

12 Cert				
CERTIFICATION AND INSPECTION BODY FOR MANAGEMENT SYSTEMS AND PRODUCTS				
Document	Code	Edition	Amendment	Effective Date
Special Certification Scheme for HACCP / Codex Alimentarius	SCS-HACCP	1	0	01/02/2025

Special Certification Scheme - HACCP Food Safety System Certification based on Codex Alimentarius Commission (CXC 1-1969 Rev. 2023)

THE CERTIFICATION AND INSPECTION BODY

DODECANESIAN CERTIFICATIONS L.P.



For the activity of

HACCP Food Safety System Certification based on Codex Alimentarius Commission (CXC 1-1969 Rev. 2023)

ISO 17065

Prepared by

QMS Manager – Deputy Technical Director
06/11/2024

Approved by

Manager and Technical Director
06/11/2024

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0. PURPOSE

- 0.1 The Scheme describes the roles, responsibilities and processes in a certification body according to ISO/IEC 17065:2012 involved in the certification of Food Safety Systems in accordance with 12 CERT Certification Scheme - HACCP Food Safety System Certification based on Codex Alimentarius Commission (CXC 1-1969 Rev. 2023) (following HACCP Standard)
- 0.2 The certification process consists of the phases:
- contract review and offer preparation,
 - audit preparation,
 - performance of the audit,
 - issue of the certificate, and
 - surveillance of the certified food safety system.
- The procedure is repeated with each recertification.
- 0.3 This Special Certification Scheme applies in conjunction with the General Certification Scheme (GCS) and other applicable standardization, regulatory, and legislative documents.

1. References

- Quality Manual (QM)
- General Certification Scheme (GCS)
- D09 – Procedure for Review of Applications, Offers, and Contracts – Management of Pre-Certification Activities
- D11 – Procedure for Inspections, Certificate Issuance, Suspension, Withdrawal, or Reduction of the Certification Scope
- D05 – Personnel Procedure
- D15 – Procedure for the Use of Marks and Logos
- ELOT EN ISO/IEC 17065:2012 – Conformity Assessment – Requirements for bodies certifying products, processes, and services
- ELOT EN ISO/IEC 17021-1:2015 – Conformity Assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements
- ELOT EN ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
- ELOT EN ISO/IEC 17067:2013 – Conformity Assessment – Fundamentals of product certification and guidelines for product certification schemes
- CODE OF PRACTICE – GENERAL PRINCIPLES OF FOOD HYGIENE – Codex Alimentarius Commission (CXC 1-1969 Rev. 2020)
- Certification Scheme Guideline – HACCP Food Safety System Certification based on Codex Alimentarius Commission (CXC 1-1969 Rev. 2023) (following HACCP Standard)
- Regulation for the Use of the Certification Mark and Local Product Indication
- Joint Ministerial Decision 267623/29.08.2007 (Government Gazette 1723/B'/29.08.2007), as in force
- ELOT EN ISO 22000:2018 – Food Safety Management Systems – Requirements
- ELOT EN ISO 22005:2007 – Traceability in the Feed and Food Chain
- ELOT EN ISO 9001:2015 – Quality Management Systems – Requirements
- ISO 19011:2018 – Guidelines for Auditing Management Systems
- UNIVAB Regulations and Guidelines (as applicable)
- IAF MD – Mandatory Documents of the International Accreditation Forum (as applicable)
- EA – Guidelines of the European co-operation for Accreditation (as applicable)

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2. Terms and Definitions - Abbreviations

Terms and Definitions

Categories of the food chain	The categories correspond to the ISO 22003-1:2022
Audit programme	Ensures timely and correct processing of (re) certification, surveillance audits within the three-year certification cycle. For this purpose, the information from the calculations and the release protocols of the previous audit are used. The verification of the audit programme and possible adaptation is made after each audit in the release protocol.
Initial Audit	Visit of all relevant locations, on-site assessment of the HACCP-standard requirements, in particular the self-monitoring system for food safety with the final objective of issue of a certificate.
Completion of audit:	Last day of initial audit and recertification audit, typically the day of the final closing meeting.
Re-Certification Audit	Overall Review of the food safety system implementation and effectiveness in the organization with respect to new issue of the certificate..
Extension Audit	Evaluation of the food safety system implementation and effectiveness in additional areas or at additional locations/factories . The objective is change of the scope of the certificate.
Short-notice Audit	Audits of certified clients at short notice to investigate complaints, or in response to changes, or as follow up of suspended client certifications
Combined or integrated audits	A combined audit is when a client is being audited against the requirements of two or more standards according to ISO/IEC 17065:2012 together. An integrated audit is when a client has integrated the application of requirements of two or more standards according to ISO/IEC 17065:2012 into a single management system and is being audited against more than one standard.
Scope of the certification	The scope of the certification includes the areas of products/services and processes of the organization.
Nonconformity	A nonconformity is the non-fulfilment of one requirement of the standard. There are two types of nonconformities: a) Critical nonconformity: will be issued when food safety is directly impacted or when legality and/or certification integrity are at risk. In case of critical non-conformity, the certificate shall be suspended within 3 days and can only be reinstated by an on-site follow-up audit. b) Major nonconformity (Major): A nonconformity that limits the ability of the food safety system to achieve its intended results
Nonconformities can be categorized as major	If there is considerable doubt that efficient process control is in place or that products or services fulfil the specified requirements; If several minor nonconformities which relate to the same requirement or the same problem could represent a system-related failure and therefore result in a major nonconformity
Minor nonconformity (Minor)	Nonconformity that does not limit the capability of the food safety system to achieve the intended results.
Follow-up Audit:	On-site assessment of the implementation and effectiveness of corrections and corrective actions for nonconformities issued during the audit.
Evaluation of documentary evidence	Off-site assessment of the implementation and effectiveness of corrective actions in connection with nonconformities identified during the audit. The assessment is carried out by means of documents that are submitted (documents or records).

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Correction	Action to eliminate a detected nonconformity.
Audit day	An audit day comprises 8 hours (net). Where it seems useful, a 10 hours audit day might be accepted.
Appointed Person	Individuals who are appointed to perform certain, defined tasks on behalf of the head of the certification body or specialist manager, i.e. QM Managers or veto persons.
Observers	The presence and justification of observers during an audit activity shall be agreed to by the certification body and client prior to the conduct of the audit. The audit team shall ensure that observers do not influence or interfere in the audit process or outcome of the audit. Note: Observers can be members of the client's organization, consultants, witnessing accreditation body personnel, regulators or other justified persons.
Guides	Each auditor shall be accompanied by a guide, unless otherwise agreed to by the audit team leader and the client. Guide(s) are assigned to the audit team to facilitate the audit. The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit.

Abbreviations

EU	European Union
OJEU	Official Journal of the European Union
ELOT	Hellenic Organization for Standardization
Hev	Harmonized European Standard
EEA	European Economic Area
ESYD	Hellenic Accreditation System
CB	Certification Body
CEN	European Committee for Standardization
ISO	International Organization for Standardization
QMR	Quality Management Representative
SEPE	Labour Inspection Body
CB	Certification Body

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3. Responsibilities and Authorities

The person responsible for overseeing compliance with the provisions of this document is the Quality Management Representative, in collaboration with the Technical Director and their deputies. All personnel of the Certification Body, including external collaborators, are involved in its implementation.

The Quality Management Representative (QMR) is responsible for the issuance and revision of this document, with the approval of top management.

4. Development of the Special Certification Regulation

4.1 General

The assessment of the degree of conformity of the organization, as well as the related techniques and actions followed under the responsibility of the Lead Auditor, are described in the Certification Body's General Certification Regulation. This assessment is based on the extent to which the audit team, using objective evidence, determines that the organization complies with the minimum requirements of the standard as described in this Special Certification Regulation, the relevant legislative requirements, the criteria established by the Certification Body, and any additional criteria arising from the obligations related to its accreditation.

4.2 Conformity Assessment Requirements – 12 CERT Certification Scheme - HACCP Food Safety System Certification based on Codex Alimentarius Commission (CXC 1-1969 Rev. 2023) (following HACCP Standard)

- 4.2.1.1 The basic requirements for businesses during the conformity assessment include:
- 4.2.1.2 The enterprise is required to ensure compliance with the legal obligations related to its operation.
- 4.2.2 The enterprise is required to comply with the hygiene and safety requirements of its products in accordance with the applicable legislation.
- 4.2.3 The enterprise must provide documentation demonstrating compliance with the requirements of the Code of Practice – General Principles of Food Hygiene of the Codex Alimentarius Commission, as outlined in the table below.

A/A	Requirement corresponding to CXC 1-1969 Rev. 2023
8	PRIMARY PRODUCTION
	Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include: - an assessment of the suitability of water used where it may pose a hazard, for example, crop irrigation, rinsing activities, etc.; - avoiding the use of areas where the environment poses a threat to the safety of food (e.g. contaminated sites); - controlling contaminants, pests and diseases of animals and plants, to the extent practicable, to minimize the threat to food safety (e.g. appropriate use of pesticides and veterinary drugs); and - adopting practices and measures to ensure food is produced under appropriately hygienic conditions (e.g. cleaning and maintaining harvest equipment, rinsing, hygienic milking practices). <u>RATIONALE</u> To reduce the likelihood of introducing a contaminant which may adversely affect the safety of food, or its suitability for consumption, at all stages of the food chain
8.1	ENVIRONMENTAL CONTROL

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A/A	Requirement corresponding to CXC 1-1969 Rev. 2023
	Potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of contaminants would lead to an unacceptable level of such contaminants in food, e.g. using polluted areas, locating near facilities emitting toxic or offensive odours which could taint foodstuffs or near sources of contaminated water such as discharge of wastewater from industrial production or runoff from agricultural land with high faecal material or chemical residues, unless there is a measure to reduce or prevent the contamination of food.
8.2	HYGIENIC PRODUCTION
	The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize and, if possible, eliminate that probability. Producers should as far as practicable, implement measures to: • control contamination from soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production; • protect food sources from faecal and other contamination (e.g. zoonotic foodborne agents); • control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product (e.g. observe the withdrawal period of veterinary drugs and pesticides, keeping records where applicable); and • manage waste and store harmful substances appropriately.
8.3	HANDLING, STORAGE AND TRANSPORT
	Procedures should be in place to: • sort food to remove material which should not be used for human consumption; • dispose of any rejected material in a hygienic manner; and • protect food from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (e.g. sorting, grading, washing), storage and transport. Care should be taken to prevent deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.
8.4	CLEANING, MAINTENANCE AND PERSONNEL HYGIENE
	Appropriate facilities and procedures should be in place to ensure that: • cleaning and maintenance are carried out effectively and do not compromise food safety (e.g. ensuring equipment used in harvest is not a source of contamination); and • an appropriate degree of personal hygiene is maintained to ensure personnel are not a source of contamination (e.g. by human faeces).
9	ESTABLISHMENT: DESIGN AND FACILITIES

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A/A	Requirement corresponding to CXC 1-1969 Rev. 2023
	Depending on the nature of the operations, and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that: - contamination is minimized; - design and layout permit appropriate maintenance, cleaning and disinfections and minimize air-borne contamination; - surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean; - where appropriate, suitable facilities are available for temperature, humidity and other controls; and - there is effective protection against pest access and harbourage. RATIONALE: Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.
9.1	LOCATION AND STRUCTURE
9.1.1	Location of establishment
	Food establishments should not be located where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures. The location of an establishment, including temporary/mobile establishments, should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, establishments should normally be located away from: - environmentally polluted areas and industrial activities which are reasonably likely to contaminate food; - areas subject to flooding; - areas prone to infestations of pests; and - areas where waste, either solid or liquid, cannot be removed effectively.
9.1.2	DESIGN AND LAYOUT OF FOOD ESTABLISHMENT
	The design and layout of food establishments should permit adequate maintenance and cleaning. The layout of premises and the flow of operations, including the movements of personnel and material within the buildings, should be such that cross-contamination is minimized or prevented.

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A/A	Requirement corresponding to CXC 1-1969 Rev. 2023
	Areas having different levels of hygiene control (e.g. the raw material and finished product areas) should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, or separation in time, with suitable cleaning and disinfection between uses.
9.1.3	INTERNAL STRUCTURES AND FITTINGS
	Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food: - the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use; - walls and partitions should have a smooth surface up to a height appropriate to the operation; - floors should be constructed to allow adequate drainage and cleaning; - ceilings and overhead fixtures should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles; - windows should be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed; - doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect; working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.
9.1.4	TEMPORARY/MOBILE PREMISES AND VENDING MACHINES
	Establishments and structures covered here include market stalls, street vending vehicles, vending machines and temporary premises such as tents and marquees. Such premises and structures should be located, designed, and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of pests. Adequate facilities for toileting and washing hands should be provided, where appropriate.
9.2	FACILITIES
9.2.1	DRAINAGE AND WASTE DISPOSAL FACILITIES
	Adequate drainage and waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the likelihood of contaminating food or the water supply is avoided. For plumbing, steps should be taken to prevent backflow, cross-connections, and backup of sewer gases. It is important that

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	drainage does not flow from highly contaminated areas (such as toilets or raw production areas) to areas where finished food is exposed to the environment. Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste disposal site should be located away from the food establishment to prevent pest infestation. Containers for waste, byproducts and inedible or hazardous substances should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent intentional or accidental contamination of food.
9.2.2	CLEANING FACILITIES
	Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas. Where appropriate, facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing
9.2.3	PERSONNEL HYGIENE FACILITIES AND TOILETS
	Adequate washing and toilet facilities should be available so that an appropriate degree of personal hygiene can be maintained and to avoid personnel contaminating food. Such facilities should be suitably located and should not be used for other purposes such as storage of food or items that contact food. They should include: - adequate means of hygienically washing and drying hands, including wash basins and a supply of hot and cold (or suitably temperature controlled) water; - hand washing basins of an appropriate hygienic design, ideally with taps not operated by hands; where this is not possible, appropriate measures to minimize contamination from the taps should be in place; and - suitable changing facilities for personnel, if needed. Handwashing basins should not be used for washing food or utensils.
9.2.4	TEMPERATURE CONTROL
	Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

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9.2.5	AIR QUALITY AND VENTILATION
	Adequate means of natural or mechanical ventilation should be provided, in particular to: • minimize air-borne contamination of food, for example, from aerosols and condensation droplets; • control ambient temperatures; • control odors which might affect the suitability of food; and • control humidity, where necessary, to ensure the safety and suitability of food. Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned.
9.2.6	LIGHTING
	Adequate natural or artificial lighting should be provided to enable the undertaking to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting color is misleading. The intensity should be adequate to the nature of the operation. Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements.
9.2.7	STORAGE
	Adequate and, where necessary, separate facilities for the safe and hygienic storage of food products, food ingredients, food packaging materials and nonfood chemicals (including cleaning materials, lubricants, fuels), should be provided. Storage should allow for segregation of raw and cooked foods or allergenic and non-allergenic food. Food storage facilities should be designed and constructed to: • permit adequate maintenance and cleaning; • avoid pest access and harborage; • enable food to be effectively protected from contamination during storage; and • where necessary, provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control). The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.
9.3	FACILITIES
9.3.1	GENERAL
	Equipment and containers coming into contact with food should be suitable for food contact; designed, constructed and located to ensure that they can be adequately cleaned

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	(other than containers which are single use only); disinfected (where necessary); and maintained or discarded as necessary to avoid the contamination of food, according to hygienic design principles. Equipment and containers should be made of materials that are non-toxic according to intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection and to facilitate inspection for pests.
9.3.2	FOOD CONTROL AND MONITORING EQUIPMENT
	Equipment used to cook, heat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and to maintain food temperatures effectively. Such equipment should also be designed to allow temperatures to be monitored, where necessary, and controlled. Where appropriate, monitoring equipment should be calibrated to ensure that temperatures of food processes are accurate. Where necessary, such equipment should have effective means of controlling and monitoring humidity, airflow and any other characteristics likely to have an effect on the safety or suitability of food.
10	TRAINING AND COMPETENCE
	OBJECTIVE: Those engaged in food operations who come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform. RATIONALE: Training is fundamentally important to any food hygiene system and the competence of personnel. Adequate hygiene training and/or instruction and supervision of all personnel involved in food-related activities contribute to ensuring the safety of food and its suitability for consumption.
10.1	AWARENESS AND RESPONSIBILITIES
	Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in proper use to prevent contamination of food.
10.2	TRAINING PROGRAMMES

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	Elements to take into account in determining the extent of training required include: - the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms; - the manner in which the food is handled and packed, including the probability of contamination; - the extent and nature of processing or further preparation before final consumption; - the conditions under which the food will be stored; - the expected length of time before consumption. - the use and maintenance of instruments and equipment associated with food. Training programmes should also consider the knowledge and skill levels of the personnel being trained. Topics to be considered for training programmes could include the following, as appropriate to a person's duties: - the principles of food hygiene applicable to the food business; - the measures relevant to the food business that are used to prevent contaminants in food; - the importance of good personal hygiene, including proper hand washing and wearing, when needed, appropriate clothing, for food safety; - the GHPs applicable to the food business; and - appropriate actions to take when food hygiene problems are observed. In addition, for retail and food service operations, whether personnel have direct customer interaction is a factor in training, since it may be necessary to convey certain information about products (such as allergens) to customers.
10.3	INSTRUCTION AND SUPERVISION
	The type of instruction and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers, supervisors and/or operators/workers should have sufficient knowledge of food hygiene principles and practices to be able to identify deviations and take necessary action as appropriate to their duties. Periodic assessments of the effectiveness of training and instruction programs should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively. Personnel tasked to perform any activities used in food control should be trained adequately to ensure that they are competent to perform their tasks and are aware of the impact of their tasks on the safety and suitability of the food.
10.4	REFRESHER TRAINING

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	Training programs should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food. Records should be kept of training activities.
11	ESTABLISHMENT: MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL
	OBJECTIVE: To establish effective systems to: • ensure adequate and appropriate maintenance and cleaning; • control pests; • manage waste; and • monitor effectiveness of maintenance and sanitation procedures. RATIONALE: To facilitate the continuing effective control of food contaminants, pests, and other agents likely to compromise food safety and suitability.
11.1	MAINTENANCE AND CLEANING
11.1.1	GENERAL
	Establishments and equipment should be kept in an appropriate state of repair and condition to: • facilitate all sanitation procedures; • function as intended, particularly at critical steps (see paragraph 5.1); • prevent contamination of food, such as from pests, metal shards, flaking plaster, debris, chemicals, wood, plastic, glass, paper. Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning. Attention should be paid to hygiene during cleaning and maintenance operations so as not to compromise food safety and suitability. Cleaning products suitable for food contact surfaces should be used in food preparation and storage areas. Cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food. Separate cleaning equipment and utensils, suitably designated, should be used for different hygiene zones e.g. food and non-food contact surfaces.

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	Cleaning equipment should be stored in an appropriate place and in such a manner to prevent contamination. Cleaning equipment should be kept clean, maintained, and replaced periodically so as not to become a source for cross-contamination of surfaces or food.
11.1.2	CLEANING AND DISINFECTION METHODS AND PROCEDURES
	Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, and vacuum cleaning (or other methods that avoid the use of water), and chemical methods using solutions of detergents, alkalis, or acids. Dry cleaning or other appropriate methods for removing and collecting residues and debris may be needed in some operations and/or food processing areas where water increases the likelihood of microbiological contamination. Care should be taken to ensure cleaning procedures do not lead to contamination of food, e.g. spray from pressure washing can spread contamination from dirty areas, such as floors and drains, over a wide area and contaminate food contact surfaces or exposed food. Wet cleaning procedures will involve, where appropriate: • removing gross visible debris from surfaces; • applying an appropriate detergent solution to loosen soil; and • rinsing with water (hot water where appropriate) to remove loosened material and residues of detergent. Where necessary, cleaning should be followed by chemical disinfection with subsequent rinsing unless the manufacturer's instructions indicate that, on a scientific basis, rinsing is not required. Concentrations and application time of chemicals used for disinfection should be appropriate for use and applied according to manufacturers' instructions for optimal effectiveness. If cleaning is not done effectively to remove soil to permit the disinfectant to contact microorganisms or if sub-lethal concentrations of the disinfectant are used, the microorganisms may persist. Cleaning and disinfection procedures should ensure that all parts of the establishment are appropriately clean. Where appropriate, programmes should be drawn up in consultation with relevant experts. Written cleaning and disinfection procedures should be used, where appropriate. They should specify: • areas, items of equipment and utensils to be cleaned, and, where appropriate, disinfected; • responsibility for particular tasks; • method and frequency of cleaning and, where appropriate, disinfection; and • monitoring and verification activities.
11.1.3	MONITORING OF EFFECTIVENESS
	Application of cleaning and disinfection procedures should be monitored for effectiveness and periodically verified by means such as visual inspections and audits to

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	ensure the procedures have been applied properly. The type of monitoring will depend on the nature of the procedures, but could include pH, water temperature, conductivity, cleaning agent concentration, disinfectant concentration, and other parameters important to ensure the cleaning and disinfection programme is being implemented as designed and verify its effectiveness. Microorganisms can sometimes become tolerant to disinfecting agents over time. Cleaning and disinfection procedures should follow the manufacturers' instructions. Periodic review with disinfectant manufacturers/suppliers, where feasible, should be conducted to help ensure the disinfectants used are effective and appropriate. Rotation of the disinfectants could be considered to ensure inactivation of different types of microorganisms (e.g. bacteria and fungi). While effectiveness of cleaning and disinfecting agents and instructions for use are validated by their manufacturers, measures should be taken for sampling and testing the environment and food contact surfaces (e.g. protein and allergen test swabs, or microbiological testing for indicator organisms) to help verify that cleaning and disinfection programmes are effective and being applied properly. Microbiological sampling and testing may not be appropriate in all cases and an alternative approach might include observation of cleaning and disinfection procedures, including the correct disinfectant concentration, to achieve the necessary results and to make sure protocols are being followed. Cleaning and disinfection and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.
11.2	PEST CONTROL SYSTEMS
11.2.1	GENERAL
	Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.
11.2.2	PREVENTION
	Establishments should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing establishments.
11.2.3	HARBORAGE AND INFESTATION
	The availability of food and water encourages pest harborage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground

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	and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers. Any potential harbourage, such as old and unused equipment, should be removed. Landscaping surrounding a food establishment should be designed to minimize attracting and harbouring pests.
11.2.4	MONITORING AND DETECTION
	Establishments and surrounding areas should be regularly examined for evidence of infestation. Detectors and traps (e.g. insect light traps, bait stations) should be designed and located so as to prevent potential contamination of raw materials, products or facilities. Even if monitoring and detection are outsourced, FBOs should review monitoring reports and, if necessary, ensure they or their designated pest control operators take corrective action (e.g. eradication of pests, elimination of harbourage sites or invasion routes).
11.2.5	CONTROL OF PEST INFESTATION
	Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food. The cause of infestation should be identified, and corrective action taken to prevent a problem from reoccurring. Records should be kept of infestation, monitoring and eradication.
11.3	WASTE MANAGEMENT
	Suitable provision should be made for the removal and storage of waste. Waste should, as far as possible, be collected and stored in covered containers and should not be allowed to accumulate and overflow in food handling, food storage, and other working areas or the adjoining environment in a manner that compromises food safety and suitability. Personnel responsible for waste removal (including hazardous waste) should be properly trained so they do not become a source of cross-contamination. Waste storage areas should be easily identifiable, be kept appropriately clean, and be resistant to pest infestation. They should also be located away from processing areas.
12	PERSONAL HYGIENE
	OBJECTIVES: To ensure that those who come directly or indirectly into contact with food: • maintain personal health; • maintain an appropriate degree of personal cleanliness; • behave and operating in an appropriate manner.

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	RATIONALE: People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers through food. Food businesses should establish policies and procedures for personal hygiene. FBOs should ensure all personnel are aware of the importance of good personal hygiene and understand and comply with practices that ensure food safety and suitability.
12.1	HEALTH STATUS
	Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of them contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management. It may be appropriate for personnel to be excluded for a specific time after symptoms resolve or, for some illnesses, to get medical clearance before returning to work.
12.2	ILLNESS AND INJURIES
	Some symptoms of illnesses that should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered, include: • jaundice; • diarrhoea; • vomiting; • fever; • sore throat with fever; • visibly infected skin lesions (boils, cuts, etc.); • discharges from the ear, eye or nose. Personnel with cuts and wounds should, where necessary, be assigned to work in areas where they will have no direct contact with food. Where personnel are permitted to continue working, cuts and wounds should be covered by suitable waterproof plasters and, where appropriate, gloves. Appropriate measures should be applied to ensure plasters do not become a source of contamination (e.g. plasters of contrasting colour compared to the food and/or detectable using a metal detector or X-ray detector).
12.3	PERSONAL CLEANLINESS
	Personnel should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head and beard covering, and footwear. Measures should be implemented to prevent cross-contamination by personnel through adequate

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	hand washing and, where necessary, the wearing of gloves. If gloves are worn, appropriate measures should be applied to ensure the gloves do not become a source of contamination. Personnel, including those wearing gloves, should clean their hands regularly, especially when personal cleanliness may affect food safety. In particular, they should wash hands: • at the start of food handling activities; • when returning to work after breaks; • immediately after using the toilet; and • after handling any contaminated material, such as waste or raw and unprocessed foods where this could result in contamination of other food items. In order not to contaminate food, personnel should wash hands with soap and water and rinse and dry them in a manner that does not recontaminate the hands. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.
12.4	PERSONAL BEHAVIOUR
	When engaged in food handling activities should refrain from behavior which could result in contamination of food, for example: • smoking; • spitting; • chewing, eating, or drinking; • touching the mouth, nose, or other places of possible contamination; and • sneezing or coughing over unprotected food. Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.
12.5	VISITORS AND OTHER PERSONS FROM OUTSIDE THE ESTABLISHMENT
	Visitors to food businesses, including maintenance workers, in particular to food manufacturing, processing or handling areas, should, where appropriate, be instructed and supervised, wear protective clothing and adhere to the other personal hygiene provisions for personnel. Visitors should be guided through a hygiene policy of the business prior to visits and encouraged to report any type of illness/injury that may pose cross-contamination issues.
13	CONTROL OF OPERATION
	OBJECTIVE: To produce food which is safe and suitable for human consumption by:

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	- formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items; and - designing, implementing, monitoring and reviewing effective control systems as appropriate to the food business. <u>RATIONALE:</u> If operations are not controlled appropriately, food may become unsafe or unsuitable for consumption. Control of operation is achieved by having an appropriate food hygiene system in place. The following section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.
13.1	DESCRIPTION OF PRODUCTS AND PROCESSES
13.1.1	PRODUCT DESCRIPTION
	An FBO that is producing, storing, or otherwise handling food should have a description of the food. Products may be described individually or in groups in a manner that does not compromise the awareness of hazards or other factors such as suitability of the products for the purpose intended. Any grouping of food products should be based on them having similar inputs and ingredients, product characteristics (such as pH, water activity [aw]), process steps and/or intended purpose. The description could include, as appropriate: - the intended use of the food, e.g. whether it is ready-to-eat or whether it is intended for further processing either by consumers or another business, for example raw seafood to be cooked; - products intended for specific vulnerable consumer groups, e.g. infant formula or food for special medical purposes; - any relevant specifications, e.g. ingredient composition, aw, pH, type of preservation method used (if any), or important characteristics associated with the food, such as any allergens present; - any relevant limits established for the food by the competent authority or, in the absence thereof, set by the FBO; - instructions provided for further use, for example keep frozen until cooking, cook to a specified temperature for a specified length of time, product shelflife (use-by date); - storage of product (e.g. refrigerated/frozen/shelf stable) and transport conditions required; and - food packaging material used.
13.1.2	PROCESS DESCRIPTION

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	The FBO should consider all steps in the operation for a specific product. It may be helpful to develop a flow diagram, which shows the sequence and interaction of all processing steps in the operation, including where raw materials, ingredients and intermediate products enter the flow and where intermediate products, by-products and waste are released or removed. The flow diagram could be used for a number of similar food products that are produced using similar production or processing steps, to ensure all steps are captured. The steps should be confirmed as accurate by an onsite review of the operation or process. For example, for restaurants, the flow diagram could be based on the general activities from the receipt of ingredients/raw material, storage (refrigerated, frozen, room temperature), preparation before use (washing, defrosting), and cooking or preparation of food.
13.1.3	CONSIDERATION OF THE EFFECTIVENESS OF GHPs
	Having considered the product and process descriptions, an FBO should determine (using information relevant to hazards and controls from various sources as appropriate) whether the GHPs and other programmes they have in place are sufficient to address food safety and suitability or if some GHPs need greater attention. For example, a cooked meat slicer may require specific and more frequent cleaning to prevent the build-up of <i>Listeria</i> spp. on its meat contact surfaces, or a conveyor belt used in direct contact with the food, such as in sandwich production, may require an increased frequency of cleaning or a specific cleaning programme. When such increased attention on GHPs is insufficient to ensure food safety, it will be necessary to implement a HACCP system (see hazard analysis and critical control point [HACCP] system and guidelines for its application).
13.1.4	MONITORING AND CORRECTIVE ACTION
	The FBO should monitor the hygienic procedures and practices as relevant to the business and as applicable to the hazard being controlled. Procedures could include defining methods of monitoring (including defining responsible personnel, frequency, and sampling regime if applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control. When monitoring results indicate a deviation, the FBO should undertake corrective action. Corrective action should consist of the following actions, as appropriate: • bringing the process back into control by, for example, altering temperature or timing, or concentration of disinfectant; • isolating any affected product and evaluating its safety and/or suitability; • determining proper disposition of affected product that is not acceptable to market; • identifying the cause that resulted in the deviation; and • taking steps to prevent reoccurrence. Records of corrective actions should be retained.

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13.1.5	VERIFICATION
	The FBO should undertake verification activities as relevant to the business, to check that GHP procedures have been implemented effectively, monitoring is occurring, where planned, and that appropriate corrective actions are taken when requirements are not met. Examples of verification activities could include the following, as appropriate: • review of GHP procedures, monitoring, corrective actions, and records; • review when any changes occur to the product, process and other operations associated with the business; and • assessment of the efficacy of cleaning. Records of GHP verification activities should be kept, where appropriate.
13.2	KEY ASPECTS OF GHPs
13.2.1	TIME AND TEMPERATURE CONTROL
	Inadequate time and temperature control, e.g. during cooking, cooling, processing and storage, are among the most common failures of operational control. These allow survival or growth of microorganisms that may cause foodborne illness or food spoilage. Systems should be in place to ensure that temperature is controlled effectively where it impacts the safety and suitability of food. Temperature control systems should take into account: • the nature of the food, e.g. its water activity, pH, and likely initial level and types of microorganisms; • the impact on the microorganisms, e.g. time in the growth/dangerous temperature zone; • the intended shelf-life of the product; • the method of packaging and processing; and • how the product is intended to be used, e.g. further cooking/processing or ready-to-eat. Such systems should also specify tolerable limits for time and temperature variations. Temperature control systems that impact safety and suitability of food should be validated, and, as appropriate, monitored and recorded. Temperature monitoring and recording devices should be checked for accuracy and calibrated at regular intervals or as needed.
13.2.2	SPECIFIC PROCESS STEPS
	There are many individual processing steps for specific foods which contribute to the production of safe and suitable food products. These vary depending on the product and can include key steps such as cooking, chilling, freezing, drying, and packaging.

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	The composition of a food can be important in preventing microbial growth and toxin production, e.g. in its formulation by adding preservatives, including acids, salts, food additives or other compounds. When formulation is used to control foodborne pathogens (e.g. adjusting the pH or aw to a level that prevents growth), systems should be in place to ensure that the product is formulated correctly and that the controlling parameters are monitored.
13.2.3	MICROBIOLOGICAL PHYSICAL, CHEMICAL AND ALLERGEN SPECIFICATIONS
	Where microbiological, physical, chemical and allergen specifications are used for food safety or suitability, such specifications should be based on sound scientific principles and state, where appropriate, sampling parameters, analytical methods, acceptable limits, and monitoring procedures. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized.
13.2.4	MICROBIOLOGICAL CONTAMINATION
	Systems should be in place to prevent or minimize contamination of foods by microorganisms. Microbiological contamination occurs through a number of mechanisms, including the transfer of microorganisms from one food to another, e.g.: • by direct contact or indirectly by food handlers; • by contact with surfaces; • from cleaning equipment; • by splashing; or • by airborne particles. Raw, unprocessed food, where not considered ready-to-eat, which could be a source of contamination, should be separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and, where appropriate, effective disinfection. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed. In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. For example, where the likelihood of product contamination is high, access to processing areas should be via a properly designed changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from that worn in other parts of the facility), including head and beard covering, footwear, and to wash their hands and where necessary sanitize them.
13.2.5	PHYSICAL CONTAMINATION
	Systems should be in place to prevent contamination of foods by foreign bodies such as personal belongings, especially any hard or sharp object(s), e.g. jewellery, glass, metal shards, bone(s), plastic, wood fragments, that could cause injury or present a choking

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	hazard. In manufacturing and processing, suitable prevention strategies, such as maintenance and regular inspection of equipment, should be undertaken. Detection or screening devices which are appropriately calibrated should be used where necessary (e.g. metal detectors, X-ray detectors). Procedures should be in place for personnel to follow in the case of breakages (e.g. breakage of glass or plastic containers).
13.2.6	CHEMICAL CONTAMINATION
	Systems should be in place to prevent or minimize contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, chemical residues from pesticides and veterinary drugs such as antibiotics. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, safely stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials. Food additives and food processing aids that may be harmful if used improperly should be controlled so they are only used as intended.
13.2.7	ALLERGEN MANAGEMENT
	Systems should be in place to take into account the allergenic nature of some foods, as appropriate to the food business. Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives (not an inclusive list; allergens of concern differ among countries and populations), should be identified in raw materials, other ingredients and products. A system of allergen management should be in place at receipt, during processing and storage to address the known allergens. This management system should include controls put in place to prevent the presence of allergens in foods where they are not labelled. Controls to prevent cross-contact from foods containing allergens to other foods should be implemented, e.g. separation either physically or by time (with effective cleaning between foods with different allergen profiles). Food should be protected from unintended allergen cross-contact by cleaning and line change-over practice and/or product sequencing. Where crosscontact cannot be prevented despite well-implemented controls, consumers should be informed. Where necessary, food handlers should receive specific training on allergen awareness and associated food manufacturing/processing practices and preventive measures to reduce the risk to allergic consumers
13.2.8	INCOMING MATERIALS
	Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should be procured according to Specifications, and their compliance with food safety and suitability specifications should be verified, where necessary. Supplier quality assurance activities, such as audits, may be appropriate for some ingredients. Raw materials or other ingredients should, where appropriate, be inspected (e.g. visual examination for packages damaged during transportation, use-by-date and declared allergens, or temperature measurement for refrigerated and frozen foods) for appropriate action before processing. Where

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	appropriate, laboratory tests could be conducted to check food safety and suitability of raw materials or ingredients. These tests may be conducted by a supplier that provides a certificate of analysis, the purchaser, or both. No incoming material should be accepted by an establishment if it is known to contain chemical, physical, or microbiological contaminants which would not be reduced to an acceptable level by controls applied during sorting and/or processing where appropriate. Stocks of raw materials and other ingredients should be subject to effective stock rotation. Documentation of key information for incoming materials (e.g. supplier details, date of receipt, quantity, etc.) should be maintained.
13.2.9	PACKAGING
	Packaging design and materials should be safe and suitable for food use, provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases, where used, should not contain toxic contaminants, and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Any reusable packaging should be suitably durable, easy to clean and, where necessary, to disinfect.
13.3	WATER
	Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based approach. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g. some water used for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from e.g. food processing operations, by evaporation and/or filtration, should be treated, where necessary, to ensure that the water does not compromise the safety and suitability of food.
13.4	DOCUMENTATION AND RECORDS
	Appropriate records for the food business operation should be retained for a period that exceeds the shelf-life of the product or as determined by the competent authority.
13.5	RECALL PROCEDURES – REMOVAL FROM THE MARKET OF UNSAFE FOOD
	FBOs should ensure effective procedures are in place to respond to failures in the food hygiene system. Deviations should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid, and effective identification, and removal from the market by the involved FBO(s) and/or return to the FBO by the consumers of any food that may pose a risk to public health. Where a product has been recalled because of the likely presence of hazards that may represent an

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	immediate health risk, other products which are produced under similar conditions which may also present a hazard to public health should be evaluated for safety and may need to be recalled. Reporting to the relevant competent authority should be required and public warnings considered where a product may have reached consumers and when return of the product to the FBO or removal from the market is appropriate. Recall procedures should be documented, maintained, and modified where necessary based on the findings of periodic field trials. Provision should be made for removed or returned products to be held under secure conditions until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to reduce the hazard to acceptable levels, where permitted by the competent authority. The cause and extent of a recall and the corrective actions taken should be retained by the FBO as documented information.
14	PRODUCT INFORMATION AND CONSUMER AWARENESS
	OBJECTIVES: Appropriate information about food should ensure that: - adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly; - consumers can identify allergens present in foods; and - the lot or batch can be easily identified and recalled if necessary. Consumers should have enough knowledge of food hygiene to enable them to: - be aware of the importance of reading and understanding the label; - make informed choices appropriate to the individual; - prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly. RATIONALE: Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain. Insufficient product information about the allergens in food can also result in illness or potentially death for allergic consumers
14.1	LOT IDENTIFICATION AND TRACEABILITY

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	Lot identification or other identification strategies are essential in product recall and also help effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) applies. A traceability/product tracing system should be designed and implemented according to the Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CXG 60-2006), specifically to enable the recall of the products, where necessary.
14.2	PRODUCT INFORMATION
	All food products should be accompanied by or bear adequate information to enable the next FBO in the food chain or the consumer to handle, prepare, display, store, and/or use the product safely and correctly.
14.3	PRODUCT LABELLING
	Pre-packaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. This should also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded. The General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) applies.
14.4	CONSUMER EDUCATION
	Consumer education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product label information and following any instructions accompanying products, and to make informed choices. In particular, consumers should be informed of the relationship between time/temperature control, cross contamination and foodborne illness, and of the presence of allergens. Consumers should also be informed of the WHO five keys to safer food ¹ and educated to apply appropriate food hygiene measures (e.g. proper hand washing, adequate storage and cooking and avoiding cross contamination) to ensure that their food is safe and suitable for consumption.
15	TRANSPORTATION
	OBJECTIVES: Measures should be taken where necessary to: protect food from potential sources of contamination, including allergen cross-contact;

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	- protect food from damage likely to render the food unsuitable for consumption; and - provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food. RATIONALE: Food may become contaminated or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.
15.1	GENERAL
	Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.
15.2	REQUIREMENTS
	Where necessary, conveyances and bulk containers should be designed and constructed so that they: - do not contaminate foods or packaging; - can be effectively cleaned and, where necessary, disinfected; - permit effective separation of different foods or foods from non-food items where necessary during transport; - provide effective protection from contamination, including dust and fumes; - can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; and - allow any necessary temperature, humidity and other conditions to be checked.
15.3	USE AND MAINTENANCE
	Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Containers and conveyances for bulk food transport should be designated and marked for food use and used only for that purpose unless controls are taken to ensure that the safety and suitability of the food are not compromised. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection, and drying should take place between loads.
19	APPLICATION OF THE HACCP SYSTEM

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19.1	Assemble HACCP team and identify scope
	The FBO should ensure that the appropriate knowledge and expertise are available for the development of an effective HACCP system. This may be achieved by assembling a multidisciplinary team responsible for different activities within the operation, e.g. production, maintenance, quality control, cleaning, and disinfection. The HACCP team is responsible for developing the HACCP plan. Where relevant expertise is not available in house, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, competent authorities, HACCP literature and HACCP guides (including sectorspecific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement a HACCP system in house. A generic HACCP plan developed externally may be used by FBOs where appropriate but should be tailored to the food operation. The HACCP team should identify the scope of the HACCP system and applicable prerequisite programmes. The scope should describe which food products and processes are covered.
19.2	Describe product
	A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including Aw, pH, etc), microcidal/static treatments (heat treatment, freezing, brining, smoking, etc), packaging, durability and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues, and times and temperatures for heat treatments prescribed by competent authorities.
19.3	Identify intended use and users
	Describe the use intended by the FBO and the expected uses of the product by the next FBO in the food chain or the consumer. The description may be influenced by external information, e.g. from the competent authority or other sources on ways in which consumers are known to use the product other than those intended by the FBO. In specific cases (e.g. hospitals), vulnerable groups of the population may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.
19.4	Construct flow diagram

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	A flow diagram that covers all steps in the production of a specific product, including any applicable rework, should be constructed. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The flow diagram should indicate all inputs, including those of ingredients and food contact materials, water, and air, if relevant. Complex manufacturing operations can be broken down into smaller, more manageable modules, and multiple flow diagrams that link together can be developed. The flow diagrams should be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of hazards. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams should, as appropriate, include but not be limited to the following: • the sequence and interaction of the steps in the operation; • where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow; • any outsourced processes; • where applicable reworking and recycling take place; and • where end products, intermediate products, waste, and by-products are released or removed.
19.5	On-site confirmation of flow diagram
	Steps must be taken to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.
19.6	List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (Principle 1)
	Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation. An example of a hazard analysis worksheet is provided in Annex III, Table 1. The HACCP team should list all potential hazards. The HACCP team should then identify where these hazards are reasonably likely to occur at each step (including all inputs into that step) according to the scope of the food business operation. Hazards should be specific, e.g. metal fragments, and the source or reason for presence should be described, e.g. metal from broken blades after chopping. The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in Step 4. The HACCP team should next evaluate the hazards to identify which of these hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to

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	the production of safe food (i.e. determine the significant hazards that have to be addressed in the HACCP plan). In conducting the hazard analysis to determine whether there are significant hazards, wherever possible the following should be considered: • hazards associated with producing or processing the type of food, including its ingredients and process steps (e.g. from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data); • the likelihood of occurrence of hazards, taking into consideration prerequisite programmes, in the absence of additional control; • the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control; • identified acceptable levels of the hazards in the food, e.g. based on regulation, intended use, and scientific information; • the nature of the facility and the equipment used in making the food product; • survival or multiplication of pathogenic microorganisms; • production or persistence in foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, allergens) or physical agents (e.g. glass, metal); • the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe; and • conditions leading to the above. The hazard analysis should consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan (see Annex III, Table 1 for an example of a hazard analysis worksheet). In some cases, it may be acceptable for a simplified hazard analysis to be carried out by FBOs. This simplified process identifies groups of hazards (biological, physical, chemical) in order to control the sources of these hazards without the need for a comprehensive hazard analysis that identifies the specific hazards of concern. There can be drawbacks to such an approach, as the controls can differ for hazards within a group, e.g. controls for pathogenic spore-formers versus vegetative cells of microbial pathogens. Generic HACCP-based tools and guidance documents provided by external sources, for example, by industry or competent authorities, are designed to assist with this step and mitigate concerns about different controls needed for hazards within a group. Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be

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	identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level. In some cases, this may be achieved with the application of GHPs, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with <i>Listeria monocytogenes</i> or to prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances, control measures will need to be applied within the process, for example at CCPs. Consideration should be given to which control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard. For example, to control <i>L. monocytogenes</i>, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment. More than one hazard may be controlled by a specified control measure. For example, a heat treatment can control both <i>Salmonella</i> and <i>E. coli</i> O157:H7 when they are present as hazards in the food.
19.7	Determine Critical Control Points (PRINCIPLE 2)
	The FBO should consider which among the available control measures listed during Step 6, Principle 1 should be applied at a CCP. CCPs are to be determined only for hazards identified as significant as the result of a hazard analysis. CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree or a CCP determination worksheet (see Annex IV, Figure 1 and Table 1). A decision tree should be flexible, given whether it is for use in production, slaughter, processing, storage, distribution, or other processes. Other approaches such as expert consultation may be used. To identify a CCP, whether using a decision tree or other approach, the following should be considered: • Assess whether the control measure can be used at the process step being analysed. – If the control measure cannot be used at this step, then this step should not be considered as a CCP for the significant hazard. – If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at another step, the step being analysed should not be considered as a CCP.

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	• Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps should be considered as CCPs. The CCPs identified could be summarized in tabular format, e.g. the HACCP worksheet presented in Annex IV, Table 2, as well as highlighted at the appropriate step on the flow diagram. If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.						
19.8	Establish validated critical limits for each CCP (PRINCIPLE 3)						
	Critical limits establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure, such as measurements of temperature, time, moisture level, pH, aw, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting. A deviation from the critical limit indicates that it is likely that unsafe food has been produced. Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented. Validation of critical limits may include conducting studies (i.e. microbiological inactivation studies). FBOs may not always need to conduct or commission studies themselves to validate critical limits. Critical limits could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party, e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008).						
19.9	Establish a monitoring system for each CCP (PRINCIPLE 4)						
	Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Monitoring procedures for CCPs should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. The method and frequency of monitoring should take into account the nature of the deviation (e.g. a drop in temperature or a broken sieve, rapid drop in temperature during pasteurization, or a						
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	gradual increase in temperature in cold storage). Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process. The personnel doing the monitoring should be Instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.
19.10	Establish corrective actions (PRINCIPLE 5)
	Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO should determine what product may have been impacted by the deviation. The corrective actions taken when a deviation occurs should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposition. External experts may be needed to conduct evaluations regarding the safe use of products when a deviation occurs. It may be determined that the product could be reprocessed (e.g. pasteurized) or the product could be diverted to another use. In other situations, the product may need to be destroyed (e.g. contamination with <i>Staphylococcus enterotoxin</i>). A root cause analysis should be conducted where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. A root cause analysis could identify a reason for the deviation that limits or expands the amount of product impacted by a deviation. Details of the corrective actions, including the cause of the deviation and product disposition procedures, should be documented in the HACCP records. Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

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19.11	Validation of the HACCP plan and verification procedures (PRINCIPLE 6)
19.11.1	Validation of the HACCP plan
	Before the HACCP plan can be implemented, its validation is needed; this consists of making sure that the following elements together are capable of ensuring control of the significant hazards relevant to the food business: identifying the hazards, critical control points, critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded. Validation of control measures and their critical limits is performed during the development of the HACCP plan. Validation could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources. Where HACCP guidance developed by external experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product, or groups of products under consideration. During the initial implementation of the HACCP system and after verification procedures have been established, evidence should be obtained in operation to demonstrate that control can be achieved consistently under production conditions. Any changes having a potential impact on food safety should require a review of the HACCP system, and when necessary, a revalidation of the HACCP plan.
19.11.2	Verification procedures
	After the HACCP system has been implemented, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur. Verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing (internal and external), calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include: • reviewing monitoring records to confirm that CCPs are kept under control; • reviewing corrective action records, including specific deviations, product disposition and any analysis to determine the root cause of the deviation; • calibrating or checking the accuracy of instruments used for monitoring and/or verification;

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	• observing that control measures are being conducted in accordance with the HACCP plan; • sampling and testing, e.g. for microorganisms⁴ (pathogens or their indicators), chemical hazards such as mycotoxins, or physical hazards such as metal fragments, to verify product safety; • sampling and testing the environment for microbial contaminants and their indicators, such as Listeria; and • reviewing the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits). Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in-house, verification should be performed on behalf of the business by external experts or qualified third parties. The frequency of verification activities should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly. Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts. The review should include confirmation that various verification activities have been executed as intended.						
19.12	Establish Documentation and Record Keeping (PRINCIPLE 7)						
	Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business. Documentation examples are: • HACCP team composition; • hazard analysis and the scientific support for the hazards included or excluded from the plan;						
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	• CCP determination; • critical limit determination and the scientific support for the limits set; • validation of control measures; and • modifications made to the HACCP plan. Examples of records include: • CCP monitoring activities; • deviations and associated corrective actions; and • verification procedures performed. A simple record-keeping system can be effective and easily communicated to personnel. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices, and checklists to record, for example, product temperatures. Where appropriate, records can also be maintained electronically
19.13	Training of personnel in food businesses, government and academia in HACCP principles and applications is an essential element for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel in charge of each CCP. Training programmes should be designed to address the concepts at a level appropriate for the knowledge and skill level of the personnel being trained. Training programmes should be reviewed periodically and updated where necessary. Re-training may be needed as part of corrective actions for some deviations. Cooperation between food business operations, trade groups, consumer organizations, and competent authorities is vitally important. Opportunities should be provided for the joint training of FBOs and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

4.2.4 An indicative list of the required documents/records maintained by the enterprise to demonstrate the implementation and compliance with the requirements of the standard is provided below:

Indicative and Summary List of Required Documents/Records for Demonstrating the Implementation and Compliance with the Requirements of the Standard		
▪ Legal operating documents of the enterprise ▪ Documentation of compliance with hygiene and safety rules (e.g., HACCP plan) ▪ Sampling and testing plan based on relevant hazard analysis. ▪ Record of analyses on raw materials and/or final products and water. ▪ List of approved suppliers ▪ Description of the facilities, main equipment, and their representation on a site layout sketch. ▪ Flow diagram of production and storage processes. ▪ Suitability of vehicles, if transport is included within the scope. ▪ Traceability procedure and documentation of its implementation. ▪ Cleaning and disinfection record		
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▪ Personnel training record
▪ Personnel hygiene record
▪ Maintenance / calibration record
▪ CCP / OPRP monitoring record
▪ Internal audit procedure

4.3 Initial Audit

- 4.3.1 The organization/enterprise that meets the aforementioned basic requirements and is interested in HACCP / CODEX ALIMENTARIUS certification shall submit the required HACCP / CODEX ALIMENTARIUS Certification Application to the Certification Body (CB), using the relevant standardized application form (D09F01.1 APP – HACCP / CODEX ALIMENTARIUS Application).
- 4.3.2 The application must be completed clearly and include at minimum the required information, which includes:
- Identification details of the legal entity submitting the application (company name, registered address, VAT number, Tax Office, NACE activity codes)
 - Contact information (telephone number, email address, etc.)
 - Full name of the legal representative responsible for signing and submitting the application
 - Legal documentation of the enterprise (e.g., operating license, General Commercial Registry certificate, business registration, etc.)
 - Requested certification scope
 - Full identification details, address, and location of all facilities where the activities under the requested scope are carried out, including any temporary facilities and agricultural plots
 - Number of personnel (administrative, operational, seasonal, etc.)
 - Number and identification details of subcontractors (if applicable), and type of subcontracted activities undertaken
 - Information regarding work shifts, seasonal operation of the facility, etc.
- 4.3.3 The Certification Application is formally reviewed using the form D09F02.1_APP REVIEW.CODEX – HACCP / CODEX ALIMENTARIUS Certification Application Review, by an appropriately authorized and technically competent person of the Certification Body. The inspection date(s) and the appointed Lead Auditor and Auditors (Audit Team) are determined. It is noted that either a single individual Auditor may be appointed or a Lead Auditor heading an Audit Team.
- 4.3.4 Technical Experts may also participate in the Audit Team. The man-days of the Technical Experts are NOT included in the audit man-days calculation referred to in Section 4.3.5.
- 4.3.5 Observers may also be present during the inspection (e.g., accreditation body assessors, witness auditors of the Certification Body, etc.). The client is informed in a timely manner by the Certification Body through the Inspection Plan.
- 4.3.6 It is noted that the audit man-days are calculated in person-days (where one person-day is defined as 8 hours of work within one calendar day), in accordance with guideline D09_0E02, which is uniformly applied by the Certification and Inspection Body regardless of the case, and based on the certification scope as requested by the enterprise.
- 4.3.7 The initially determined audit man-days may be increased at the discretion of the Lead Auditor, provided that there are sufficiently justified reasons (e.g., discrepancies between the information in the application and the actual situation observed during the on-site inspection, delays in executing the audit schedule due to unavailability of company personnel, etc.).
- 4.3.8 The aforementioned audit man-days apply to all types of inspections, namely Initial Assessment, Annual Assessment, and Surveillance Inspection.
- 4.3.9 Upon acceptance of the relevant certification offer by the applicant, a Certification Agreement/Contract is signed between the organization and the Certification Body, outlining the terms governing the certification process. Specifically, the Certification Agreement shall include at least the following attachments: the General Certification Regulation (GCR), the present Special Certification Regulation HACCP / CODEX ALIMENTARIUS (SCR-HACCP), the Procedure for the Use of Logos and Marks (D15), and the Procedure for Handling Complaints, Appeals, and Customer Satisfaction Inquiries (D03), in order to ensure that the client is informed of the fundamental obligations involved in the certification.

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- 4.3.10 The Certification Body prepares and sends, in a timely manner, an Inspection Plan (form D11 F00.0.CERT PROGRAM.CODEX – Inspection Program and D11 F00.0.CERT PLAN.CODEX – Inspection Plan) for each inspection and prior to its implementation. This plan forms the basis of the agreement for conducting and scheduling the detailed on-site inspection/conformity assessment activities. The inspection plan is based on the documented requirements of the Certification Body (General Certification Regulation, present Special Certification Regulation).
- 4.3.11 Prior to the inspection, and in order to facilitate its implementation, the enterprise shall submit to the Certification Body at least the following:
- Legal documentation (operating license, business registration certificate, General Commercial Registry certificate – GEMI)
 - Product Flow Diagrams / HACCP Plan
 - Analysis plan
- 4.3.12 The inspections conducted by the Certification Body include the following:
- Initial Assessment
 - Annual Regular Assessment
- 4.3.13 All inspections are conducted on-site at the audited enterprise. The audited organization/enterprise must be in operation and have the necessary personnel available to accompany the auditors of the Certification Body. Access to the enterprise's records and facilities must be unrestricted. Each inspection includes an opening and a closing meeting, which are documented using form D11F00.2_CERT OPEN CLOSE.
- 4.3.14 The findings and results of the inspection are documented in D11 F00.1_CERT REPORT – Inspection Report. Additionally, a supporting checklist D11F00.3.CERT HACCP / CODEX CHECKLIST is used, which includes a list of control points where all findings (both positive and negative – conformities and non-conformities) are recorded. These findings are communicated to the enterprise after the completion of the inspection using form D11F00.4_NC.
- 4.3.15 The (Lead) Auditor collects sampling-based evidence of findings, which is attached to the inspection report using form D11F00.3_NOTES and submitted to the Certification Body for the decision on certification. The supporting evidence may include, but is not limited to, the items listed in the table of Section 4.2.3.
- 4.3.16 The Certification Body authorizes a suitable, technically competent, and independent individual—who has not participated in the inspection process—to review the inspection report and the attached evidence in order to make the certification decision. This decision is based on the evaluation of the findings and conclusions of the inspection, the auditor's recommendation, as well as other relevant information (e.g., public information, client comments on the inspection report, etc.).
- 4.3.17 An enterprise found to be in compliance with the requirements of the HACCP / CODEX ALIMENTARIUS standard and other applicable regulatory and standardization documents shall be granted a HACCP / CODEX ALIMENTARIUS Certificate with a validity of one (1) year.
- 4.3.18 It is noted that the validity of the Certificate of Conformity is maintained for the designated one-year period only if there have been no changes to the essential conditions of production, processing, standardization, packaging, and distribution of the certified products. In the event of any significant changes, the validity of the certificate is either suspended or revoked, and a new inspection is conducted.
- 4.3.19 The Certificate referred to in the above paragraph, issued by the Certification Body, must comply with the template
- 4.3.20 The negative findings (Non-Conformities and Observations) of the inspection are delivered to the company at the end of the inspection. The inspection report may be communicated to the company no later than two (2) weeks after the completion of the inspection.

4.4 Surveillance Audit

- 4.4.1 The annual regular evaluation inspection is carried out in accordance with the principles of the initial inspection, as required by the present Special Certification Regulation (SCR) and the certification category of the company.

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- 4.4.2 The Certification and Inspection Body (CIB) conducts surveillance inspections (within the one-year validity period of the Certificate) when deemed necessary, taking into account the need to monitor the implementation of the standard's requirements, findings from previous inspections, or other findings or suspicions. These inspections are referred to as special (extraordinary) inspections.
- 4.4.3 The enterprise must inform the Certification Body (CB) of any modifications it intends to make to essential production conditions and processes, as well as of any sanctions imposed by governmental or other authorities related to the HACCP / CODEX ALIMENTARIUS certification scope. The CB, under the responsibility of the Technical Director, decides whether the declared changes require an extraordinary inspection and further investigation.

4.5 Documentation

The Inspector of the Certification Body, during the course of the Inspection, must collect at minimum the following documentation, while simultaneously referencing the collected evidence in the inspection report.

Evidence	Inspection	Unannounced or Extraordinary Inspection
- Operating License / GEMI Certificate - Business Commencement Registry indicating the facilities and NACE codes (Activity Codes)	√	When changes occur
- Product Flow Diagrams / HACCP Plan - Facility Layouts and Equipment Placement - Water and Product Analysis Plan	√	When changes occur
- Traceability Procedure - Raw Material Purchase Records - Product Sales Records - Documentation of Compliance with Hygiene and Safety Rules - Copies of Laboratory Analysis Reports - List of Approved Suppliers - Label Mock-ups Intended for Use with Logos and Certification Marks ☐ Cleaning and Disinfection Records ☐ Staff Training Records ☐ Personnel Hygiene Records ☐ Maintenance / Calibration Records ☐ CCP / OPRP Monitoring Records - Vehicle Suitability Documentation (if transportation is included in the scope) - Contracts with Clients and Suppliers	√ (by sampling)	√ (by sampling)
Various items at the Inspector's discretion	√	√

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4.6 Certification Body Requirements

- 4.5.1 The Certification Body employs Inspectors who must hold a university-level academic qualification in the field of agricultural products and food, with at least two years of experience relevant to the audited activities. In addition, they must demonstrate participation in at least 20 hours of training seminars on the standard CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE of the Codex Alimentarius Commission (CXC 1-1969 Rev. 2023).
- 4.5.2 Specifically, the Certification Body (CB) makes relevant decisions and appoints Inspectors who possess:
- A university degree (tertiary education) in one of the following disciplines: Veterinary Science, Agronomy, Food Technology, Chemistry, or Chemical Engineering.
 - Documented training in Food Safety Management Systems (FSMS) based on HACCP/Codex, with a minimum duration of two (2) man-days.
 - Documented training specifically on HACCP/Codex with a minimum duration of twenty (20) man-hours.)
 - Minimum of two (2) years of work experience in products and processes relevant to the certification scope being inspected.
- 4.5.3 In cases where the requested certification scope includes primary production of animal and/or plant origin, it is mandatory that a Veterinarian and/or an Agronomist, respectively, is appointed as a member of the Audit Team.
- 4.5.4 The Audit Team may collectively possess the required experience and technical competence. The Audit Team may also be supported by Technical Experts to fulfill the above purpose.
- 4.5.5 The Certification Body ensures the rotation of its Inspectors for the audit of each company within a period not exceeding four (4) years or four (4) consecutive audits of the same company, starting from the date of the initial audit activity conducted at that company.
- 4.5.6 Any selection of production lines to be audited during the assessment inspection must be based on a documented risk analysis carried out by the Certification and Inspection Body (CIB).
- 4.5.7 The Certification Body must ensure that any company to which it has granted a HACCP/Codex Certification meets the requirements of the CODE OF PRACTICE – General Principles of Food Hygiene of the Codex Alimentarius Commission (CXC 1-1969 Rev. 2023), as well as those of the relevant Guideline.
- 4.5.8 The inspections must also include the assessment of units or facilities involved in processes related to the Scope of Certification (whether subcontracted or not).
- 4.5.9 The Certification Body must ensure that the company complies with the requirements for the proper use of the Certificate and the mark.
- 4.5.10 The Certification Body does NOT provide consultancy services to the enterprise.

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