bsi.

HACCP & GMP Certification Criteria

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bsi HACCP & GMP Food Safety Management CERTIFIED

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Contents

Summary

BSI HACCP & GMP Certification Criteria

BSI has developed this HACCP & GMP Certification Criteria for primary industry, food retail, food service, food manufacturers, packaging manufacturers, distributers and wholesaler organizations that do not necessarily require international recognition of their food safety system but who need to demonstrate to their suppliers and customers that they have implemented a preventative system of food safety hazard controls based on the principles and practice outlined in Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its Application, issued by the Codex Alimentarius Commission.

BSI's HACCP and GMP certification can also be used for the following types of food sector suppliers:

- Producers of ingredients and additives
- Transport and storage operators
- Producers of equipment
- Producers of cleaning and sanitizing equipment
- Producers of packaging materials
- Producers of pesticides, fertilizers and veterinary drugs
- Producers of animal food or pet food/feed (including feed supplements)
- Food brokers

To achieve certification to the BSI HACCP & GMP Certification Criteria the organization shall develop, document, implement and maintain a food safety system that meets the requirements of this criteria document. Certification is specific for the product range, scope of operation and the site in which these products are handled.

Certification of a HACCP & GMP food safety system is not a guarantee by BSI of an organization's food safety performance, or that there will be no food safety hazards caused by the certified organization, or that legislative requirements and food safety standards and codes of practice will always be met. Certification is a statement of compliance with these BSI HACCP & GMP Certification Criteria at the time of certification, and a statement of the assessed overall ability of the organization to identify and control potential food safety hazards.

Ultimately, the food safety performance and value which is added to the organization with a HACCP & GMP food safety system certified by BSI depends on the efforts made by the organization to establish and maintain a HACCP & GMP system that meets the legal and industry requirements, complies with the HACCP & GMP Certification Criteria and demonstrates the organization's commitment to continually improve their food safety performance.

The organization may also wish to consider other hazards such as quality and legality in their food safety system. Should these hazards be considered, they shall be developed, documented, implemented and maintained throughout the food safety system.

In addition to the requirements set out in this document, the organization shall first ensure that it meets its food safety obligations in the country of manufacture and the county of sale by ensuring that relevant legislation, standards, codes of practice, guidelines and industry standards have been documented and implemented.

Where there is a difference between the requirements of the BSI HACCP & GMP Certification Criteria and those of any relevant legal requirement, then the highest requirement shall be applied.

Structure of criteria

The HACCP & GMP Certification Criteria consists of three modules which can be applied in totality or in part to achieve different types of certification dependent on the certification criteria selected for HACCP & GMP, Codex HACCP or GMP.

References

General Principles of Food Hygiene issued by the Codex Alimentarius Commission of the World Health Organization (WHO) and Food & Agriculture Organization (FAO) of the United Nations (CXC-1-1969, revised 2020).

Organizations are also required to meet their local food safety regulations as applied within each state, province, territory or country.

Definitions

Allergen	A known component of food which causes physiological reactions due to an immunological response (e.g. nuts, wheat, sesame, etc.).
Audit	A systematic assessment to substantiate if the activities and results comply with the documented system and the system has been implemented effectively to achieve the desired objectives.
Batch	A discrete quantity of food prepared or required for one operation.
Brittle plastic	Plastics made from acrylic resins which are considered brittle or they break into pieces when subjected to forces beyond their impact resistance.
Brokers	Suppliers that source all types of food through domestic and import channels; procuring consignments according to a buyer specification, but do not sight or handle the product. Brokers may also be referred to as “agents.” Brokers/agents do not manufacture, transport or store products in their own facilities.
Building fabric	The materials used to clad the internal walls, floors and ceilings of buildings.
Clean in place (CIP) systems	Method of cleaning the interior surfaces of pipes, vessels, process equipment, filters and associated filling without disassembling and cleaning individual parts.
Claim	Statements on a food label that make assertions about the properties of the food.
Codex Alimentarius Commission	The body responsible for establishing internationally recognized standards, codes of practices and guidelines, of which HACCP is one standard.
Compliance	The ability to meet the requirements of a standard, guideline, policy or specification.
Consultant	A person, sometimes a group of people, selling specialist knowledge and/or skill to an organization to assist in the development of their product, process or procedures. Consultants aren’t directly employed by the business.
Control point	Any point, step or operation in a process where the process or hazard can be controlled.
Critical control point (CCP)	A step in a process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limits	Prescribed tolerances that shall not be exceeded to ensure that the critical control point effectively controls the identified hazard.
Documented information	Includes the hardcopy and electronic documentation that contains the information that outlines an organization's processes and procedures that support the food safety system.
Flow diagram	A schematic or systematic representation of the sequence and interactions of the process steps in the production or manufacture of food products.
Food grade	The specification for a food, ingredient or food packaging that meets accepted definitions of purity for use in, or in contact with, food.
Food safety	Assurance that food will not harm the consumer when it is prepared and eaten as intended by the manufacturer.
Food safety hazard	A biological/physical/chemical agent in food, or condition of food, with the potential to cause an adverse health effect.
Food suitability	Assurance that food is acceptable for human consumption according to its intended use.
Good Manufacturing Practices (GMP)	Implemented procedures and best practices undertaken to remove, reduce and control physical, chemical and biological hazards in the processing environment.
HACCP system	A system which identifies, evaluates and controls hazards which are significant for food safety.
HACCP audit table	A document that specifies requirements for monitoring and controlling significant food safety.
HACCP plan	A documented program that addresses the 7 principles and 12 steps of HACCP in order to ensure the control of significant food safety hazards.
HACCP study	A HACCP study corresponds to a family of products with similar hazards and similar production technology.
High-risk area	A production area where a food is processed where there is the potential for post process contamination with pathogenic microorganisms.
Internal verification activities	An audit activity that is carried out by the organization as a form of self-assessment.

Monitoring	Monitoring is the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is operating as intended.
Non-conforming product	Product that does not conform to specified requirements.
Organization	The company or other entity maintaining ownership and control of the food safety system and the associated product/service being provided within the scope of certification.
Organoleptic assessment	Evaluation of the taste, sight, smell and/or texture of foods.
Outsourced process steps	Steps in the manufacturing process that are conducted off-site usually by a contracted provider.
Pathogen	A biological agent that causes disease or illness to its host.
Personal Protective Equipment	Equipment with the function to protect the food handlers from the environment i.e. earmuffs, high visibility vests.
Potable water	Water being safe to drink, free from pollutants and harmful organisms and conforming to local, legal requirements of the World Health Organization (WHO) guidelines in the absence of local, legal requirements.
Pre-requisite programme (PRP)	The basic environmental and operational conditions in a food business that are necessary for the production of safe products. These control generic hazards covering Good Manufacturing Practice and good hygienic practice and shall be considered within the HACCP study.
Primary packaging	The packaging directly in contact with the product.
Product assessments	The process of determining the degree to which a product meets the required specification.
Product specification	A document that lists a specific set of requirements that shall be met by the product.
Protective clothing	Clothing that prevents contamination of the product by the product handler i.e. aprons, overalls, gumboots.
Quarantine	To isolate and secure non-conforming or potentially non-conforming product.
Recall	Action taken to remove from distribution, sale and consumption, product which may pose a health and safety risk to consumers.
Recirculated water	Water that flows through an enclosed system in a circuit.

Responsible person	A person employed by the organization who has authority to make decisions and take action, based on experience and training, relating to results and findings in the food safety system.
Rework	Food that has been removed from processing for reasons other than food safety that's suitable for reprocessing and consumption.
Root cause	The underlying cause of a problem which, if adequately addressed, will prevent a recurrence of that problem.
Sanitize	Process of applying heat or chemicals, heat and chemicals, or other processes, to a surface so that the number of microorganisms on the surface is reduced to a level that: does not compromise the safety of product with which it may come into contact and does not permit the transmission of infectious disease
Secondary packaging	The outer packaging not in direct product contact.
Shall	Where there is a requirement to comply with the requirements of the criteria.
Should	Where there is an expectation of compliance with the requirements of the criteria. Requirements for compliance are based on the products covered under the scope of certification, the processes, premises and/or, for some criteria, the size of the organization.
Shelf life	The length of time for which an item remains usable, fit for consumption or saleable.
Significance	Significance is determined by the consideration of the severity and likelihood of a hazard occurring.
Site	The physical location of activities performed by an organization
Soft plastics	Thin, flexible plastics often used to line cartons/bags, food materials or packaging, or to wrap food materials.
Traceability	The ability to trace and follow a food, feed, food-producing animal or raw material that's intended to be, or expected to be, incorporated into a food, through all stages of receipt, production, processing and distribution.
Use by date of the product	The date at which product becomes either unsafe or unfit for consumption when stored as recommended by the manufacturer.

Validation	Evidence that the control measures managed by the HACCP plan are capable of being effective (usually by theoretical or scientific research or analytical data).
Verification	Confirmation, through provision of objective evidence, that specified requirements in the HACCP plan have been fulfilled.
Withdrawal	Separate from a recall, this is action taken to remove product from the supply chain where there is no public health and safety issue such as underweight product or a quality-related issue.

BSI HACCP & GMP Certification Criteria

Module 1: Management System

1.1 Management commitment

1.1.1 Senior management shall demonstrate commitment to safe food production and handling through: the promotion of food safety awareness throughout the organization; facilitation of communication relating to food safety issues and incidents; and the provision of adequate resources to fully implement the HACCP system to achieve compliance to the BSI HACCP & GMP Certification Criteria.

1.1.2 Senior management shall provide appropriate and trained resources to ensure the safety and suitability of the food products covered under the scope of certification.

1.2 Continual improvement

1.2.1 The effectiveness and continual improvement of the HACCP system shall be demonstrated through the review of internal verification activities, non-conforming product actions, corrective actions and the results of external audits. New scientific developments, advances in technology and industry best practice should also be considered.

1.3 Food safety policy

1.3.1 The organization shall develop a policy which states the organization's commitment and measurable objectives for the supply of safe and suitable food products that meet customer expectations and legal requirements in the country of manufacture and the country of sale.

1.3.2 A programme to measure and improve food safety culture shall be established and maintained.

1.4 Roles, responsibilities and authorities

1.4.1 Roles, responsibilities and authorities with an impact on food safety shall be clearly communicated in the organization.

1.4.2 Position descriptions or equivalent, should be available for all positions that have a responsibility for food safety and maintenance of the HACCP system.

1.5 Controls for documented information

1.5.1 A system to manage documented information (electronic and hardcopy) shall be implemented to ensure the currency of documentation in use and provide a system for records to be retained and readily retrieved. Documentation and record keeping should be appropriate to the nature and size of the organization and sufficient to verify that the HACCP controls are in place and being maintained. This may include, but is not limited to:

- The responsibilities for the development, maintenance and authorization of all documentation within the HACCP system
- Methods of ensuring obsolete documents are removed from use
- Responsibilities for the communication of changes to documentation within the HACCP food safety system
- Methods for ensuring the security of the documented HACCP food safety system
- The method of destruction and control of customer-owned/branded/trademarked documentation, product and packaging

Module 2: HACCP

1.6 Document register

1.6.1 A document register (list) of the documents referenced in the HACCP system shall be developed. This may include, but is not limited to the following;

- HACCP team composition
- Product description and intended use
- Hazard analysis, including risk assessment and associated scientific references
- CCP determination
- Critical limit validation
- HACCP audit table
- Specifications (raw materials and finished product)
- Formulations (recipes)
- Pre-requisite programmes
- Standard operating procedures and work instructions
- Policies
- Forms

1.6.2 The organization shall have access to, and control of, external documents or references required to maintain the HACCP system. This may include but is not limited to food safety statutory and regulatory requirements, codes of practice, guidelines and standards appropriate to the country in which the food products are manufactured and sold.

2.1 HACCP system

2.1.1 The organization shall develop, document and implement a HACCP system based on the Codex Alimentarius General Principles of Food Hygiene as outlined in the Application section of this certification criteria.

2.2 HACCP team

2.2.1 The organization shall identify and document the members of the HACCP team.

2.2.2 The HACCP team shall comprise those within the organization who have the skills and knowledge to develop and maintain the HACCP plan. It is preferable to have a multi-functional HACCP team.

2.2.3 Where a consultant has been engaged by the organization to assist in the development and ongoing maintenance of the HACCP system, the organization shall ensure that the consultant holds appropriate qualifications.

2.2.4 The organization shall demonstrate they are responsible for the day-to-day management of the HACCP system.

2.3 Scope and purpose of the HACCP plan

2.3.1 The scope of the HACCP plan shall be defined and documented to define the start and end point of the process(es) under consideration and the products covered in the HACCP system.

2.3.2 The purpose of the HACCP system shall include the intent that all food safety hazards will be identified and controlled. Food safety hazards may include but are not limited to: biological, chemical, physical (foreign matter), allergen and radiological hazards as appropriate to the products in the scope of the HACCP plan.

2.4 Product description and intended use

2.4.1 A product description shall be developed and documented for all products included within the scope of the HACCP system.

2.4.2 'Like' products that are processed in similar ways may be grouped together in one product description. Products that are processed using different food safety controls, processing techniques or packaging methods shall have a separate product description.

2.4.3 A product description for each product or group of products shall detail the following information:

- Composition (e.g. formulation/ingredients)
- Physical and chemical characteristics (e.g. final product aW, pH, addition of preservatives)
- Production methods and technologies (e.g. heat treatment, high pressure processing (HPP), freezing, drying, brining, etc.)
- Primary and secondary packaging (e.g. type of packaging used, durability, functional effect on food safety such as extension of shelf life etc.)
- Storage, handling and distribution methods (e.g. refrigerated/ambient transport requirements)
- Shelf life (including best-before or use-by date coding)
- Intended use of the product(s)
- Labelling requirements including any claims as per local legislation in the country of sale
- Allergens as per local legislation in the country of sale
- Sensitive consumers

Some or all of this information may be contained within finished product specifications.

2.5 Process flow diagram

2.5.1 A process flow diagram shall be documented for each product or group of products. Every step in the process(es) shall be identified and be sufficiently detailed to include the sequence and interaction of steps, inputs, outsourced processes, intermediate products, rework, end products, waste and by-products relevant to the process. Complex manufacturing operations may be broken into a series of linked flow diagrams to provide a clear and accurate representation of the process flow.

2.5.2 Once developed, the HACCP team shall verify the accuracy of the flow diagram through a physical walk-through of the process at least annually, or when there are significant changes to the product or process.

2.5.3 Records of this activity verification shall be kept.

2.6 Hazard analysis and control measures

2.6.1 A hazard analysis shall be undertaken and documented for each step of the process and process inputs as identified in the flow process. The HACCP team shall reference the verified process flow diagram in the hazard analysis to identify all potential food safety hazards (as identified in the purpose of the HACCP plan) which need to be prevented, eliminated or reduced to accepted levels.

2.6.2 Both the hazard and the cause of the hazard shall be documented.

2.6.3 Identification and assessment of hazards are not to be grouped (e.g. foreign matter which shall be separated into wood splinters, packaging materials, hair, etc.). The identification of potential hazards should also take into consideration hazards reported in food recalls and outbreaks of foodborne illness as appropriate to the product, process and global supply chains.

2.6.4 The HACCP team shall evaluate the hazards to identify the hazards that are essential to prevent, eliminate or reduce to acceptable levels for the production of safe food (i.e. identify significant hazards).

2.6.5 Hazards that are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present shall be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level.

2.6.6 Where the organization has included quality hazards in the HACCP plan, these are to be identified in the risk assessment. These hazards shall be considered separately to the food safety hazards.

2.6.7 When determining significant hazards, the HACCP team shall consider the following as applicable to the product and process:

- Hazards known to be associated with the type of food, ingredients used in the product and process steps
- Likelihood of occurrence of hazards, taking into consideration pre-requisite programmes, in the absence of additional control
- 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. permissible additives and maximum residue limits defined by regulations in the country of sale)
- The food-handling environment and equipment used to produce the food product
- The likelihood of survival and/or growth of pathogenic micro-organisms
- The potential for the presence of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues) or foreign matter (e.g. glass, metal, soft plastic)
- The intended use and/or probability of the product being mishandled by potential consumers that may cause the food to become unsafe

Guidance note: There is no specific methodology required to be used to determine the significance of hazards.

2.6.8 For all hazards determined to be significant, there shall be at least one control measure designed to prevent or eliminate the hazard, or reduce the hazard to an acceptable level. Control measures may reference the application of a pre-requisite programme to reduce, prevent or eliminate a significant hazard (e.g. cleaning of equipment to prevent cross contact of food allergens from one food to another food that does not contain that allergen). In other instances, the control measures shall be applied within the process at critical control points (CCPs).

2.7 Critical control points

2.7.1 The HACCP team shall determine the critical control points for hazards identified in the hazard analysis as significant hazards. CCPs shall be established at steps where control is essential to safe food production and where a deviation could result in potentially unsafe food. There may be more than one CCP in a process at which control is applied to address the same hazard. If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.

Guidance note: There is no specific methodology required to be used to determine CCPs.

2.8 HACCP audit table

2.8.1 A HACCP audit table shall be developed, documented and applied which includes all steps of the process where CCPs have been identified. The corresponding monitoring activities, corrective actions in the case of deviations and verification activities shall be documented for each CCP.

2.9 Validated critical limits

2.9.1 Validated critical limits shall be determined for each CCP to separate acceptable products from unacceptable products.

2.9.2 Critical limits shall be measurable or observable. There may be multiple critical limits identified for a CCP, (e.g. heat treatments may include critical limits for time at temperature). 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.

Guidance note: Critical limit criteria may include minimum and/or maximum values (e.g. temperature, time, pH, available chlorine, contact time, conveyor belt speed, flow rate, etc.).

2.9.3 Validation of critical limits shall consider if the appropriate critical limit has been determined and the capability of the organization to consistently achieve the limit(s). Validation data shall be documented.

Guidance note: validation data may include, but is not limited to: regulations, industry codes of practice, guidance from competent authorities, studies conducted by equipment manufacturers and site-specific information confirming their capability to consistently achieve the critical limit(s).

2.10 System to monitor control of CCPs

2.10.1 A monitoring system for each CCP shall be established.

Guidance note: monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits.

2.10.2 Monitoring procedures shall define what is being monitored, how the monitoring is carried out, the frequency of monitoring, where the monitoring is to take place and who is responsible for undertaking the monitoring.

2.10.3 The monitoring procedures for CCPs shall be capable of timely detection of a deviation from the critical limit to allow non-conforming products to be isolated. The monitoring of CCPs should be continuous, where possible. If monitoring is not continuous, then the frequency of monitoring shall be sufficient to ensure that the CCP is under control (e.g. critical limits based on observation such as the application of the correct label to a product containing allergens, need a monitoring frequency based on the capability of the organization to prevent distribution of non-conforming product).

Guidance note: 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.

2.10.4 The organization shall also ensure that personnel who conduct monitoring checks are trained in the correct method and that training for CCP monitoring activities is assessed and documented.

2.10.5 Records of CCP monitoring shall be maintained to demonstrate a history of compliance to critical limits.

2.10.6 All CCP records shall be signed or initialled by the person performing the monitoring and shall report the results and timing of the monitoring activity.

2.11 CCP corrective actions

2.11.1 Specific written corrective actions shall be developed for each CCP in the event that critical limits are not achieved to prevent the release of potentially unsafe food. Actions shall be taken to segregate the affected product and assess the safety of the food product to ensure the appropriate disposition.

2.11.2 The procedures shall state what action is to be taken regarding the affected product, who is responsible and what action is to be taken regarding the process.

2.11.3 A root cause analysis should be conducted to identify and correct the cause(s) of the deviation to prevent recurrence.

2.12 Validation of the HACCP plan and procedures for verification

2.12.1 Verification procedures

2.12.1 Validation of the entire HACCP plan shall be completed prior to implementation to ensure the elements of the HACCP plan are capable of ensuring control of the significant hazards. This includes validation of the identified 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.

Guidance note: validation of control measures and their critical limits is completed during the development of the HACCP plan. Validation may include a review of scientific literature, in-house validation studies, and/or using guidance developed by external authorities.

2.12.2 Verification procedures shall be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed, that the HACCP system is able to control hazards on an ongoing basis and show that the control measures are effective to control the hazards as intended.

2.12.2 HACCP system review

2.12.2.1 Verification activities shall be completed on a planned, ongoing basis to ensure that the HACCP system remains capable of safe food production. Verification activities may include but are not limited to:

- Review of monitoring records to confirm that CCPs are under control
- Review of corrective action records, including specific deviations, product disposition and root cause to determine the cause(s) of the deviation
- Calibration or confirmation of the accuracy of instruments used for monitoring and/or verification activities
- Observation to confirm control measures are conducted in accordance with the HACCP plan
- Product sampling and analysis (e.g. microbiological hazards such as pathogen testing, chemical hazards such as mycotoxins or physical/foreign matter hazards such as metal fragments), to verify product safety
- Environmental monitoring (e.g. Listeria and/or Salmonella)
- Review of the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits)

2.12.2.2 Verification shall include a comprehensive review of the HACCP system annually or when changes occur, to confirm the efficacy of all elements of the HACCP system. The review of the HACCP system shall confirm the following:

- Appropriate significant hazards have been identified
- Control measures and critical limits are adequate to control the hazards
- Monitoring and verification activities occur as planned and are capable of identifying deviations
- Corrective actions are appropriate for deviations that have occurred

Guidance note: this review can be carried out by individuals within a food business or by external experts.

2.12.2.3 Records shall be maintained for HACCP system reviews.

2.12.2.4 Verification shall be carried out by a person other than the individual(s) responsible for performing the monitoring and corrective actions. Verification activities may be performed by external experts or qualified third parties.

2.12.2.5 The organization shall monitor the pre-requisite programmes and control measures applied to control hazards. Procedures may include a description of the monitoring methods, responsible personnel, frequency and sampling (as applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control.

2.12.2.6 The organization shall undertake verification activities to confirm that GMP procedures have been effectively implemented and that monitoring is occurring as planned, and appropriate corrective actions are taken when requirements are not met. Examples of verification activities may include but are not limited to the following:

- Review of GMP procedures, monitoring, corrective actions and records
- Review when any changes occur to the product, process and other operations associated with the organization
- Validation of the cleaning programme to meet the required cleaning standards
- Records of GMP verification activities shall be retained

2.12.3 Microbiological and chemical testing

2.12.3.1 The sampling methodology and test limits shall be documented and include the corrective actions for test results that are outside the limits.

2.12.3.2 Testing shall be conducted by suitably trained personnel or by an external laboratory that holds laboratory accreditation for the tests being completed.

2.12.3.3 Results of the tests shall be reviewed by a trained and responsible person within the organization and within an appropriate timeframe with respect to the purpose of the test (e.g. product clearance to release product on hold).

2.12.3.4 Corrective action shall be taken when results indicate that limits have been exceeded. Appropriate actions shall be taken to identify and isolate the product as per clause 3.8 Control of Non-Conforming Product.

2.12.4.5 Records of test results and corrective actions shall be kept.

2.12.4 Shelf life testing

2.12.4.1 New and re-developed products with a shelf life of less than two (2) years, shall have a schedule of shelf life testing documented and implemented. The shelf-life testing schedule shall include the type of testing to be undertaken and shall be carried out after the expiry date of the product (i.e. not on the date of expiry). Considerations for shelf-life testing may include, but are not limited to the following:

- Where the product can be frozen, as part of the storage instructions, the end of shelf-life testing shall be carried out after the end of the frozen period has been reached
- Shelf-life tests may include chemical, microbiological, organoleptic and physical testing (e.g. weight loss during storage)
- Where shelf-life limits are being established for new products, the process for determining the shelf-life and any assumptions shall be clearly documented
- End of shelf-life testing results shall demonstrate that the parameters of the product at the end of shelf life continue to meet the finished product specification. If this is not met, corrective action shall be taken.

2.12.5 Finished product assessments

2.12.5.1 A schedule of finished product assessments against the finished product specifications including organoleptic, biological, chemical and physical parameters shall be developed, documented and implemented.

2.12.5.2 Results of finished product assessments shall be reviewed by a suitably trained and knowledgeable person within the organization to identify the need for changes to the HACCP system. Records of the results shall be maintained.

Module 3: Good Manufacturing Practices (GMP)

2.12.6 Monitoring and corrective actions of verification activities

2.12.6.1 An organization shall review the results from HACCP verification activities to ensure that the HACCP system is under control.

2.12.6.2 The scheduled verification/review processes shall be documented to include the monitoring of corrective actions taken to address findings from verification activities.

2.12.7 Customer complaints

2.12.7.1 Customer complaints relating to food safety issues shall be recorded and managed by suitably trained personnel to ensure adequate investigation and consideration of the issue in the context of the HACCP system.

2.13. Establish HACCP plan documentation

2.13.1 A system of record keeping relevant to the HACCP system shall be documented and implemented. All records associated with the HACCP system shall be retained including:

- Monitoring of CCPs
- Corrective actions taken regarding CCPs
- Changes to the HACCP system
- Pre-requisite programmes
- Procedures for verification
- Validation of critical limits

2.13.2 Records shall be retained for a minimum of 12 months, or the shelf life of the subject product(s), whichever is the greater.

2.13.3 Hardcopy and electronic records shall be protected from damage or loss, easily accessible and securely stored.

3.1 Personal hygiene

3.1.1 A personal hygiene policy and procedure shall be developed, documented and implemented. As a minimum, the following elements shall be included:

- Personnel illness and injury (it may be appropriate for personnel to be excluded for a specific time after symptoms resolve or to obtain medical clearance before returning to work)
- Eating, drinking, smoking and vaping restrictions
- Hand-washing requirements
- Hygienic behaviours when sneezing, coughing and blowing of nose
- Protection of cuts and wounds and bandage requirements
- Clothing and Personal Protective Equipment (PPE) requirements
- Jewellery restrictions (including watches and piercings)
- Control of personal items including medication and mobile phones
- False nails (including acrylics) and false eyelashes
- Personnel movement restrictions
- Control of visitors and contractors
- Procedures to ensure the storage of protective clothing worn in areas of different hygiene risks is not contaminated
- Protocols for returning to work after breaks
- Use of signs in the language spoken by employees, located in prominent and sensible locations and made of suitable materials to prevent the risk of product contamination

3.2 Cleaning

3.2.1 The organization shall develop, document, implement and maintain a cleaning programme to remove food residues which may be a source of contamination, including allergens. Cleaning may be carried out using wet or dry cleaning methods, (e.g. heat, scrubbing, turbulent flow, vacuum) and chemical methods using solutions of detergents, alkalis or acids. Cleaning methods and materials shall be appropriate to the food type and the surface to be cleaned.

3.2.2 The programme shall identify the following (where appropriate):

- Areas within and outside the building that require cleaning
- Equipment that requires cleaning (including cleaning equipment and waste)
- Between batch cleaning
- Method of cleaning and, where required, sanitation (disinfection)
- Frequency of cleaning
- Chemicals used, if applicable (all cleaning chemicals shall be approved for use within a food production facility)
- Chemical concentrations, contact time and temperature
- Persons responsible for cleaning
- Records of the monitoring of cleaning
- Appropriate training for cleaning personnel

3.2.3 The cleaning programme shall state how monitoring of cleaning is undertaken, the frequency of monitoring and corrective action to be taken if monitoring reveals that the cleaning is not effective.

Guidance note: Micro-organisms may become tolerant to sanitizing (disinfecting) agents over time. A periodic review with the organization's chemical supplier(s) should be completed to ensure the sanitizer(s) (disinfectant(s)) used are effective to ensure inactivation of different types of micro-organisms (e.g. bacteria and fungi).

3.2.4 The condition of cleaning utensils and equipment shall be assessed regularly to ensure any worn equipment or utensils do not pose a risk of cross contamination to the production process.

3.2.5 Environmental monitoring (e.g. protein and allergen test swabs or microbiological testing for indicator organisms) to validate the effectiveness of the cleaning programmeme should be undertaken commensurate with product and process risk. Records of sampling locations, methodology, corrective actions and retests of sampling locations shall be maintained.

3.2.6 Where required, clean in place (CIP) systems shall have procedures documented and implemented to ensure there are no residual cleaning chemicals in products.

3.2.7 Validation of the CIP system shall be completed to ensure that the system is capable of removing soiling and preventing contamination of food products. The frequency of validation should be based on product and process risk.

3.2.8 Housekeeping and cleaning standards shall be maintained in all areas area to prevent environmental contamination.

3.3 Approved supplier programme

3.3.1 An approved supplier programme shall be documented and implemented for products and services (ingredients, packaging, chemicals, outsourced processes and third-party contractors) that may affect the food safety or quality of the finished product.

3.3.2 The approved supplier programme should include criteria for:

- Selecting and approving suppliers and service providers
- Emergency suppliers/providers removing suppliers/providers

Records of approval may include evidence of regulatory compliance, certificates of food safety certification, supplier questionnaires and other formal agreements.

3.3.3 The method of monitoring incoming products and services shall be documented and implemented and records maintained. Methods of monitoring may include but are not limited to:

- Visual inspection to check for packages damaged during transportation, sufficient use-by-date or best-before-date, contamination with foreign matter or allergens during transit and correct temperature for refrigerated and frozen foods
- Receipt of a Certificate of Analysis or other

details of compliance to specification
- Reconciliation of purchasing documentation for supplier details, date of receipt and quantity
- Incoming materials that do not meet food safety criteria should not be accepted by the organization

3.4 Specifications

3.4.1 Documented specifications shall be available for all raw materials (including packaging) and finished products to ensure compliance with relevant food safety and legislative requirements for food products handled by the site.

3.5 Labelling

3.5.1 The organization shall ensure there is a process for the preparation and review of labels which includes:
- Confirmation that the information on the label complies with food safety regulations and other applicable regulations that may apply to specific industry sectors in the country of sale
- Confirmation that clear instructions have been provided to enable the next person in the food chain to handle, display, store and use the product safely
- Review of label information in the event of the following:

1. Changes in labelling laws and regulations
2. Changes in raw materials and recipes including the introduction of ingredients that contain allergens applicable in the country of sale
3. Changes in processing that may impact food safety of the finished product (e.g. change from pasteurization to high-pressure processing)

The label shall be checked prior to production commencing to confirm the correct label, correct date coding for use by/best before date and legibility.

3.5.2 Records of labelling reviews shall be maintained.

3.6 Allergen management programme

3.6.1 An allergen management programme shall be documented and implemented to ensure the effective management of allergenic materials to prevent contamination and cross contact. This programme shall include but is not limited to:
- A documented risk assessment of ingredients containing allergens (this may form part of the raw material food safety risk assessment)
- Receipt and storage practices for ingredients containing allergens
- A list of all allergenic ingredients on site
- Control measures to prevent contamination and cross contact of allergens in products that do not contain the allergen
- Scheduling of production to prevent contamination and cross contact of allergens through shared equipment and processing areas
- Policies relating to the use of allergenic ingredients in rework
- Consideration of allergens during product development
- Mandatory declaration of allergens on product labels as required in the country of sale
- Allergen ‘free from’ claims shall be validated and reviewed on an annual basis
- Validation and verification procedures for cleaning and maintenance programmes

3.6.2 Employees and contractors shall be trained in the allergen management programme.

3.6.3 Compliance to the site allergen management programme shall be maintained in all areas of operation.

3.7 Packaging

3.7.1 All packaging shall be fit-for-purpose taking into consideration the product characteristics and handling in the supply chain.

3.7.2 Packaging shall be protected from contamination when in storage. Packaging should be stored in a designated area separate to food ingredients, finished products and non-food chemicals (including cleaning materials, lubricants).

3.8 Control of non-conforming product

3.8.1 Controls for non-conforming product shall be developed, documented and implemented. As a minimum, non-conforming product shall be segregated and identified to prevent accidental release or use.

3.8.2 The procedures shall state what action is to be taken regarding the affected product, who has responsibility for the action, the need for root cause analysis and what actions should be taken to prevent recurrence.

3.8.3 Records of non-conforming product for raw materials and through all stages of the process including rework shall be maintained to ensure full traceability. Records may include product hold, corrective actions and disposal.

3.9 Traceability

3.9.1 The organization shall have a documented procedure that ensures, for all stages of production from receival through to finished goods, products are clearly identified. This shall include (where applicable):

- Raw material receival
- Storage
- Work in progress
- Rework
- Final product
- On hold product
- Reject product, quarantined/non-conforming product
- Returned product, downgraded/damaged stock
- Food waste designated to animal feed
- Waste product(s)
- Cleaning chemicals and
- Packaging
- New product development materials

3.9.2 The procedure shall document how product is traced to the customer (one forward) and back to the supplier (one back).

3.9.3 Records of traceability shall be maintained.

3.10 Corrective action

3.10.1 The organization shall demonstrate that they are able to use information from identified failures in the HACCP system to identify the root cause, make necessary corrections and prevent re-occurrence.

3.11 Recall

3.11.1 The organization shall have a documented recall procedure in place that complies with the requirements of the local legislation in the country of sale.

3.11.2 The annual review shall include a test of the traceability process on at least an annual basis. This may be performed as a component of the mock recall and should include a test of the forwards and backwards traceability (this makes up part of the product traceability exercise referred to in clause 3.9 of this Criteria document).

3.11.3 Clear and accurate records of the recalls, withdrawals and mock recalls shall be maintained.

3.12 Design of facilities and equipment

3.12.1 Facility requirements

3.12.1.1 The facility design and construction shall be suitable for the type of food products handled at the site.

3.12.1.2 The facility shall be of an appropriate size and layout to reduce the risk of contamination and ensure the production of safe and legal food products.

3.12.1.3 A process for monitoring the condition of the facility shall be implemented. The frequency of monitoring processes shall be determined based on risk and shall be documented. Records of monitoring activities shall be retained.

3.12.2 External areas

3.12.2.1 The external areas around the facility shall be maintained in a clean condition with no overgrown vegetation that could compromise preventative pest controls.

3.12.2.2 Smokers waste shall be controlled to prevent potential contamination of food products stored and handled by the facility.

3.12.3 Layout, product flow and segregation

3.12.3.1 The layout of premises and the flow of operations, including the movement of personnel, raw materials, utensils, packaging rework and/or waste shall not compromise the food safety of products.

3.12.3.2 Food handling areas that have different levels of hygiene control (e.g. low risk vs. high risk area) shall have appropriate segregation to minimize cross-contamination. Segregation may include walls, partitions and/or allocation of areas within an open production area and separation in time as appropriate to product and process risks.

3.12.4 Building fabric and equipment

3.12.4.1 The fabrication of the buildings shall be suitable for the intended purpose and constructed of durable materials that are able to be maintained, effectively cleaned and where appropriate, sanitized (disinfected). Building materials should be constructed of non-toxic materials according to intended use and normal operating conditions.

3.12.4.2 Walls shall be impervious to moisture, maintained in good condition and easy to clean and maintain clean.

3.12.4.3 Floors shall be impervious to moisture, maintained in good condition and easy to clean and maintain clean. Where required, floors shall be graded to drains to prevent pooling.

3.12.4.4 Where required for wet cleaning operations, coving between the floor and wall should be used to facilitate cleaning.

3.12.4.5 Drains shall be in maintained in good condition and easy to clean and maintain clean. Drain grates and basket traps should be removable to allow for ease of cleaning.

3.12.4.6 In facilities where there is segregation between areas of different hygiene controls (e.g. low and high risk areas), wastewater shall not drain from low risk to high risk areas.

3.12.4.7 Ceilings (including false ceilings) shall be smooth, impervious to moisture, easy to clean and maintain clean and not allow for the entry of pest or dust ingress.

3.12.4.8 Windows located in production areas with open and exposed products shall be kept closed or have adequate pest proofing or screens.

3.12.4.9 Doors into production areas shall be close-fitting to prevent the entry of pests and dust ingress.

3.12.4.10 Doors (including rapid roller doors) shall be kept closed at all times when not in use. Doors that operate as an airlock should not allow for both doors to be open at the same time as this would compromise airlock controls intended to minimize contamination.

3.12.4.11 Light fittings shall be protected to ensure food is not contaminated by breakage. The replacement of light fittings above open product areas should be scheduled to occur when production is not in process.

3.12.4.12 Glass windows shall be protected to prevent glass contamination in the event of a breakage.

3.12.4.13 Equipment used for thermal processes or to chill/freeze food should be designed to achieve the process requirements to ensure food safety and suitability. Where necessary, equipment should also be designed to allow for temperature monitoring.

3.12.4.14 Equipment used in food processes must be industry standard and maintained in a suitable condition.

3.12.5 Employee amenities

3.12.5.1 Employee amenities shall be suitably located and include as required, designated areas for employees to keep personal belongings, changerooms, toilets, hand-washing and drying facilities as well as areas for eating, drinking and smoking. These facilities shall not be used for other purposes such as storage of food or items that contact food.

3.12.5.2 Hand-washing stations shall be located in appropriate locations throughout the site, made of suitable materials and in good condition and have a supply of warm, running, potable water, with liquid soap and a suitable method of drying hands.

3.12.5.3 Hand-washing facilities shall be of an appropriate hygienic design and should have hands-free taps; where this is not possible appropriate measures are required to minimize contamination from taps should be in place.

3.12.5.4 Where personal protective clothing and footwear is required for employees, contractors and visitors, there shall be suitable provisions provided (e.g. this may require multiple sizes of protective clothing and footwear to be maintained).

3.12.5.5 Lunchrooms shall have adequate refrigeration space for personnel to store perishable food items and be of suitable size for the number of personnel using the lunchroom at the same time.

3.13 Receival and storage

3.13.1 Procedures for the safe and suitable storage of products shall be implemented. These procedures shall include reference to allergen management, cleaning, stock/inventory control, segregation of non-conforming product and handling to minimize stock damage and cross contamination.

3.13.2 Facilities for the storage of ingredients, packaging, work in progress and finished product shall be fit for purpose, clean and large enough for use at peak times of production.

3.13.3 Ingredients, raw materials, work in progress, finished product and packaging shall be stored in such a manner that they do not pose a food safety (or quality) risk to the product.

3.13.4 Climate controlled (temperature and humidity) storage areas shall be monitored with records of monitoring activities maintained.

3.13.5 Deliveries and receivals that are unloaded in external areas shall be protected from environmental damage and contamination (e.g. rain and dust) with products moved to covered and protected areas as soon as practicable.

3.13.6 A process for stock rotation shall be in place and based on First in/First out (FiFo) or First expiry/First out (FeFo) principle for raw materials and finished products.

3.13.7 Where offsite storage facilities under the direct control of the organization are used, these shall be included in the HACCP system and monitored for compliance to GMP requirements.

3.13.8 Where storage of raw materials or finished products is contracted to a third-party service provider they shall be included in the approved supplier programme.

3.14 Dispatch and transport

3.14.1 The transport vehicle(s) required to transport temperature controlled foods shall be able to maintain appropriate temperatures.

3.14.2 The methods for securing transport for the transportation of products (including the transport of interim products that are transported to a third party for part of the process) shall be documented and records of checks maintained.

3.14.3 Procedures shall be documented and implemented for the breakdown of transport vehicles used to transport food products requiring temperature, humidity, atmosphere and other conditions necessary to protect food from microbial growth and deterioration.

3.14.4 Contingencies for loading and dispatching product in adverse weather shall be documented and implemented as required.

3.15 Control of water, ice, air and other gases

3.15.1 An adequate supply of potable water shall be available to ensure the safety and suitability of the products supplied. Potable water shall be used for post-harvest wash treatments, hand-washing, cleaning, ingredient, making and drinking water.

3.15.2 Water recirculated for reuse and recovered water (e.g. water recovered from food production operations, evaporation and/or filtration) shall be treated where necessary to ensure the safety and suitability of food is not compromised.

3.15.3 Water, ice and steam shall be fit for the intended purpose. This may require a risk-based testing programme to be documented and implemented.

3.15.4 Where a risk-based water testing programme is required, the programme shall include the frequency of testing, test method, limits and action to be taken for results that are outside of limits.

3.15.5 Air, steam and other gases used directly in contact with food product shall be suitable and not present a contamination risk.

3.16 Control of foreign materials

3.16.1 Controls for foreign materials in food handling areas (e.g. glass, metal, hard and soft plastics, wood splinters, jewellery) shall include suitable prevention strategies including preventative maintenance and regular inspection of equipment. Procedures for the control of foreign materials shall be documented, with appropriate records of compliance to procedures retained.

3.16.2 Personnel responsible for monitoring equipment related to control of foreign material shall be trained in the use of the equipment, monitoring methods and corrective actions

3.16.3 Controls for metal items including, but not limited to, knives, needles, wires, staples and knife sharpening equipment shall be implemented to manage the potential contamination risk from these items.

3.16.4 Where possible, glass and brittle materials shall be excluded from food handling areas or protected against breakage.

3.16.5 There shall be a documented and implemented policy on the use of glass, brittle plastics, ceramics and similar materials in food handling areas.

3.16.6 Where the final product is packed into glass packaging there shall be appropriate controls and documented procedures in place for line cleaning following breakages.

3.16.7 A policy for the use and control of soft plastic items shall be documented and implemented.

3.16.8 Soft plastic items shall be of an appropriate gauge to prevent tears and rips and used for the intended purpose.

3.16.9 Where possible, the soft plastic item shall be a contrasting colour to the product.

3.16.10 A wood policy outlining the control of wood within the processing environment shall be documented and implemented. Wood shall be excluded from the processing areas unless the wood is part of the processing equipment.

3.16.11 Where wooden pallets cannot be excluded from the processing area, adequate controls shall be in place to ensure that the pallets are dry, in good condition and free from damage.

3.17 Control of chemicals

3.17.1 A procedure outlining the control of chemicals used on the site shall be documented. This procedure shall include the identification and secure storage of chemicals used in maintenance, cleaning and CIP activities.

3.17.2 A list of chemicals stored and used on the site and the intended use for each chemical should be documented.

3.17.3 Evidence shall be available to demonstrate that the chemicals are suitable for use in a food premise and appropriate for the intended use by the organization.

3.17.4 Chemicals (e.g. cleaning materials, non-food grade lubricants, chemical residues from pesticides and veterinary drugs such as antibiotics) shall not present any direct contamination risks to the process and/or product.

3.17.5 All personnel and contractors who handle chemicals on the site shall have appropriate training.

3.18 Maintenance

3.18.1 The organization shall have in place a documented preventative maintenance programme covering the premises, equipment, services and external areas. Maintenance activities shall not pose a food safety risk to the products.

3.18.2 The preventative maintenance schedule shall be implemented.

3.18.3 Temporary repairs shall be controlled to ensure the food safety and legality of the product. Temporary repairs shall be permanently repaired as soon as practicable.

3.18.4 Maintenance employees and contractors shall take measures to ensure all tools are suitable for food production areas and that measures are in place to ensure tools and maintenance debris is removed when maintenance activities are completed. This is critical for intrusive maintenance activities where maintenance tools and debris will not be visible to production employees following maintenance activities.

3.18.5 Food products, ingredients and packaging shall be removed from the immediate area where there is a risk of contamination while maintenance is to be carried out.

3.18.6 The area/equipment undergoing maintenance should be checked to ensure the area and equipment has been cleaned and sanitized, tools and materials used or any swarf or shavings have been removed and that equipment has been reassembled correctly.

3.18.7 Maintenance workshops shall be maintained in a clean condition and pest-proofed.

3.18.8 A record shall be kept of planned maintenance and breakdown maintenance.

3.18.9 Equipment used in direct contact with food products shall be constructed of suitable food grade materials and capable of being cleaned and maintained clean.

3.18.10 Equipment inspections to ensure continued food safety suitability (e.g. inspection of sieves, screens and filters) shall be completed.

3.18.11 Steel wool and wire brushes, where required, shall be maintained in good condition to minimize the risk of foreign matter contamination.

3.19 Calibration

3.19.1 The organization shall have in place a documented procedure to ensure that all equipment used to inspect, measure or test the product is reading accurately so that the results are valid.

3.19.2 Personnel conducting calibrations and reviewing calibration records shall be appropriately trained.

3.19.3 Records shall be available for all calibrations, calibration checks and any corrective action taken when equipment is found to be out of calibration.

3.20 Training

3.20.1 A food safety training programme shall be implemented to ensure personnel handling food have the necessary knowledge and skills. The training programme should consider the food safety knowledge required for the product and process risks including:

- Type of food safety hazards known to be associated with the food products handled by site (e.g. growth of pathogenic or spoilage micro-organisms, foreign matter containments, allergens)
- The production and packing processes used by the organization

3.20.2 The training programme shall include, but is not limited to; environmental and personal hygiene practices (GMP), preventative controls for food safety (HACCP), allergen controls, cleaning and prevention of food contamination.

3.20.3 Personnel in a role that directly or indirectly impacts food safety shall be competent in food safety at a level appropriate to the role they perform.

3.20.4 Any personnel responsible for an activity that is associated with a CCP, or responsible for the implementation of a pre-requisite programme, shall be competent in that activity or programme.

3.20.5 Personnel moving into new roles shall be appropriately trained in the new role.

3.20.6 Records of all training, qualifications and competence reviews undertaken by personnel shall be maintained.

3.20.7 Refresher training shall be carried out at a suitable frequency commensurate with the product risk and role of personnel; regardless of their competency or length of employment.

3.21 Waste management

3.21.1 Waste shall be removed from the processing area at regular intervals and not allowed to accumulate.

3.21.2 Waste receptacles shall be clearly identified and visually different from product, work in progress or rework receptacles.

3.21.3 External waste bins shall have a lid which is kept closed when not in use.

3.21.4 External waste bins (including recycling) shall be emptied at an appropriate frequency with the area kept clean.

3.21.5 Equipment used in waste management shall be included in the cleaning programme.

3.22 Pest management

3.22.1 The organization shall have a documented pest management programme in place which includes a schedule for the application and frequency of treatments.

3.22.2 The programme shall cover all areas of the premise up to and including the boundary, maintenance areas and roof spaces (if appropriate).

3.22.3 The programme shall state how monitoring is undertaken, the frequency of monitoring and the corrective action to be taken if monitoring indicates the programme is not effective.

3.22.4 The programme shall also include:

- Bait maps depicting the type and location of treatments
- Bait stations shall be secured against movement and tampering
- Records of the chemicals used and the concentration
- Where required by local regulations, current information for pest control chemicals used or stored on site
- If pest control chemicals are stored on site, these shall be stored in a separate area away from food handling areas and chemicals used for production or maintenance purposes
- Where an external pest control contractor is used, evidence of their competency to perform pest inspection and treatment activities shall be maintained
- Where pest control activities are carried out by internal personnel, these personnel shall be suitably trained and records of training retained

3.22.5 The facility must be maintained free of pest infestation and/or pest harbourage.

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