisfy the food factory's specific food safety requirements as well as applicable food laws and regulations. The approved supplier assessment procedure shall include evaluation, implementation methods and continued monitoring frequency. Results shall be recorded. Raw materials shall be sourced from approved suppliers. In the event of an emergency, if it is necessary to acquire raw materials from a non-approved supplier, an assessment procedure for emergency procurement shall be in place to ensure that the products satisfy related regulations and the food safety specifications of the food factory. The special procurement procedure shall include specifications for products and services subject to special procurement to ensure they do not cause a food safety risk.
Technical Guideline
Purchasing management
<ol style="list-style-type: none"> A purchasing procedure for outsourced food safety related services such as facilities maintenance, instrument calibration, sanitation services, pest control, and logistics, shall be established and maintained.
Supplier management
<ol style="list-style-type: none"> The food factory shall evaluate the business information, management, and quality and food safety processes of required suppliers when considering procurement and outsourcing services. The selection, approval and inspection procedures for suppliers shall be established based on food safety hazard evaluation. Supplier assessment procedure for emergency procurement shall be established to ensure emergency products meet food laws and regulations and specifications. This procedure shall only be conducted if raw materials need to be acquired from a non-approved supplier in the event of an emergency.

4. The supplier shall be advised of the food factory’s allergen management requirements, and the supplier required to inform the food factory of any known allergens or change in allergens in the supplied material.

Outsourced manufacturing

1. Outsourced manufacturing or co-manufacturing refers to other factories that are entrusted to process, pack, or store part or all of the food factory’s products. Processing procedures shall be established and agreed by the food factory and monitored to avoid food safety risk to outsourced products.
2. The co-manufacturer shall take responsibility for the food safety of outsourced manufacturing.
3. The following shall be evaluated to establish the suitability of outsourced manufacturing:
 - (1) Confirmation of the food safety management system of the co-manufacturer.
 - (2) Confirmation of the co-manufacturer’s process management.
 - (3) Regular verification of product safety and quality.
 - (4) Monitoring food safety regarding the absence of physical, chemical, and biological hazards.
4. The completeness of the food safety management system, the ability to produce food factory product, and an examination of facilities and review of previous records shall be conducted when investigating a new co-manufacturer if the regular co-manufacturer is no longer available.

FSM 13 Specifications for Purchased Materials

General Requirement

- The food factory shall establish, implement, and maintain specifications for raw materials and services to ensure that they do not negatively impact product safety and achieve product expectations.
- The specifications and requirements for raw materials and services shall be regularly reviewed and revised where necessary.

Technical Guideline

1. The food factory shall establish and apply the specifications (including source, and potential hazards), inspection items, receipt standards, and sampling and test plans.
2. Suppliers shall be advised of the factory’s specifications before purchasing, and purchasing shall confirm that materials meet the factory specifications and customer requirements.
3. The content of specifications shall include requirement for service, compliance with legal requirements, actions when the specification changes, expected frequency of modification, and the conditions for recommissioning the supplier.

FSM 14 Contract Management

General Requirement

- The food factory shall establish, implement, and maintain procedures for contract review and business coordination.

Technical Guideline

1. Before accepting a contract, the requirements shall be reviewed to ensure they are clearly stated, and the contractor is able to meet the requirements.
2. Amendments to a contract during its tenure shall be recorded. The amended version shall be communicated to the relevant departments and the latest version implemented.

FSM 15 Traceability

General Requirement

- The food factory shall document, implement, and maintain a product traceability system able to trace materials and ingredients back to their source, and finished product to the next customer, such as the distributor or retailer. Products shall be traceable from material supplier to finished customer.

<ul style="list-style-type: none"> The validity of the traceability system shall be tested at least annually.
Technical Guideline
<ol style="list-style-type: none"> A product traceability system shall be implemented for the food factory using batch numbers of similar methods to identify the name and address of the source. The system shall be able to identify and trace raw materials and services provided by all suppliers that have a food safety impact and be able to trace products to customers and delivery locations. Traceability records shall be retained. Co-manufactured products shall also meet the requirement of the traceability system of this certification standard. Co-manufacturers shall be able to trace the source of raw materials and verify the content and purity of co-manufactured products. Records shall be kept to demonstrate product quality. Shelf-life evaluations shall be conducted to establish product durability and preservation if required. Retention samples for each batch of finished products shall be held until after the expiry date, except for perishable ready-to-eat products which shall be retained until one or two days after the expiry date. Shelf-life evaluation of finished products shall be conducted to establish product expiry dates.

FSM 16 Product Development
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain product design and development procedures to ensure the safety and quality of new products or changes to existing products or processes, and satisfy food laws and regulations.
Technical Guideline
<ol style="list-style-type: none"> Product design and development procedure for the food factory shall meet related food laws and requirements and customers' requirements. The following safety related conditions shall be considered in the design of new products or product changes: <ol style="list-style-type: none"> Established critical control points in similar processes. Additional critical control points that may be required during processing, storage, and transportation. Requirements of related food laws. Problems and challenges that were identified in past product developments. Amendment procedures shall be established for changes in the specification of materials, ingredients, packaging materials, or product formulas. A hazard analysis shall be conducted for changes to the design of products, and critical control points shall be established for the changes.

FSM 17 Allergen Management
General Requirement
<ul style="list-style-type: none"> The food factory shall document, implement, and maintain an allergen management procedure to prevent the risk to products of cross-contact from allergenic sources. Finished products shall satisfy the allergen labelling requirements applicable in the territories of sale.
Technical Guideline
Allergen Management
<ol style="list-style-type: none"> The food factory shall establish and maintain an allergen list, which contains at least the allergen regulatory requirements in the countries of sale, and shall manage raw materials, semi-finished products, rework, and finished products containing allergens included on the list. Procedures shall be established to identify, transport, store and separate raw materials, semi-finished products, rework, and finished products containing allergens to avoid cross-contact with other raw materials, semi-finished products, rework, and finished products. Monitoring shall be implemented to verify the absence of cross-contact.

3. A procedure shall be established to confirm and verify the cleaning effectiveness of equipment and production sites that process products containing allergens to avoid cross-contact. Records shall be kept of the effectiveness of cleaning and product transfers.
4. Indirect allergen cross-contact from non-processing areas shall be evaluated, including quality control laboratories, offices, cafeteria, or visitors etc.
5. Products containing allergens or products from production lines that also process allergenic products shall meet legal requirement to provide information and safeguard the rights and interests of customers.

FSM 18 Control of Measuring and Monitoring Equipment

General Requirement

- The food factory shall have effective measures in place to manage instruments and equipment used to monitor critical control points, conduct product analysis and other food safety controls.
- Procedures shall be documented, implemented, and maintained to calibrate, maintain, and label all instruments and gauges used in processing, inspection, and testing. The frequency of calibration shall be based on instrument use.
- The methods applied for calibration shall follow national or international standards.
- Calibration results shall be recorded and maintained, and corrective action taken if necessary.

Technical Guideline

1. The food factory shall monitor and label measuring and recording instruments used for measurement, control, and recording (e.g., thermometers, pressure gauges and scales). A detailed list of all instruments shall be kept, and an annual calibration plan to confirm the effectiveness of measuring and recording instruments.
2. External calibration reports shall be reviewed to confirm their correctness.
3. Personnel who review external calibration reports and conduct internal calibrations shall successfully complete relevant training.

FSM 19 Product Labeling and Information

General Requirement

- The products manufactured by the food factory shall be labeled in accordance with the laws and regulations applicable in the territories of sale. If product labeling is not required, customers and consumers shall be provided with product information to ensure that they are able to use the product correctly and safely.

Technical Guideline

1. Packaged products shall be clearly labeled with the following information.
 - (1) Name of product
 - (2) Name of ingredients: Two or more types of the mixed ingredients shall be labeled separately
 - (3) Product weight, volume, or quantity
 - (4) Name of food additives
 - (5) Name, contact and address of the food manufacturer or local responsible agent
 - (6) Location (country) of origin
 - (7) Nutritional panel
 - (8) Genetically modified ingredients (if applicable)
 - (9) Shelf-life or product expiration date
 - (10) Batch number that enables product traceability back to the production site, date, and time
 - (11) Instructions for consuming or cooking (if required)
 - (12) Other labeling as required in the country of manufacture or sale
2. A bar code shall be applied to the finished packaged product.
3. Batch numbers shall be labeled on the external package of the product for better storage management and recall of the end product (if required).

4. A control procedure for product labeling shall be established including purchasing, manufacturing, use and disposal. Records shall be kept of product labeling.

FSM 20 Analysis and Testing

General Requirement

- The food factory shall establish, implement, and maintain a sampling and testing procedure which includes an applicable sampling plan for materials, work-in-progress, and finished product.
- Critical testing for food safety shall apply sampling and testing methods in accordance with the applicable requirements of ISO/IEC 17025.
- Outsourced testing shall be conducted by a laboratory accredited to ISO/IEC 17025 or equivalent international standard.

Technical Guideline

1. Product testing shall be conducted using national or equivalent international standards. If alternative methods are used (e.g., rapid test), they shall meet the requirements of EN/ISO 16140 or other accredited international methods. If there is no applicable standard method, the food factory shall provide clear evidence of the testing method used, with proof of validation against an internationally recognized reference standard.
2. Chemicals for product testing shall be used within their expiry date and be managed and stored correctly.
3. Raw material, semi-finished products, rework, and finished products that have been sampled and tested shall be labeled and treated accordingly.

FSM 21 Environmental Monitoring

General Requirement

- The food factory shall implement an environmental monitoring plan based on food safety risk which assesses potential microbiological pathogens and allergens.

Technical Guideline

1. Environmental monitoring is a risk-based verification of the sanitary condition of food manufacturing equipment and environment to minimize product safety risk.
2. The food factory's environmental monitoring plan shall include monitoring frequency, sampling method (e.g., smearing), sample quantity, sampling locations (including direct and indirect surfaces) along with information and limitations of the standard for the tested pathogen or indicator microorganism. The plan shall be implemented, analyzed, reviewed, and modified regularly to ensure it is implemented effectively. Records of environmental monitoring shall be maintained.

FSM 22 Internal Audit

General Requirement

- The food factory shall establish, implement, and maintain an effective internal audit procedure covering all elements of the food safety management system, including the HACCP plans. Internal audits shall be conducted at least annually by trained internal auditors delegated by management to identify and resolve actual and potential non-conformances.

Technical Guideline

1. The food factory shall establish, implement, and record an effective internal audit plan, and determine the frequency and scope of the audit. All scopes shall be audited at least once every year. The frequency of internal audits shall increase when there are changes to the food safety system that impact its effectiveness.
2. Personnel conducting internal audits shall undertake audit training to ensure competence and impartiality when auditing.

FSM 23 Customer Complaints
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain a customer complaint procedure. The procedure shall analyze, assess, and respond to any complaints or suggestions proposed by customers in writing or verbally, and take corrective actions where necessary.
Technical Guideline
<ol style="list-style-type: none"> The receipt, evaluation, correction and reply to written or verbal complaints and suggestions from customers shall be recorded and labeled with the product name, batch number, quantity, reason for complaint, date of complaint, and the date of response. The complaint and follow-up shall be recorded, reviewed, and communicated to related departments for reference and improvement.

FSM 24 Extraordinary Event Management
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain an extraordinary event management procedure for any significant event likely to occur, which shall at least include expected responses and product recall procedures. The extraordinary event procedure shall be periodically tested.
Technical Guideline
Emergency Response
<ol style="list-style-type: none"> The emergency response procedure shall include at a minimum: <ol style="list-style-type: none"> The appointment of an emergency response team and person in charge. Annual testing of the emergency response procedure for all relevant personnel. Documentation and maintenance of an emergency contact list, including internal and external contacts, the Total Quality Food Association (TQFA) and certification bodies.
Product Recall and Withdrawal
<ol style="list-style-type: none"> A product recall, withdrawal, and disposal procedure shall be established which includes the standard, level, degree, and period of recall and withdrawal. It shall be tested annually. Shipped product batches shall be recalled or withdrawn if the products are determined to be unsafe. Product recall and withdrawal procedures shall include at a minimum: <ol style="list-style-type: none"> Senior management shall appoint the personnel responsible for implementing the recall or withdrawal procedure and for recycling or otherwise disposing of the affected product Informing the relevant authority, customers, and consumers Ensuring the recalled or withdrawn product is never released to the market Recording the cause, product details, and outcome of the recall or withdrawal The outcome shall be reviewed by senior management following a recall or withdrawal. TQFA and the certification bodies shall be listed as a priority for reporting of product recalls or withdrawals that violate the food safety regulations in the country of sale

FSM 25 Product Release
General Requirement
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain product release procedures to ensure that the released product meets the specifications and satisfies food safety requirements. All inspection and test records related to the product shall be reviewed by trained personnel before the product is released.
Technical Guideline
Control of end-product release
<ol style="list-style-type: none"> The food factory shall establish, implement, and maintain quality specification, inspection items and standards, and sampling and testing methods for the finished product to ensure it meets customer requirements and the laws and regulations of the location of manufacture and sale.

2. Every batch of product shall undergo finished product testing and shall not be shipped if it does not meet specifications.
3. Records of the verification of manufactured products shall be reviewed prior to shipping, including compliance with critical limits, the appropriateness of corrective actions taken, and product handling. The review shall be conducted by trained and experienced personnel.

FSM 26 Control of Non-Conformity

General Requirement

- The food factory shall establish, implement, and maintain a procedure for control of non-conforming product to expressly identify and control defective products and ensure that defective raw materials, semi-finished products, rework, and finished products are not released or distributed to the market.

Technical Guideline

1. Non-conforming products shall be clearly labeled and isolated to avoid misuse.
2. When non-conformities are identified in raw materials, semi-processed products, rework, and finished products, the safety of all associated products shall be reviewed. When product safety is affected, the product range shall be defined, and the non-conformity control strategy implemented.
3. Non-conforming products shall be reworked or disposed of and be clearly identified and traceable.
4. Shipped products shall be recalled or withdrawn if they are determined to be unsafe.

FSM 27 Corrective Actions

General Requirement

- The food factory shall establish, implement, and maintain corrective and preventive actions to determine the root cause of non-conformances and take appropriate corrective actions and process changes necessary to prevent a recurrence. Records shall be kept of all identified deviations and their corrective actions.

Technical Guideline

1. The food factory shall immediately investigate, correct, and record problems associated with the implementation of sanitary management, process management, the quality system, management system, the customer complaint procedure, abnormal condition treatment, the end-product recall procedure, labeling, supplier assessment, internal audits, and the food safety system. The food factory shall focus on the problems created by the implementation of any of the aforementioned food safety procedures, implement corrective actions and improvements to the food safety system, and record the changes and updates.
2. Corrective actions shall be implemented by personnel with the ability to analyze reasons and establish countermeasures.

4 Quality Management (QM) (Applicable only at TQF L2)

QM 1	Quality Assurance Commitment and Responsibilities
General Requirement	
<ul style="list-style-type: none"> The senior management of the food factory shall declare their commitment to maintain and improve product quality and quality management procedures to satisfy internal product specifications and customer requirements. 	
Technical Guideline	
<ol style="list-style-type: none"> Senior management shall commit to providing sufficient effective resources to satisfy the operation of the quality management plan. The food factory senior management shall prepare, sign, and publish a quality policy that defines the responsibilities for quality control, and reviews it periodically to ensure the establishment, implementation, maintenance, and continuous improvement of product quality management. The quality management plan shall be created in the form of “Plan, Do, Check, Act (PDCA)”, and continuously improve to ensure the effective operation of the quality system, and the prevention of quality failures. 	

QM 2	Quality Assurance Procedures and Specifications
General Requirement	
<ul style="list-style-type: none"> The food factory shall establish, implement, and maintain product quality assurance procedures and standards, and product quality specifications to meet internal and customer requirements. 	
Technical Guideline	
<ol style="list-style-type: none"> Customer and retailers product quality specifications shall be established, supported by sampling and test methods documented in “TQF Specifications and Standards for Product Test Items” along with national or international standards for relevant products. The food factory may use customized quality standards that do not affect food safety if products have specific quality specifications. Related references shall be provided. Statistical analysis shall be conducted and recorded in production and quality control and communicated to relevant departments as a reference for quality improvement. 	

QM 3	Integrated Quality Program
General Requirement	
<ul style="list-style-type: none"> The food factory’s Integrated Quality Program (IQP) shall be based on the process flowchart (quality flowchart) or HACCP guidelines from the Codex Alimentarius Commission and shall identify the critical points that impact product quality, including raw material management, process control, resource utilization, the application of technology, packaging, storage, and transportation. 	
Technical Guideline	
<ol style="list-style-type: none"> A quality flowchart shall be established, implemented and reviewed periodically to define the quality production processes. It shall include the product name, quality control points, control standards, sampling frequency and test methods. The quality control plan shall identify all process quality control points according to the processing procedure, and with particular reference to critical quality points (CQPs). All CQPs shall have established and validated critical quality limits and monitoring procedures. The food factory shall establish corrective action procedures (i.e., reworking and or disposal) when the process at a CQP deviates from the critical quality limits. Production systems shall stop operating as per the quality control procedure until the production system is corrected and critical quality limits is re-established. All IQP records shall be retained. 	

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| 5. The quality flowchart and HACCP plans shall be included in the integrated quality program (IQP). |
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QM 4 Shipping Quality

General Requirement

- The food factory shall test and review finished product quality against the quality specifications using defined test methods, or the test method prescribed by customers. Only products which meet quality specifications shall be shipped.

Technical Guideline

1. Finished product shall be inspected and tested for compliance to quality specifications before shipping, and sensory analysis shall be conducted by trained personnel according to established methods or retailer requirements.