FSSC Development Program

FSSC DEVELOPMENT PROGRAM

ASSESSMENT REQUIREMENTS
FOOD AND FEED MANUFACTURING (BIII, C, D & K)

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CONTENTS

1. INTRODUCTION

This document defines the requirements for organizations in the Food and Feed Manufacturing sector. The organization's Food Safety System will be assessed against these requirements by a licensed conformity assessment body (CAB) in order to receive a valid conformity statement.

Sector requirements are normative as defined in the assessment requirements of the FSSC Development Program, Part 1, Table 1, linked to the scope of the organization.

2. ASSESSMENT REQUIREMENTS FOR FOOD AND FEED MANUFACTURING (CATEGORY BIII, C, D & K)

Clause no.	Requirement
1. Food Safety System Requirements	
1.1	**Leadership and commitment**
1.1.1	Evidence shall be available to demonstrate that management is committed to providing sufficient and necessary resources to develop, implement and maintain their food safety program to comply with customer and legal requirements.
1.1.2	Senior management shall ensure that employees are aware of their responsibilities related to food safety including the importance of the food safety program.
1.1.3	The organization shall maintain the appropriate legal registration for a food establishment, when required by legislation.
1.2	**Organizational roles, responsibilities and authorities**
1.2.1	The organization shall establish a clear organizational chart outlining the organizations' structure.
1.2.2	Documented roles, responsibilities and authorities related to food safety and legality shall be defined, implemented, communicated and understood in a manner to ensure product safety.
1.3	**Externally developed elements of the food safety system**
1.3.1	Externally developed elements of the food safety system shall be verified to ensure they cover and are suitable for the activities of the organization. The responsibility for the operation of the food safety system still belongs to the organization. Note: externally developed elements may include PRPs, the hazard analysis and the hazard control plan.
1.4	**Competence**

1.4.1	The organization shall ensure that all people are adequately trained in food safety and practices according to their job responsibilities. Training records shall be maintained.
1.4.2	All new personnel (including maintenance personnel) shall be effectively trained on hygiene requirements, allergen awareness, cleaning, and pest control awareness.
1.4.3	A HACCP training program shall be in place, for the HACCP/food safety team and those responsible for the operation of the hazard control plan.
1.4.4	A refresher training program shall be documented and implemented. All relevant personnel shall receive refresher training, to ensure personnel remain aware of all procedures necessary to maintain the food safety of the products produced.
1.4.5	A documented training program shall be in place and effectively implemented for all personnel whose work can impact food safety.
1.4.6	Food defense awareness training shall be in place.
1.5	**Communication**
1.5.1	**External communication**
1.5.1.1	Food safety requirements or technical guidance, from statutory and regulatory authorities, customers and industry organizations, shall be available and kept up to date.
1.5.1.2	Effective arrangements for communicating with external stakeholders (suppliers and contractors, customers, statutory and regulatory authorities, and industry organizations) shall be established, implemented and maintained. A designated and responsible person shall be identified to manage these communications.
1.5.1.3	Organizations shall inform their Conformity Assessment Body within three (3) working days of the commencement of the events or situations listed below: • Serious events that impact the food safety system, legality and/or the integrity of the conformity statement, as a result of a Force majeure, natural or man-made disasters (e.g., war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.); • Serious situations where the integrity of the conformity statement is at risk and/or where the Foundation can be brought into disrepute. These include, but are not limited to (1) recalls, (2) actions imposed by regulatory authorities as a result of a food safety issue(s), where additional monitoring or forced shutdown of the site/facility is required, (3) legal proceedings, prosecutions, malpractice, and negligence; and (4) fraudulent activities and corruption.
1.5.1.4	Records of communication with suppliers, contractors, customers, statutory and regulatory authorities, and industry organization, shall be maintained.

1.5.2	**Internal communication**
1.5.2.1	Senior management shall ensure effective internal communication within its organization on all relevant information related to food safety and legality, including when changes relevant to the food safety system occur.
1.6	**Specifications including product release**
1.6.1	Specifications shall be accurate and available for all product inputs (raw materials, ingredients, additives, packaging materials, rework), intermediate and finished products.
1.6.2	Specifications shall be compliant with relevant safety, legislative and customer requirements.
1.6.3	Specifications shall be kept up to date, unambiguous and available to relevant personnel.
1.6.4	Changes to specifications shall be clearly communicated both internally and externally as applicable. Evidence of this shall be available.
1.6.5	A documented product release procedure shall be in place and implemented to ensure that the final product meets the specification.
1.6.6	A designated person with responsibility for controlling specifications shall be appointed.
1.7	**Documented information**
1.7.1	Records shall be available to demonstrate that the organization complies with the food safety system, including all applicable regulatory and customer food safety requirements.
1.7.2	Records shall be: • genuine and maintained in good condition, to preserve legibility. • securely stored and accessible. • protected from unintended alterations, and alterations or corrections to completed records shall be approved and justification for this maintained. Electronic records shall be secured and backed up to prevent loss.
1.7.3	The organization shall set timescales for record retention which comply with regulatory or customer requirements. Where there are no regulatory or customer requirements, records shall be kept covering the shelf life of the product as a minimum.
1.8	**Procedures**
1.8.1	Procedures shall be documented, implemented and maintained for all processes and operations that affect food safety.
1.8.2	Procedures shall be clearly communicated to relevant personnel.
1.9	**Traceability System**

1.9.1	The traceability system shall be implemented and maintained to uniquely identify incoming material from suppliers, through all stages of production and the first stage of the distribution route of the end product.
1.9.2	The traceability system shall be fully operational and effective, and shall consider as a minimum the: a) relation of lots of received materials, ingredients and intermediate products to the end products; b) reworking of materials/products; c) distribution of the end product. The organization shall ensure that applicable statutory, regulatory and customer requirements are met.
1.9.3	The traceability process shall incorporate all relevant records of: • receipt • processing at all steps • use of rework • work in progress • distribution. Traceability shall be ensured and recorded until delivery to the customer.
1.9.4	There shall be clear labelling procedures that ensure continuous identification of the product through all stages of production and delivery.
1.9.5	The effectiveness of the traceability system shall be verified and tested (backwards and forwards) at least annually. The verification of the system shall include the reconciliation of quantities of end products produced and distributed.
1.9.6	The system shall be documented, updated as necessary and records shall be maintained.
1.10	**Food safety incident management**
1.10.1	**Withdrawal/recall**
1.10.1.1	The organization shall have an effective incident management procedure for all products including incident reporting, communicating with interested parties, and management of product withdrawal and recall.
1.10.1.2	This shall include having systems in place to ensure that products failing to meet requirements are identified, located and removed from all necessary points of the supply chain.
1.10.1.3	A designated responsible person shall be identified to provide information to customers, consumers and regulatory authorities.
1.10.1.4	The incident management system shall be reviewed, tested and verified at least once a year and records thereof shall be maintained.
1.10.1.5	All incidents shall be recorded and assessed to establish their severity and the risk to the consumer. Relevant actions shall be taken to address the risks identified.

1.10.2	**Emergency preparedness and response**
1.10.2.1	Top Management shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety which are relevant to the role of the organization in the food chain. Note: Emergency situations include natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents, e.g. interruption of essential services such as water, electricity or refrigeration supply.
1.10.2.2	Documented information shall be established and maintained to manage these situations and incidents.
1.11	**Nonconformity and corrective Action**
1.11.1	When a nonconformity occurs, the organization shall: • react to the nonconformity and take appropriate correction to deal with the immediate issue; • undertake a root cause analysis to determine the cause of the nonconformity; • implement suitable and effective corrective action in a timely manner to prevent recurrence, and • maintain records there-of.
1.11.2	The organization shall have a documented procedure for nonconformity management and corrective actions.
1.12	**Complaint Handling**
1.12.1	A documented complaint management program shall be in place and effectively implemented for the management of customer and consumer complaints relating to food safety (not quality), including analysis of trends.
1.12.2	Records of all customer and consumer complaints, including investigations and corrective actions for food safety issues, shall be maintained.
2. Pre-Requisite Programmes	
2.1	**Construction and layout of buildings**
2.1.1	The facility shall be of suitable size and located, designed, constructed and maintained so as to reduce the risk of contamination and enable the production of safe and legal products.
2.1.2	The facility shall be effectively maintained, cleaned and disinfected (where appropriate) to prevent physical, chemical and microbiological product contamination.
2.1.3	The grounds and surrounding areas of the facility shall be maintained and kept free of waste and accumulated debris. Vegetation surrounding the facility shall be tended or removed and not attract and harbour pests. Any

	potential harbourage, such as decommissioned equipment, should be removed.
2.1.4	Buildings shall be provided with adequate ventilation.
2.1.5	Buildings shall be protected from pest entry.
2.1.6	Where outside space is used for storage, stored items shall be protected from weather or pest damage.
2.2	**Layout of premises and workspace**
2.2.1	The organization's premises and workspace shall be designed and maintained to reduce the risk of contamination and enable the production of safe and legal products.
2.2.2	Structures, surfaces and materials that come in contact with food shall be easy to maintain, cleanable and where appropriate allow for disinfection. Materials of construction shall be resistant to the cleaning system applied.
2.2.3	Adequate drainage and waste disposal systems and facilities shall be provided and well maintained. They shall be designed and constructed so that the likelihood of contaminating food or the water supply is avoided.
2.2.4	Internal structures and fittings The organization shall design and maintain: • floors, walls, doors, openings, ceilings and overhead fixtures to a degree of hygiene appropriate to the operation; • In wet process areas, floors shall be sealed and drained. Drains shall be trapped and covered. • ceilings and overhead fixtures that are constructed and finished to minimize the build-up of products, foreign matter, dirt and condensation, and the shedding of particles; • external openings (e.g. doors, windows) to prevent entry of foreign matter, including pests, appropriate to the operation; • floors and joints to avoid stagnant water; • drains to prevent entry of foreign matter and pests and to be appropriate to the operation, to be cleanable and repairable;
2.2.5	The lighting shall be of the appropriate intensity and design to ensure that food safety practice is effective. Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in the case of breakages.
2.2.6	Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products. They shall not open directly on to a production, packaging or storage area.
2.2.7	The movement patterns of materials, products and people, and the layout of equipment, shall be designed to protect against potential contamination sources.
2.3	**Utilities**

2.3.1	The organization's utilities shall be designed and maintained to reduce the risk of contamination and enable the production of safe and legal products.
2.3.2	Processes shall be in place to ensure that the quality of water, steam and ice does not compromise the food safety of the finished product. The facility shall be equipped with clean or potable water inlets appropriate to the intended use.
2.3.3	Potable and non-potable water pipes shall be identified, and a system shall be in place to prevent the cross-contamination of potable water by non-potable water.
2.3.4	Suitable and sufficient ventilation shall be provided to remove excess or unwanted steam, dust and odours, and air shall not flow from contaminated areas to clean areas.
2.3.5	Controls shall be in place for compressed air and other gas systems, where there is a direct or indirect food safety risk.
2.4	**Waste disposal**
2.4.1	The organization shall have a program in place for the collection and disposal of waste material.
2.4.2	Suitable provisions shall be in place for the storage and removal of waste, which prevents product contamination.
2.4.3	Containers designated for inedible products, waste or by-products shall be clearly marked and properly utilized linked to their intended purpose and use.
2.4.4	The organization shall have in place a documented waste management program including the identification of waste; waste collection; and containment, removal and disposal of waste.
2.4.5	Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed to ensure that trademarks cannot be reused.
2.5	**Equipment suitability, cleaning and maintenance**
2.5.1	Equipment, containers and surfaces in direct or indirect contact with water and food shall not be a source of food contamination.
2.5.2	Equipment, containers and surfaces in direct contact with food shall: • be designed and constructed to ensure that they can be cleaned, disinfected, drained, inspected and maintained. • be smooth, accessible and have cleanable surfaces. • be made from material compatible with the intended products and cleaning chemicals/methods. • not be penetrated by holes, nuts and/or bolts on its framework. • have piping and ductwork (where relevant) which is cleanable, drainable and with no dead ends. • have product contact surfaces which are impermeable and rust or corrosion free.

2.5.3	Forklifts and other driven transport trolleys shall be clean, well maintained and of suitable type to avoid contamination through emissions.
2.5.4	Manufacturer's instructions shall be followed to install, use and maintain equipment which may affect food safety.
2.5.5	**Maintenance**
2.5.5.1	The organization shall establish and implement a documented program/system of planned, preventive and corrective maintenance to ensure an adequate level of food safety in the facility.
2.5.5.2	A documented hygiene and clearance procedure shall be in place and effectively implemented for all maintenance activities.
2.5.5.3	Equipment failure, and defects to premises, that are essential to food safety shall be identified, assessed and documented to enable prompt actions and improvement of the maintenance program.
2.6	**Management of purchased materials**
2.6.1	The organization shall control purchasing processes to ensure that all externally sourced materials (raw materials, ingredients, additives, packaging materials, processing aids, etc.) and services conform to specifications and contractual agreements, to ensure product safety.
2.6.2	Purchased materials that have an impact on food safety shall be sourced from approved suppliers that are identified, evaluated, and monitored.
2.6.3	Purchased products shall be inspected upon delivery.
2.6.4	Records shall be kept of purchased products with the identification of the supplier and documented information relevant to food safety.
2.6.5	Testing results or a COA or COC shall be available to verify conformity with specified requirements prior to acceptance or use.
2.6.6	Delivery vehicles shall be checked prior to, and during unloading to verify the quality and safety of the material has been maintained during transit (e.g. integrity of seals, free from infestation, temperature records where applicable). Delivery vehicles and deliveries that do not conform with specifications shall be refused or their access limited to a controlled area until the product has been disposed of or returned to the supplier.
2.6.7	Results of evaluation, inspection and monitoring of suppliers and purchased products, investigations, analyses and follow up actions shall be recorded.
2.6.8	Outsourced activities which have an impact on food safety shall be sourced from approved contractors that are identified, evaluated, and monitored.
2.6.9	Outsourced activities which have an impact on food safety shall be recorded with the identification of contractors.

2.6.10	Procedures shall be available and implemented for the approval and monitoring of all suppliers whose products or services affect product safety. The results of the evaluations and follow-up actions shall be recorded.
2.7	**Measures for prevention of cross-contamination**
2.7.1	The organization shall ensure that appropriate facilities (e.g., physical barriers) and effective measures and procedures are in place to minimize the risk of any potential physical, chemical or microbiological contamination of the product.
2.7.2	**Physical contamination control**
2.7.2.1	Where brittle materials are used, periodic inspection requirements and defined procedures in the case of breakage shall be put in place. Brittle materials, such as glass and hard plastic components in equipment, should be avoided where possible. Records for monitoring of brittle materials (glass and hard plastic) shall be in place, including in the case of breakage.
2.7.2.2	Measures shall be in place to prevent, control or detect potential physical contamination, with consideration for the following: • restriction on use of staples, paperclips and drawing pins; • adequate covers over equipment or containers for exposed materials or products; • use of screens, magnets, sieves or filters; • use of detection or rejection devices such as metal detectors or X-ray. Note: Potential physical contamination sources include wooden pallets and tools, rubber seals, and personal protective clothing and equipment, etc.
2.7.3	**Chemical contamination control**
2.7.3.1	Measures shall be in place to prevent contamination of foods or food contact materials by chemicals (e.g. cleaning agents, disinfectants, lubricants, pesticides, etc.)
2.7.3.2	The organization shall ensure the chemicals used: • have been approved by competent authorities for its intended use, where applicable; • are applied according to the manufacturers/product instructions (concentrations, temperature, mechanical action/method of application, waiting time before rinsing, if any, etc.); • are applied by competent personnel; • are labelled; • are stored separately from food and food contact materials, in a locked or secured area; and • lubricants coming into contact with food and water shall be approved for food contact purpose.

2.7.4	**Microbiological cross-contamination control**
2.7.4.1	Areas with the potential for microbiological cross-contamination shall be identified and suitable controls implemented. The following controls should be considered: • separation of raw from finished or ready-to-eat products; • physical barriers, walls or separate buildings; • access controls with requirements to change into dedicated workwear; • traffic patterns or equipment segregation: people, materials, equipment and tools (including use of dedicated tools); • Airflow controls; and • zoning.
2.8	**Allergen management**
2.8.1	A documented program shall be in place to control allergens and prevent cross-contamination of product through all stages of production.
2.8.2	Regulations and appropriate customer requirements shall be addressed in the development of the allergen control program.
2.8.3	Potential causes of cross-contamination shall be identified and procedures established for the handling of raw materials, intermediate and finished products to avoid cross contamination.
2.8.4	Allergens present in the product by design shall be declared. The need for allergen labelling due to potential manufacturing cross-contact shall be assessed. The declaration shall be on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing. Applying warning labels does not exempt the organization from implementing the necessary allergen control measures.
2.8.5	Procedures for control shall consider: • a system to identify allergens in raw materials and intermediate products during storage and use (e.g., specifications and allergen identification labelling) • cleaning and line change-over practices; • production scheduling; • airflow control; • additional protective clothing; • use of dedicated tools/equipment; and • control of onsite catering and vending machines.
2.8.6	Procedures relating to the cleaning and sanitation of product contact surfaces shall be in place and shall be effective to remove all potential allergens from food contact surfaces.
2.9	**Cleaning and Disinfection**
2.9.1	Documented cleaning and disinfection procedures shall be in place and effective, including monitoring and verification activities, to ensure the cleanliness of the facility and equipment. Records of monitoring and verification shall be maintained.

2.9.2	Operating procedures shall specify: • The premises and equipment subjected to cleaning and disinfection, • A description of the process or method of cleaning, • Frequency of cleaning, • Responsibility for cleaning, • Cleaning agents and tools, • Source of water, and • Monitoring and verification arrangements for the effectiveness of cleaning, including frequency of these activities.
2.9.3	Cleaning equipment and chemicals shall be clearly marked, stored in a segregated area away from product, equipment, packaging and suitable for intended use.
2.9.4	Cleaning equipment shall be fit for purpose and utilized in accordance with the manufacturer's instructions and in such a way that cleaning and/or disinfection is effective.
2.9.5	Where CIP (cleaning in place) systems are used, these shall be separated from active product lines, and the parameters for CIP shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).
2.9.6	The cleaning and disinfection program shall be validated.
2.10	**Pest Control**
2.10.1	An effective pest control program shall be in place to reduce or eliminate the risk of pest infestation, which shall: • be appropriate to the raw material, product, process and facility; • have identified and designated a competent person(s) to manage the program and related activities; • identify target pests (e.g., rodents, insects and birds), relevant to the organization and operation; • have documented plans, methods, schedules and control procedures; and • include documentation of the chemicals used.
2.10.2	Pest-monitoring programs shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be sufficient in number, designed for purpose, placed in appropriate positions and located to prevent potential contamination of materials, products or facilities.
2.10.3	The inspection program shall be undertaken by a competent person at an appropriate frequency and findings shall be addressed.
2.10.4	Pest control inspections and resulting actions shall be documented/recorded, including the monitoring and implementation of actions.
2.10.5	Any infestation shall be documented and appropriate control measures taken in a timely manner.

2.10.6	The cause of infestation shall be identified, and corrective action taken to prevent reoccurrence. Records shall be kept of infestation, monitoring and eradication.
2.11	**Personal hygiene and employee facilities**
2.11.1	The organization shall ensure the implementation and adherence to appropriate hygiene practices for all personnel, visitors and contractors, including requirements on: • handwashing; • protective clothing / workwear; • restrictions on smoking, eating, drinking, spitting, personal items, nail polish / false nails, jewellery, etc; and • illness and injury. These requirements shall be compliant with legislation (if applicable) and be available in a form that is easily understood.
2.11.2	Personnel, visitors and contractors shall wear suitable protective clothing and footwear that is cleaned and changed regularly. Hair shall be protected / fully enclosed.
2.11.3	Personnel, visitors and contractors shall wash hands frequently, sanitize where necessary, and cover injuries on hands or forearms with suitable waterproof dressings. Controls shall be in place for the issue and use of gloves to prevent contamination.
2.11.4	Personnel, visitors and contractors shall leave personal belongings in a dedicated place.
2.11.5	Personnel, visitors and contractors, known to be infected with, or carrying a disease or illness transmissible through food or people, shall be prevented from contact with foods and with materials which come in contact with food.
2.11.6	**Personnel hygiene facilities and toilets**
2.11.6.1	The organization shall ensure that staff facilities are designed, located and operated to prevent contamination.
2.11.6.2	Suitable changing rooms shall be provided for personnel.
2.11.6.3	Toilets shall be provided, operational, accessible and adequately segregated from processing and food handling areas.
2.11.6.4	Suitable and sufficient hand-washing and drying facilities shall be provided and accessible, including the supply of water at a suitable temperature, soap and, where relevant, sanitizer. Taps and waste bins should be handsfree.
2.11.6.5	Separate eating facilities shall be provided away from production, packaging and storage areas.
2.12	**Rework**

2.12.1	Rework shall be managed effectively to prevent contamination and maintain food safety.
2.12.2	Rework shall be stored, handled and used in such a way that product safety, traceability and regulatory compliance are maintained.
2.13	**Warehousing**
2.13.1	The organization shall ensure that all raw materials (including packaging), intermediate and finished product are stored and transported under conditions that protect product integrity.
2.13.2	All vehicles, including contracted vehicles used for the transportation shall be suitable for the purpose, maintained in good repair and be clean.
2.13.3	There shall be adequate facilities for the storage of raw materials, ingredients, packaging materials, intermediate and finished products, including: • Storage off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out. • Storage in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.
2.13.4	The storage facilities shall be properly constructed / organized to protect materials (raw materials, ingredients, packaging materials, intermediate, and finished products, etc.) and avoid cross-contamination.
2.13.5	Storage and transport shall be appropriate to minimize the deterioration of the raw materials, ingredients, intermediate and finished products (e.g., by temperature and humidity control).
2.13.6	Maintenance and hygiene processes shall be effectively implemented for vehicles and equipment used for loading and unloading.
2.13.7	A product transport procedure shall be in place and effectively implemented.
2.14	**Management of analysis/testing services**
2.14.1	The organization shall implement a program to ensure that analysis of products and ingredients is systematically undertaken for issues that are identified as being critical to food safety and legal requirements, as well as customer specifications.
2.14.2	Where out of specification results are obtained, the organization shall handle the affected lot(s) of product as nonconforming products and apply appropriate correction and corrective actions.
2.14.3	Appropriate methods, relevant for food safety, shall be used to provide valid results (e.g. by procedures set forth in ISO 17025 and/or industry recognized methods).

2.14.4	Analysis procedures shall be in place to ensure that all specified product requirements are met, including legal requirements and customer specifications.
2.15	**Product Information and consumer awareness**
2.15.1	End products shall be accompanied by, or bear adequate information, to enable the next organization in the food chain or the consumer to handle, prepare, display, store, and/or use the products safely and correctly. This shall include allergen declarations and meet legislative and customer requirements.
2.15.2	Information shall be presented to consumers in such a way that enables them to understand its importance and make informed choices.
2.16	**Labelling**
2.16.1	The organization shall ensure that finished products are labelled according to applicable statutory and regulatory requirements in the country of intended sale, including allergen and customer specific requirements.
2.16.2	Line start-up and change-over procedures shall be established and implemented to ensure products, including packaging and labelling, meet applicable customer and legal requirements. This shall include having controls in place to ensure labelling and packaging from the previous run have been removed from the line.
2.17	**Logo Use**
2.17.1	Conforming organizations shall use the FSSC 22000 Development Program logo only for marketing activities such as the organization's printed matter, website, and other promotional material.
2.17.2	The confirming organization is not allowed to use the FSSC 22000 Development Program logo, any statement or make reference to its conforming status on: • a product; its labelling; its packaging (primary, secondary or any other form); • certificates of analysis or certificates of conformance (CoA's or CoC's); • in any other manner that implies FSSC approves a product, process, or service and • where exclusions to the scope apply.
2.17.3	Where the FSSC 22000 Development logo is being used, it shall comply with the design specifications included within the Program document.
2.18	**Food Defense**

2.18.1	The threats to the product as a result of intentional product tampering or intentional contamination shall be assessed.
2.18.2	The points in the process which are vulnerable to intentional product tampering/intentional contamination shall be identified and subjected to additional control.
2.18.3	Measures shall be in place to address what to do with the product, if prohibited access took place and the product may have been tampered with or intentionally contaminated.
2.19	**Food Fraud Mitigation**
2.19.1	The organization shall conduct a food fraud vulnerability assessment identifying potential vulnerabilities in raw materials, ingredients, packaging materials and outsourced processes.
2.19.2	For each vulnerability identified, the organization shall establish and implement appropriate mitigation measures.
2.19.3	Document the above mentioned within a food fraud mitigation plan, which shall be kept up to date and reviewed annually.
2.20	**PRP Verification**
2.20.1	The organization shall establish, implement, and maintain routine (e.g., monthly) site inspections/PRP checks to verify that the site (internal and external), production environment and processing equipment are maintained in a suitable condition to ensure food safety. The frequency and content of the site inspections/PRP checks shall be based on risk with defined sampling criteria.
3.HACCP Control	
3.1	**Preliminary steps to enable hazard analysis**
3.1.1	The organization shall identify and comply with relevant regulatory and customer requirements related to the product and product categories.
3.1.2	Task 1: Establish a multi-disciplinary food safety team. A multi-disciplinary team with different responsibilities for food safety shall have undertaken the tasks described in this section of the checklist (Tasks 2-5). Note: The team should comprise of personnel with the knowledge and experience in the organization's products, processes, equipment and food safety hazards.
3.1.3	Task 2: A complete product description shall be available of the product/product category including all ingredients, raw materials, packaging, intermediate and finished product, and the conditions for storage and distribution. The product description shall include product characteristics (biological, chemical and physical), composition, source, place of origin, method of

	production, packaging, storage and delivery conditions and shelf life, and preparation and/or handling before use or processing.
3.1.4	Task 3: The intended use of the product shall be described and the target consumer identified, including vulnerable consumer groups.
3.1.5	Task 4: All the process steps taken to produce the product shall be documented in a process flow diagram. Flow diagrams shall be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. It shall include the following as appropriate: • sequence and interaction of the steps; • any outsourced processes; • where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow; • where reworking and recycling take place; • where end products, intermediate products, by-products and waste are released or removed.
3.1.6	Task 5: Onsite verification of the process flow diagram(s) shall take place at least annually, or more often when changes occur, to ensure it accurately reflects the production process.
3.2	**Hazard analysis** ***The approach for analysis and control of hazards shall be in line with the seven (7) HACCP principles and 12 steps of the CODEX Alimentarius.***
3.2.1	The organization shall conduct a hazard analysis of their food manufacturing process, based on the preliminary information, to determine if there are any food safety hazards associated with the production of their food products that might cause a food safety risk.
3.2.2	**Principle 1:** A hazard analysis shall be conducted for each process step in the manufacturing of the food item. • identify and document all food safety hazards that are reasonably expected to occur; • determine the acceptable level in the end product for each food safety hazard identified; and • conduct a hazard assessment for each food safety hazard identified (likelihood of occurrence versus severity of its adverse health effects)
3.2.3	The hazard analysis shall be conducted by a competent multi-disciplinary team.
3.2.4	**Principle 2:** Determining Critical Control Points (CCPs) and Operational Prerequisite Programmes (OPRPs) Where the hazard analysis indicates any significant hazards not minimized or eliminated by PRPs, and based on the outcome of the decision tree, then OPRPs and/or CCPs shall be identified for their control and properly categorized.
3.2.5	If these hazards are identified within the process/operation, the organization shall have effective control measures that ensure the elimination of the hazards or to reduce them to acceptable levels. The organization shall implement specific controls for all relevant steps not

	identified as CCPs or OPRPs e.g., effective implementation and management of PRPs.
3.2.6	**Principle 3:** Critical Limits shall be established for each CCP and action criteria for OPRPs. Critical limits at CCPs shall be measurable. Action criteria for OPRPs shall be measurable or observable.
3.2.7	Critical limits and action criteria shall be validated and the validation shall be documented.
3.2.8	**Principle 4:** Monitoring procedures shall be established for each CCP and OPRP, and undertaken by competent personnel to ensure that CCPs and OPRP's are effectively implemented. It shall consist of: • monitoring methods or devices used; • monitoring frequency; • monitoring results; • responsibility and authority related to monitoring; and • responsibility and authority related to evaluation of monitoring results. Deputies shall be identified, trained and available in case of the absence of the person responsible for monitoring.
3.2.9	**Principle 5:** Corrections and/or corrective actions shall be established for each CCP and OPRP in the event that critical limits or action criteria are not met. It shall ensure that: • the potentially unsafe products are not released; • the cause of nonconformity is identified; • the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria; and • recurrence is prevented.
3.2.10	**Principle 6:** Verification procedures shall be established and effectively implemented for PRPs, OPRPs and CCPs.
3.2.11	**Principle 7:** Record keeping and documentation for HACCP procedures shall be established and effectively implemented.
3.2.12	The organization shall establish, implement and maintain a documented hazard control plan which shall include the following for each CCP or OPRP: • food safety hazard(s) to be controlled at the CCP or by the OPRP; • critical limit(s) at CCP or action criteria for OPRP; • monitoring procedure(s); • correction(s) to be made if critical limits or action criteria are not met; • responsibilities and authorities; and • records of monitoring.
3.2.13	In the event of changes to raw materials, packaging materials, processes, infrastructure, equipment, etc., the hazard control plan (HACCP / OPRP Plan) shall be reviewed and updated if needed.
3.3	**Control of monitoring and measuring**

3.3.1	Measuring and monitoring devices critical to food safety and regulatory requirements shall be appropriate to the intended use, reliable, accurate, and function properly. They shall be well maintained and, where appropriate, calibrated.
3.3.2	Measuring and monitoring devices critical to food safety shall be identified, calibrated on a regular basis, traceable to recognized national or international standards, and be effectively controlled.
3.3.3	Actions shall be taken and recorded when measuring and monitoring devices are found to be outside of specified limits.
3.4	**Handling of potentially unsafe products**
3.4.1	The organization shall ensure that potentially unsafe product is clearly identified and controlled to prevent unintended use or delivery. It shall be reprocessed or further processed within or outside the organization to ensure that food safety hazards are eliminated or reduced to acceptable levels, or destroyed and/or disposed of as waste.
3.4.2	Products affected by a nonconforming situation shall be held under control until they have been evaluated.
3.4.3	The organization shall be able to take measures for the reporting, containment, reprocessing, withdrawal or recall when products are potentially unsafe.
3.4.4	The control of non-conforming product shall be managed by competent and sufficiently trained personnel.
3.4.5	A documented procedure shall be in place to identify and manage all non-conforming raw materials, product inputs, semi-finished and finished products, processing equipment and packaging materials.