HACCP & GMP Certification Criteria

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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, brokers, distributers and wholesaler organizations that do not necessarily require international recognition of their Food Safety Management System but who need to demonstrate to their suppliers and customers that they have implemented a system of food safety hazard control's 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.

To achieve certification to the BSI HACCP & GMP Certification Criteria the organization shall develop, document, implement and maintain a Food Safety Management 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 Management 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 Management System certified by BSI is dependent 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 the Food Safety Management System. Should these hazards be considered, they shall be developed, documented, implemented and maintained throughout the Food Safety Management 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 four modules which can be applied in totality or in part to achieve different types of certification, HACCP & GMP, HACCP or GMP (refer to clause 4.5) of this criteria.

Levels of Certification

Two levels of certification are available through the successful application of this criteria, Essential and Excellence.

Essential – Organizations meeting the requirements of the criteria will be awarded either a HACCP & GMP, HACCP or GMP certificate depending on the modules/clauses selected.

Excellence – Organizations wishing to demonstrate best in class practice may opt to include the "Excellence" criteria in their assessment. Successful application of these additional criteria will result in an "Excellence in HACCP & GMP" or "Excellence in GMP" certificate being awarded.

References

Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its Application, issued by the Codex Alimentarius Commission of the World Health Organization (WHO) and Food & Agriculture Organization (FAO) of the United Nations (Alinorm 97/13A, Appendix II) (CAC/RCP 1-1969 (Rev. 4 - 2003)

Organizations are also required to meet their local Food Safety regulations as applied within each state, territory or country.

Definitions

Accelerated Shelf Life Testing	An indirect method of determining the shelf-life of a food in which the trial period is shortened by deliberately increasing the rate of deterioration. This is usually done by increasing the storage temperature. The results are then used to estimate the shelf life under normal storage conditions.
Accreditation	The procedure by which an authoritative body gives formal recognition of the competence of a Certification Body to provide certification services against a specified Standard.
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.
Claims	Statements on a food label that make assertions about the properties of the food.
Codex Alimentarius Commission	The body responsible for establishing internationally recognised 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(s) who sells specialist knowledge and/or skill to an organization to assist in the development of their product, process or procedures. A consultant is not a direct employee of 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.
Critical Non Conformance	A serious system failure that is likely to cause an imminent public health or consumer risk.
Decision Tree	A tool that may be used to determine the Critical Control Points using a series of questions.
Document Control	The process of controlling documents to ensure that only the most current and authorised version is available for use.
Dwell Times	The contact time that a cleaning and sanitising solution is in contact with the item to be cleaned and sanitised.

Definitions

Excluded Products	A term applied to products that the supplier does not wish to be included in the HACCP & GMP audit scope.
Flow Diagram	A schemetic 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 Management System	A set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives, used to direct and control an organization with regard to food safety. This system provides assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
Food Safety Hazard	A biological, physical, chemical agent in food, or condition of food, with the potential to cause an adverse health effect.
Foreign Materials	Extraneous matter in food that contaminates it and may make it unfit for human consumption.
Good Manufacturing Practice (GMP)	Implemented procedures and best practices undertaken to remove, reduce and control physical, chemical and biological hazards in the processing environment.
Good Warehouse Practices (GWP)	Implemented procedures and best practices undertaken by a warehouse to remove, reduce and control chemical, physical and biological hazards in the processing environment.
HACCP	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 hazards which are significant for food safety.
HACCP Study	A HACCP Study corresponds to a family of products with similar hazards and similar production technology.
Head Office	A site where the Food Safety Management System of multiple manufacturing/processing sites is controlled but no processing, manufacturing or storage activities occur.
High Risk Area	The production area where a food is processed where there is the potential for growth of pathogenic micro-organisms in the food.
High Risk Products	A chilled ready-to-eat/heat product or food where there is a high risk of growth of pathogenic micro-organisms.
Internal Audit	An audit activity that is carried out by the organization as a form of self-assessment.
Microbiological Swabbing	A verification activity that estimates the level of microbial contamination on a surface in a food handling area.
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.

Definitions

Non-Conforming Product	Product that does not conform to specified requirements.
Nutritional Claims	Statements on a food label that make assertions about the nutritional properties of the food.
Organization	The company or other entity maintaining ownership and control of the Food Safety Management System and the associated product/service being provided within the scope of certification.
Organoleptic Testing	Sensory testing of food, including taste, sight, smell and texture.
Outsourced Process steps	Steps in the food 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 whose function is to protect the good handlers from the environment i.e. earmuffs, high visibility vests.
Post-Harvest	Activities conducted after harvesting of a crop.
Potable Water	Water being safe to drink, free from pollutants and harmful organisms and conforming to local legal requirements of the World Health Organisation (WTO) guidelines in the absence of local legal requirements.
Potentially Hazardous Food	Food that has to be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food.
Pre-Requisite program (PRP)	The basic environmental and operational conditions in a food business that are necessary for the production of safe food. 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 food 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	The function of protective clothing is to prevent contamination of the food by the food handler i.e. aprons, overalls, gumboots.
Quarantine	To isolate and secure non-conforming or potentially non-conforming product.
Ready to Cook Food	Food designed by the manufacturer to require cooking effective to eliminate or reduce to an acceptable level micro-organisms of concern immediately prior to consumption.
Ready to Eat Food	Food that is ordinarily consumed in the same state as that in which it is sold. It does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.
Ready to Re-Heat Food	Food designed by the manufacturer as suitable for direct human consumption without the need for cooking, but which may benefit in organoleptic quality from warming prior to consumption.
Recall	A recall is an action taken to remove from distribution, sale and consumption, product which may pose a health and safety risk to consumers.

Definitions

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 Management System.
Rework	Food that has been removed from processing for reasons other than food safety that is suitable for reprocessing and consumption.
Root Cause	The underlying cause of a problem which, if adequately addressed, will prevent a recurrence of that problem.
Sanitise	Process of applying heat or chemicals, heat and chemicals, or other processes, to a surface so that the number of micro-organisms on the surface is reduced to a level that: a) does not compromise the safety of food with which it may come into contact; and b) 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 is 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 occuring.
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 is 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 food 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	A withdrawal, which is separate from a recall, 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.

1.1 Management Commitment

1.1.1 Senior management shall demonstrate commitment to the effective implementation of the requirements of the Criteria.

1.1.2 Senior Management shall provide appropriate and trained resources to ensure food safety of the products produced or handled under the scope of certification.

1.1.3 The organization shall have in place a documented and implemented system to ensure that it has access to the food safety regulatory guidelines, codes of practice and standards appropriate for the country in which the product is to be manufactured and sold.

1.1.4 How this system is maintained shall be documented and implemented.

1.2 Continual Improvement

1.2.1 The organization shall have a documented procedure for continual improvement which includes a review of the entire Food Safety Management System on at least an annual basis.

1.2.2 Consideration shall be given to the outcomes from external audits, internal audits, corrective actions, verification activities and non-conforming product as a minimum.

1.2.3 Records of continual improvement activities shall be kept.

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 food products that meet customer expectations, legal requirements and are suitable for consumption in the country of manufacture/production and the country of sale.

1.3.2 The documented food safety policy shall outline the business' commitment to continual improvement, be signed by the senior executive manager, and be communicated effectively to all staff within the business.

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1.3.3 The organization shall hold a certificate of currency for public and product liability insurance.

1.3.4 The value of the insurance should be appropriate for the size of the business, local and customer requirements.

1.4 Organization Chart & Job Descriptions

1.4.1 A current organization chart that identifies all management and staff positions within the organization shall be documented.

1.4.2 Position descriptions shall be available for all positions on the organization chart who have responsibility for food safety and maintenance of the Food Safety Management System.

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1.4.3 Deputies should be in place for key roles with responsibilities for food safety.

1.5 Document Control

1.5.1 The organization shall document a procedure on how all documents (paper based and electronic) within the Food Safety Management System are controlled.

1.5.2 The organization shall ensure only the most current and authorised version is available to all staff for use.

1.5.3 The procedure shall include:

- Where documents and records are kept and the processes in place to implement the Food Safety Management System

- The responsibilities for the development, maintenance and authorisation of all documentation within the Food Safety Management System
- Methods of ensuring obsolete documents are removed from use
- Responsibilities for the communication of changes to documentation within the Food Safety Management System
- Methods for ensuring the security of the documented Food Safety Management System
- The method of destruction and control of customer owned / branded / trademarked documentation, product and packaging

1.6 Document Register

1.6.1 A list of all the documents that are included in the Food Safety Management System shall be developed. The register shall include documents describing:

- Scope and Purpose
- Product Description and Intended Use
- Hazard Analysis, including Risk Assessment
- HACCP Audit Table
- Specifications (finished product, chemicals, raw materials and packaging)
- Formulations, Standard Operating Procedures
- Pre-requisite programs
- Policies
- Forms
- Work Instructions
- The date and/or version number shall be indicated within each document

1.6.2 The organization shall also have access to and control of external documents or references required to maintain the system. This includes relevant industry standards, or guidelines, regulations, recall protocols, codes of practice etc.

1.6.3 An amendment register shall be maintained to record changes to documents that are listed in the document register.

2.1 Preliminary Steps

2.1.1 The organization shall develop, document, and implement a HACCP based Food Safety Management System.

2.1.2 This system shall be based on Codex Principles as outlined in the Application section of the Codex reference.

2.2 The HACCP Team
(Codex HACCP – Step 1)

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 One HACCP team member shall be the designated HACCP team leader, who shall also have the operational accountability within the organization and who is competent in the application of HACCP systems.

2.2.4 The HACCP team leader shall attend a competency-based and assessed training course in the application of HACCP Principles (or equivalent).

2.2.5 Where a consultant has been engaged by the organization to develop and maintain the Food Safety Management System the organization shall ensure that the consultant holds appropriate qualifications.

2.2.6 Evidence of the consultant's qualifications shall be available.

2.2.7 The organization shall demonstrate they are responsible for the day to day management of the Food Safety Management System.

2.3 Scope and Purpose of the HACCP Plan
(Codex HACCP - Step 1)

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

2.3.2 The purpose of the HACCP plan shall be defined and documented.

2.3.3 The purpose shall include the intent that all food safety hazards will be identified and controlled.

2.4 Product Description and Intended Use
(Codex HACCP - Steps 2 & 3)

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

2.4.2 'Like' products that are processed in similar ways may be grouped together in one product description.

2.4.3 Products that are processed using different food safety controls, processing techniques or packaging methods shall have a separate product description.

2.4.4. Each product description shall cover the following elements:

- Description of product
- Composition
- Physical, chemical and microbial characteristics
- Method of preservation
- Packaging – primary and secondary
- Storage, handling and distribution methods (e.g. pallet configurations, 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 the Finished Product Specifications.

2.5 Flow Diagram
(Codex HACCP - Steps 4 & 5)

2.5.1 Every step in the process(es) shall be identified and documented in the flow diagram. This shall include;
- Rework
- Inputs (including packaging, chemicals, air, water and steam)
- Outsourced Process steps
- Waste

2.5.2 Once developed, the HACCP Team shall verify the accuracy of the flow diagram on site at least annually or if there are any significant changes to the product or process.

2.5.3 Records of this activity verification shall be kept.

2.6 Hazard Analysis
(Codex HACCP - Step 6, Principle 1)

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.

2.6.2 At each step, all potential food safety hazards (biological, chemical and physical) shall be identified and assessed to identify hazards that need to be prevented, eliminated or reduced to accepted levels.

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

2.6.4 All potential hazards are to be specific with the identification and assessment undertaken separately.

2.6.5 Identification and assessment of hazards are not to be grouped e.g. foreign matter. It shall be seperated into wood, hair etc.

2.6.6 Potential hazards shall also include global hazards which may or may not be present in the country of manufacture or sale i.e. Avian Flu, Melamine contamination, species adulteration. Consideration shall also be given to food poisoning outbreaks in the same or similar industry (i.e. Salmonella in peanuts US in 2009).

2.6.7 A risk assessment shall be undertaken to determine which hazards are significant for the organization and which are not.

2.6.8 Significance shall be determined by severity of the hazards against the likelihood of the hazard occurring.

2.6.9 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.

2.6.10 The risk methodology that is used shall be applied consistently throughout the HACCP system.

2.6.11 The risk methodology source shall be referenced.

2.6.12 For all hazards that are determined to be significant, at least one control measure shall be identified and documented to prevent it from occurring or reduce it to an acceptable level.

Guidance Note:
This standard does not require a specific methodology to be used to determine significance.

2.7 Determining Critical Control Points
(Codex HACCP - Step 7, Principle 2)

2.7.1 For each hazard that requires control, the Control Points shall be reviewed to determine those steps that are critical. These steps are Critical Control Points (CCPs).

Guidance Notes:
There is no specific methodology required to be used to determine CCPs. The organization may develop the method or utilise the Codex HACCP Decision Tree. However the CCP determination shall identify all the process steps where control is necessary to eliminate or reduce a food safety hazard, and shall be applied consistently to all process steps.

To assist in finding where the correct CCPs are, the organization can use a CCP Decision Tree (refer Codex HACCP). The Decision Tree consists of a logical series of questions which can be asked for each hazard at each step in the flow chart. Using a Decision Tree encourages structured thinking, ensures a consistent approach, encourages discussion amongst team members and hence a better understanding of the process and the hazards. However, Decision Trees should always be used with flexibility.

Since the aim of the HACCP system is to prevent problems before they occur and to detect and remove non-conforming products before the product reaches the customer, the CCPs chosen shall give a rapid result. Thus, microbial levels are not generally used as Critical Control Points, as the response time is too long. In this case, temperatures of e.g. cold storage may be used as critical limits, as long as the critical limits set are validated to ensure they do achieve the required level of microbiological safety.

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.

Guidance Notes:
Where used, all CCPs relating to quality, regulatory etc. have been referred to as CCPs in the Criteria document for simplicity. It is important to note that critical limits shall be set on the basis of product safety (and/or quality), and are not based on process capability. Where there is a difference, the process shall be adjusted to ensure that it is capable of producing safe product.

2.9 Establish Critical Limits
(Codex HACCP - Step 8, Principle 3)

2.9.1 For all CCPs, critical limits shall be established and documented in the HACCP Audit Table.

2.9.2 The critical limit shall be measurable.

2.9.3 Where critical limits are not available through industry standards, legislation, code of practice or published research, it is the responsibility of the organization to undertake a validation study to ensure any limits will control the significant hazard.

2.9.4 Validation data shall be documented and maintained by the organization.

2.10 Monitoring of CCPs
(Codex HACCP - Step 9, Principle 4)

2.10.1 The organization shall document how each CCP is to be monitored.

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 When determining the frequency of monitoring, it shall be sufficient to ensure that the CCP is under control.

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

2.10.5 Records of CCP monitoring shall be maintained.

2.10.6 All CCP monitoring records shall be signed by the person responsible for the monitoring and by a responsible reviewing officer. These shall not be the same person.

2.11 CCP Corrective Actions
(Codex HACCP - Step 10, Principle 5)

2.11.1 CCP corrective actions shall be developed, documented and implemented.

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 shall be undertaken to identify the problem and prevent recurrence.

Guidance Notes:
Corrective actions shall be clear and unambiguous. The food safety policy objectives cannot be achieved if the HACCP Plan fails at this step by releasing product that is potentially unsafe. Thus actions required, including responsibilities, shall be clearly documented and followed if the process fails to achieve the critical limits.

2.12 Verification Activities
(Codex HACCP - Step 11 Principle 6)

2.12.1 Verification Procedures

2.12.1.1 Verification procedures are required to ensure that the Food Safety Management System is being followed and are effective.

2.12.1.2 As a minimum, the verification activities that shall be undertaken include:
- Internal audits
- HACCP Plan review
- Microbiological and chemical testing (where applicable)
- Shelf life testing (where applicable)
- Finished product assessments (where applicable)
- Review of monitoring records
- Review of corrective action records

2.12.1.3 A verification schedule including the activity performed, frequency, personnel responsible and records to be kept shall be documented and maintained.

2.12.2 Food Safety Management System Review

2.12.2.1 The Food Safety Management System shall be reviewed at least annually, including the food safety policy, organization chart, document control, verification activities, and pre-requisite programs.

2.12.2.2 In addition to the annual review the Food Safety Management System shall also be reviewed where any changes occur which could potentially introduce change to the content or application of the Food Safety Management System.

2.12.2.3 Records shall be maintained of Food Safety Management System reviews.

2.12.3 Internal Audits

2.12.3.1 An internal audit procedure shall be documented and implemented.

2.12.3.2 An internal audit schedule indicating elements to be audited, scope and proposed date/s shall be documented.

2.12.3.3. Internal audit/s of the entire Food Safety Management System (including prerequisite programs) shall be carried out on a (minimum) annual basis.

2.12.3.4 The internal audit shall be sufficiently detailed to identify any areas of non-conformance that needs to be addressed to maintain the effectiveness of the system.

2.12.3.5 Records of internal audits shall be retained.

2.12.3.6 Internal auditors shall be suitably trained and competent.

2.12.3.7 Internal auditors shall be independent from the process key audited where the records are in and from there shall be evidence that records have been checked and verified.

2.12.3.8 The internal audit program shall also include a program for documented GMP Inspections to ensure that the factory environment, processing equipment and external areas to ensure that these areas are appropriately maintained.

2.12.3.9 The frequency of the GMP inspections shall be carried out according to the product risk.

2.12.4 Microbiological & Chemical Testing

2.12.4.1 Where microbiological and/or chemical hazards have been identified during the HACCP risk assessment process (or to meet regulatory, customer requirements or to assure quality and food safety parameters) a schedule of testing shall be documented and implemented.

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

2.12.4.3 Testing shall be conducted by suitably trained personnel.

2.12.4.4 Results of the tests shall be reviewed by a trained and responsible person within the organization and within a reasonable timeframe.

2.12.4.5 Corrective action shall be taken when results indicate that limits have been exceeded.

2.12.4.6 Appropriate actions shall be taken to identify and isolate the product as per clause 3.8 Control of Non-Conforming Product.

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

2.12.5 Shelf-Life Testing

2.12.5.1 For all new and re-developed products with a shelf life of less than two (2) years, a schedule of shelf-life testing shall be documented and implemented.

2.12.5.2 The shelf-life testing schedule shall include the type of testing to be undertaken and shall be carried out on each new product, or product type and where a significant change in product or process is undertaken.

2.12.5.3 End of shelf life testing shall be carried out after the expiry date of the product (i.e. not on the date of expiry)

2.12.5.4 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.

2.12.5.5 Shelf life tests may include chemical, microbiological, organoleptic and physical testing (e.g. weight loss during storage).

2.12.5.6 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.

2.12.5.7 Where biological hazards have been identified (refer 2:12.4) a schedule for pathogen testing shall be carried out at the end of shelf life.

2.12.5.8 Where shelf life limits are being established for new products, the process for determining the shelf life and any assumptions shall be clearly documented.

2.12.5.9 Accelerated shelf life testing may be used, but shall not replace, shelf life testing under typical storage conditions.

2.12.5.10 Results of the tests shall be reviewed and signed by a responsible and trained person within the organization. Records of the results shall be maintained.

2.12.5.11 Corrective action shall be taken when results indicate that limits have been exceeded.

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2.12.5.12 Retention samples shall be stored under typical conditions and in the retail packaging for that product.

2.12.5.13 Shelf life testing shall include establishing the shelf life (which is indicated in the product description) and from then on, end of shelf life testing to verify that shelf life is being met. This also applies to products shipped for further manufacturing or rework.

2.12.6 Finished Product Assessments

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

2.12.6.2 Assessments shall be performed against the finished product specifications and include appropriate documented parameters e.g. organoleptic, physical, chemical etc.

2.12.6.3 Records of these assessments shall be kept.

2.12.7 Monitoring and Corrective Actions of Verification Activities

2.12.7.1 An organization shall review the results from the verification activities to ensure that the Food Safety Management System is under control.

2.12.7.2 The scheduled review process shall be documented for monitoring the corrective actions of verification activities.

2.12.8 Customer Complaints

2.12.8.1 A process for reviewing customer complaints that relate to food safety (and quality) issues shall be developed, documented and implemented.

2.12.8.2 This shall be undertaken at least annually.

2.12.8.3 Customer complaints shall be recorded and managed by suitably trained staff members.

2.12.8.4 Customer complaint records, records of the review, investigation undertaken and corrective action shall be kept.

2.12.8.5 Corrective action shall be prompt and appropriate.

2.13 Record Keeping

(Codex HACCP - Step 12, Principle 7)

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

- Monitoring of CCPs;
- Corrective actions taken regarding CCPs;
- Changes to the HACCP system;
- Pre-Requisite programs
- Verification activities
- Validation activities

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 Records shall be protected from damage or loss, easily accessible and securely stored.

The following Good Manufacturing Practices (GMP) Prerequisite (Support) Programs shall be included in the HACCP & GMP Food Safety Management System. The extent to which they apply will vary with the type of organization and food safety risk. However, they shall all be considered and applied where appropriate. Justification for exclusion shall be documented and included within the HACCP & GMP Food Safety Management System.

Guidance Notes:
Good Warehouse Practices (GWP) Prerequisite (Support) Programs shall be applied in the Food Safety Management System where applicable to warehousing systems or environments.

3.1 Personal Hygiene

3.1.1 A personal hygiene policy and procedure shall be developed, documented and implemented.

3.1.2 As a minimum, the following elements shall be included:

- Staff illness
- Eating, drinking and smoking restrictions
- Hand-washing requirements
- Sneezing, coughing and blowing of noses
- Cuts, wounds and bandage requirements
- Clothing requirements
- Jewellery restrictions (including watches)
- Control of personal items including medication and mobile phones
- False nails (including acrylics) and false eyelashes
- Staff Movement restrictions
- Control of visitors and contractors
- Procedures shall be in place to ensure the storage of protective clothing is such that there is no cross contamination risk from low risk to high risk protective clothing e.g. storage of gum boots and personal protective clothing
- Returning to work after breaks
- Use of signs (Signs displayed are maintained and understandable, placed in prominent and sensible locations, and made of suitable material to prevent the risk of product contamination)

Excellence

3.1.3 Staff Hygiene compliance checks shall be undertaken and records of these checks maintained.

3.1.4 The frequency of the checks is to be determined by the organization and defined within the policy.

3.2 Cleaning

3.2.1 The organization shall develop, document, implement and maintain a cleaning program.

3.2.2 The program 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
- Frequency of cleaning
- Chemicals used (if applicable). All cleaning chemicals shall be approved use within a food processing facility
- Chemical concentrations, dwell Times and temperatures
- Persons responsible for cleaning
- Records of the monitoring of cleaning and pre-operational checks
- Personnel responsible for review of cleaning records
- Appropriate training for cleaning personnel

3.2.3 The cleaning program 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.

3.2.4 The frequency of verification shall be determined by the organization.

3.2.5 A documented verification program for the cleaning program shall be in place.

3.2.6 Product contact, non-product contact surfaces and cleaning equipment shall be included in the verification program.

3.2.7 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.

3.2.8 Squeegees for high risk processes shall be controlled so they do not pose a cross contamination risk.

3.2.9 Squeegees used to control condensation shall be cleaned and sanitised daily.

3.2.10 High pressure hoses shall not be used during production or where there is exposed product.

Excellence

3.2.11 Steel wool/wire brushes shall not be used within the processing areas.

3.2.12 Verification by microbiological swabbing should be undertaken commensurate with product and process risk.

3.2.13 Records of swab locations, methodology, corrective action and retests of swab locations shall be maintained.

3.2.14 Clean in Place (CIP) systems shall have procedures documented and implemented to ensure there are no residual cleaning chemicals in products.

3.2.15 Verification of the CIP system is required to be carried out on at least an annual basis.

3.3 Approved Supplier Program

3.3.1 An approved supplier program shall be documented and implemented for all products and services that could affect the food safety or quality of the finished product at a minimum.

3.3.2 The scope of the approved supplier program shall include raw ingredients, packaging, chemical, service providers and third party contractors. Processes and procedures shall be in place to control any outsourced processing activity.

3.3.3 For each supplier, the following requirements shall be defined for:
- the selection and approval of suppliers and service providers
- emergency suppliers/providers
- removing suppliers/providers

3.3.4 A list of approved suppliers shall be documented, maintained and reviewed annually (as a minimum).

3.3.5 An annual review of all approved suppliers shall be undertaken to verify their performance.

3.3.6 Methods of monitoring incoming products and services shall be documented and implemented and records maintained

3.3.7 Records of approval evidence shall be maintained and may include current copies of third party food safety certification certificates, and questionnaires and formal agreements, methods of insurance and licences for service contractors.

Excellence

3.3.8 Suppliers should be risk assessed and assigned a risk rating

3.3.9 Requirements on suppliers, if applicable, for product verification (domestic and international) shall be documented and ensure compliance of all relevant regulatory requirements in the country of manufacture and sale.

Guidance Note:
Examples of approval requirements could include: the requirement for the supplier to have a certified HACCP system in place, internal audits of the supplier by the organization, product testing by the supplier (including certificates of analysis), product testing by the organization or a combination of these requirements. The rigour of the Approved Supplier Process will be determined according to the food safety risk. Examples of approval requirements could include evidence that the packaging is food grade (if it makes contact with the food), certified HACCP /or quality assurance system in place. Services include but are not limited to; Pest control, Laundry services, Contracted cleaners and Calibration, contracted maintenance, off-site storage, laboratories, consultants and waste management.

3.4 Specifications

3.4.1 Manufacturers, further processors and/or repackers shall have documented specifications available for all raw materials (including packaging) and finished products that are handled by the site.

3.4.2 Where products are not manufactured, further processed or repacked, finished product specifications shall be available.

3.4.3 The specifications shall contain appropriate information to ensure compliance with relevant food safety and legislative requirements.

3.5 Labelling

3.5.1 The organization shall document, develop and implement a procedure for the preparation of and reviewing of labels which includes:

- Labels shall be prepared so as to comply with all relevant regulatory requirements, trade measurement requirements and other applicable regulations that may apply in certain specific sectors (e.g. meat industry) in the country of manufacture and sale
- Labels shall be reviewed at least annually and more frequently if any of the following occur;
    - Changes to laws in relation to labelling
    - Changes in raw materials
    - Changes to processing equipment
    - Changes to recipes including the introduction of ingredients that contain allergens
    - Changes to the labels/packaging are made
    - Nutritional, health or related claims made on labels / packaging shall be validated
    - The label shall be checked prior to production commencing. This shall include; the correct label, use by/best before date and legibility

3.5.2 All records of labelling reviews shall be maintained.

3.6 Allergen Management Program

3.6.1 An Allergen Management Program shall be documented and implemented to ensure the effective management of allergenic materials to prevent cross contamination. It shall include:

- A documented risk assessment for raw materials. The risk assessment shall be considered as part of the Approved Supplier Program, product development, production scheduling and cleaning procedures
- Receipt and storage of allergenic raw materials
- A list of all allergenic ingredients on site
- Control measures to prevent cross contamination into products not containing the allergen
- Scheduling of production around allergens
- Policies relating to the use of allergenic ingredients in rework
- Consideration of allergens during product development
- Mandatory declaration of allergens on product labels
- Allergen claims shall be validated on at least an annual basis
- Validation and verification procedures

3.6.2 Staff shall be trained in the Allergen Management Program

Guidance Note:
In premises where allergen control is essential, "allergen cleans" are required between product runs, including retention of first-run product following the clean to test for allergen traces.

3.7 Packaging

3.7.1 All packaging shall be fit for purpose. This shall take into account the product characteristics.

3.7.2 Packaging should be stored separately from raw materials and finished product.

3.7.3 Packaging shall be protected from contamination.

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.

3.8.2 The controls shall define the action(s) to be taken when monitoring and verification procedures reveal that products do not meet specifications.

3.8.3 The procedures shall state what action is to be taken regarding the affected product, the process for root cause analysis and what will be done to prevent recurrence.

3.8.4 The person who has the responsibility for the control on non-conforming product shall be documented (this includes identifying non-conforming product and the decision for release, rework or discard).

3.8.5 Records of non-conforming product from raw material, work in progress, packaging, through all stages of the process shall be maintained to ensure full traceability. Records may include quarantine records, corrective action 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.

3.9.2 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
- Pet food/animal feed
- Waste product(s)
- Cleaning chemicals and
- Packaging
- Research and Development materials

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

3.9.4 Records of traceability shall be maintained.

3.9.5 Traceability procedures shall be reviewed annually.

3.9.6 This annual review shall include a test of the traceability process on at least an annual basis.

3.10 Corrective Action

3.10.1 The organization shall have in place a documented corrective action procedure in addition to the corrective action requirements detailed on the HACCP Audit Table and prerequisite programs.

3.10.2 The organization shall demonstrate that they are able to use information from identified failures in the Food Safety Management System to identify the root cause, make necessary corrections and prevent re-occurrence.

3.10.3 Corrective action procedures shall be implemented for the following situations:
- Customer complaints
- Continual product rejections
- Production of unsafe products
- HACCP & GMP Food Safety System failures

3.10.4 The organization shall identify the personnel who have the authority to investigate and address the corrective action.

3.10.5 The organization shall ensure that the corrective actions have been completed in a timely manner.

3.10.6 The procedure shall describe how corrective actions are to be recorded, reviewed and investigated. Records shall be maintained.

3.10.7 Appropriate action shall be taken to ensure that non-conforming product has been identified and isolated as per clause 3.8 Control of Non-Conforming product.

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 organization shall undertake an annual mock recall to verify the effectiveness of the recall procedure and demonstrate actions taken as a result of that recall. (This makes up part of the product traceability exercise refered 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 Premise

3.12.1 Premise Requirements

3.12.1.1 The premise shall be suitable for the type of product being manufactured.

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

3.12.1.3 A documented process for monitoring the condition of the premise shall be in place.

3.12.1.4 The monitoring frequency shall be documented.

3.12.1.5 Records shall be kept and corrective actions addressed within an appropriate time frame.

3.12.1.6 Where required, the premise shall be registered with the local council or relevevant government authority.

3.12.2 External Areas

The external areas around the facility shall be maintained in a clean and tidy manner that does not pose a risk to the products.

3.12.3 Layout, Product Flow and Segregation

3.12.3.1 The process flow together with the use of effective, implemented procedures, shall be in place to mimize the risk of contamination of raw materials intermediate/semi processed products and finished products.

3.12.3.2 The movement of personnel, raw materials, utensils, packaging rework and/or waste shall not compromise the food safety of products.

3.12.3.3 Appropriate segregation shall be maintained between areas of low risk and high risk.

3.12.4 Building Fabric

3.12.4.1 The fabrication of the buildings and facilities shall be suitable for the intended purpose.

3.12.4.2 Walls shall be in good condition and easy to clean.

3.12.4.3 The walls shall be light in colour, smooth and impervious to moisture.

3.12.4.4 Floors shall be in good condition with no pooling water areas.

3.12.4.5 Floors shall be smooth and impervious to moisture.

3.12.4.6 There shall be coving between the floor and wall joins to facilitate cleaning in production area.

3.12.4.7 Drains shall be in good condition.

3.12.4.8 Any flowing water shall be directed into drains.

3.12.4.9 The fall of the floor shall be towards the drains and of an appropriate gradient to facilitate drainage.

3.12.4.10 Waste water shall not drain from low risk to high risk areas.

3.12.4.11 Ceilings (including false ceilings) shall be light coloured, easy to clean and not allow pest or dust ingress

3.12.4.12 Windows in the processing areas shall be kept closed or have adequate pest proofing.

3.12.4.13 Doors shall be close fitting into production areas.

3.12.4.14 Doors shall be kept closed at all times when not in use.

3.12.4.15 Lighting shall be adequate for the activities being carried out.

3.12.4.16 Glass including lights shall be laminated to minimise and contain any breakage.

Excellence

3.12.4.17 Glass windows should be kept to a minimum within the processing areas or removed.

3.12.5 Staff Amenities

3.12.5.1 Staff amenities include areas for staff to keep personal belongings, toilets, hand-washing and drying facilities, areas for eating drinking and smoking.

3.12.5.2 Staff amenities shall be of a sufficient size to accommodate the number of personnel.

3.12.5.3 The facilities shall be maintained in a clean and tidy manner.

3.12.5.4 Toilets shall not open directly to processing areas and shall be equipped with hand washing stations.

3.12.5.5 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.

3.12.5.6 Hand washing stations in high risk areas shall have hands free operation.

3.12.5.7 Hand sanitiser shall be used in high risk process areas. For low risk process areas, hand sanitiser should be used.

3.12.5.8 Designated facilities for eating, drinking, smoking are located away from food production areas.

3.12.5.9 Personal outdoor clothing shall be kept separated from protective clothing.

3.12.5.10 There shall be an appropriate amount of personal protective clothing for staff and visitors. There shall be appropriate receptacles for staff and visitors to place dirty personal protective clothing.

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

3.13 Receival and Storage

3.13.1 Documented and implemented procedures shall be in place to outline the controls that are in place for the storage of products.

3.13.2 These procedures shall include stock rotation, allergen management, cleaning, stock/inventory control, segregation of non-conforming product and handling to minimise stock damage and cross contamination.

3.13.3 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 the busiest time of year.

3.13.4 Temperature controlled storage facilities shall be able to maintain temperature and ice free.

3.13.5 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.

3.13.6 Temperature controlled monitoring records of storage areas shall be maintained.

3.13.7 Receival records shall be maintained.

3.13.8 If deliveries/receivals are unloaded outside the facility controls shall be in place to ensure that the product is moved inside as soon as practical.

3.13.9 Contingencies for receiving product in bad weather shall be documented and implemented.

3.13.10 A process for stock rotation shall be in place and based on first in/first out principle for ingredients and packing.

3.13.11 There shall be processes in place to control the rotation of these materials.

3.13.12 When alternative storage facilities are used these shall be included in the HACCP Plan and monitored for GMP.

3.13.13 Where the alternative storage facilities are owned by a third party they shall be included in the Approved Supplier Program.

3.14 Dispatch and Transport

3.14.1 All vehicles used to transport raw materials, packaging, work in progress and/or finished product shall be maintained in a good state of repair and in a clean and hygienic condition to maintain integrity and to prevent cross contamintation.

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

3.14.3 Records shall be maintained of all cleaning, maintenance (including calibration), inspection and temperature control of the vehicle.

3.14.4 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.

3.14.5 Procedures shall be documented and implemented for the breakdown of transport vehicles.

3.14.6 Where applicable, transport vehicles shall be registered with the local relevant government authority.

3.14.7 Contingencies for dispatching product in bad weather shall be documented and implemented.

3.15 Control of Water, Ice, Air and Other Gases

3.15.1 Water

3.15.1.1 An adequate supply of potable water shall be available to ensure the safety and suitability of the products supplied.

3.15.1.2 Potable water shall be used for the following activities – post-harvest wash treatments, hand-washing, cleaning, ingredient, making and drinking water.

3.15.1.3 Recirculated ice water for reuse in production, hand-washing and/or cleaning shall be treated.

3.15.1.4 The treatment process shall be effectively monitored and the treated water tested to verify its safety (potability).

3.15.1.5 The requirement for water testing shall be based on the risk of the product and/or process.

3.15.1.6 Where applicable, water (including ice where applicable) testing program including shall be documented and implemented.

3.15.1.7 The program shall include the frequency of testing, test method, limits and action to be taken for results that are outside of limits.

3.15.1.8 The frequency for water testing shall be based on the risk of the product and if the water or ice is used in the process.

3.15.1.9 Water testing shall be carried out at least annually if water testing is deemed necessary in clause 3.15.1.6.

3.15.1.10 Any sources of non-Potable Water used on the site shall be risk assessed and monitored to ensure that there is no risk of cross contamination with product. Testing of non-potable water sources should be included in the water testing program depending on the product and/or process risk.

3.15.1.11 Where ice is manufactured on the site, ice shall be included in the raw material risk assessment.

3.15.2 Air and other Gases

3.15.2.1 Air, steam and other gases used directly in contact with product shall be food grade.

3.15.2.2 Filters and other equipment used for air and other gases shall be included in the maintenance and calibration procedures.

Excellence

3.15.2.3 Air, steam and other gases used directly in contact with product shall be food grade and shall be verified as appropriate on at least an annual basis.

3.15.2.4 This program shall be documented and include the frequency of testing, test, test method, limits and action to be taken for results that are outside of limits

3.16 Control of Foreign Materials

3.16.1 General

3.16.1.1 Procedure for the control of foreign materials shall be documented and implemented.

3.16.1.2 Foreign material hazards shall be included in the HACCP Plan.

3.16.1.3 The organization shall register all equipment that is used for the control of foreign materials (i.e. metal detection, sieves, optical sorters).

3.16.1.4 The control methods shall be validated and verified.

3.16.1 .5 Where metal detectors, X rays, magnets and/or optical sorters are used they shall be serviced at least annually or as recommended by the equipment manufacturer.

3.16.1.6 The operating parameters for the equipment shall be according to manufacturer's instructions.

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

3.16.2 Metal

3.16.2.1 There shall be a documented and implemented policy in place for the control of metal items including but not limited to knives, needles, wires, staples and knife sharpening equipment.

3.16.3 Glass, Brittle Plastic, Ceramics and Similar Products

3.16.3.1 Glass and other Brittle Plastics shall be excluded from the processing area or protected against breakage.

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

3.16.3.3 This policy shall include the handling of breakages.

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

3.16.4 Soft Plastics

Excellence

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

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

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

Guidance Note:
Soft plastic includes but is not limited to gloves, aprons and product liners.

3.16.5 Wood

3.16.5.1 A wood policy outlining the control of wood within the processing environment shall be documented and implemented.

3.16.5.2 Wood shall be excluded from the processing areas unless the wood is part of the processing equipment.

3.16.5.3 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.

3.17.2 A list of chemicals available on the site, any dilutions and the intended use for each chemical shall be documented.

3.17.3 Current Material Safety Data Sheets (MSDS) shall be maintained for any chemical that is being used or stored on site.

3.17.4 Where these is no recorded expiry date on the MSDS the expiry date shall be five (5) years from the date of issue.

3.17.5 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.

3.17.6 Chemicals shall be stored according to the manufacturers' instructions and stored in a locked cupboard when not in use.

3.17.7 Controls shall be in place for the dilution of chemicals. Chemicals shall be labelled at all times.

3.17.8 Chemicals shall not present any direct contamination to the process and/or product.

3.17.9 All staff 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 procedure and schedule for all food processing plant, equipment, services, premises and surrounds.

3.18.2 The preventative maintenance schedule shall be implemented.

3.18.3 Maintenance activities conducted shall ensure it does not pose a food safety risk to the products.

3.18.4 Personnel (staff or contractors) involved in maintenance activities shall adhere to the personal hygiene requirements outlined in section 3.1.

3.18.5 Temporary repairs shall be controlled to ensure the food safety and legality of the product.

3.18.6 Temporary repairs shall be permanently repaired as soon as practicable.

3.18.7 Maintenance staff and contractors shall take measures to ensure any tools they use are suitable for food production areas and ensure they remove all equipment, utensils when maintenance is completed.

3.18.8 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.

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

3.18.10 Maintenance workshops shall be maintained in a clean and tidy manner.

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

3.18.12 Materials used for equipment used to produce, prepare, store, process, or pack food shall be suitable for purpose, food grade (if in direct contact with food), easily cleaned, and assessed regularly to ensure it is in good condition.

Excellence

3.18.13 A record shall be kept of equipment inspections.

3.18.14 Steel wool, where required, shall be maintained in good condition. (steel wool shall not be used inside the processing area).

3.18.15 Maintenance workshops shall be pest proofed.

Guidance note: Steel wool is permitted in maintenance areas for the purpose of conducting maintenance. The steel wool shall be kept in good condition and appropriate checks are to be carried out to ensure no fragments become trapped in the equipment or can enter the processing areas.

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 can be relied upon.

3.19.2 A calibration schedule shall be available and include the following:
- A list identifying all equipment that requires calibration
- Frequency of calibration
- Method of calibration
- Acceptable degree of accuracy
- A method of identifying equipment that is out of calibration
- A method for taking Corrective Action on product produced whilst equipment was out of calibration
- Any specific requirement/s for calibration e.g. calibration to be undertaken by an ISO17025 accredited service provider.

3.19.3 Staff conducting calibrations and reviewing calibration records shall be appropriately trained.

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

Guidance Note:
Examples of equipment that require calibration include, but is not limited to; temperature measuring devices, pH meters, flow meters, boom sprayers, weighing scales, data loggers, etc.

3.20 Training

3.20.1 The organization shall develop and implement a skills and knowledge training program.

3.20.2 The training program shall include, but not be limited to; food safety, HACCP, allergens, cleaning, and GMP/GWP.

3.20.3 Staff members whose actions directly or indirectly impact food safety shall be competent in food safety at a level appropriate to the role they perform.

3.20.4 Staff members shall be made aware of the policies on hygiene practices at the beginning of their employment at a level appropriate to the role they perform.

3.20.5 Any staff member who is responsible for an activity that is associated with a CCP or responsible for the implementation of a prerequisite program, shall be competent in that activity or program.

3.20.6 Staff members moving into new roles shall be trained in that role.

3.20.7 The food safety skills and knowledge training program shall include a review of staff competence as part of the Internal Audit program (section 2.12.3) and the HACCP & GMP Food Safety Management System Review (section 2.12.2).

3.20.8 Records of all training, qualifications and competence reviews undertaken by staff shall be maintained.

3.20.9 A training matrix shall be documented and include the skills required and the individual competencies for each skill.

Excellence

3.20.10 The organization shall document the responsibility and the process for ensuring that the appropriate personnel have been trained in any changes to legislation.

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

3.21 Waste Management

3.21.1 The organization shall have a documented and implemented waste management system in place.

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

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

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

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

3.21.6 Equipment used in waste management shall be included in the cleaning program.

3.22 Pest Management

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

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

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

3.22.4 The program shall also include:

- Bait maps depicting the type and location of treatments
- Bait stations shall be secured against movement and tampering
- The chemicals used and the concentration
- A current Material Safety Data Sheets (MSDS) shall be maintained for any pest control chemical that is being used or stored on site. Where no expiry date is recorded the expiry date shall be determined to be five (5) years from the date of issue
- If chemicals are stored on the site, these shall be stored separate from processing areas and chemicals used for production or maintenance purposes
- Where an external pest control contractor is used a copy of the contractor's current licence shall be maintained. The license shall be valid for the state in which the premise is located or;
- Where pest control activities are carried out by internal personnel, these personnel shall be suitably trained and records of training kept

Guidance Notes:
"Suitably trained personnel" are required to be trained in accordance with local laws for chemical handling

- Records of monitoring and corrective action shall be maintained
- Chemicals used to control pests on or near food, food packaging, or food contact surfaces shall be suitable for use in a food premise
- Toxic bait stations shall not be located in the production areas
- Staff shall be trained to report pest sightings
- Electric Fly Killers/Flying Insect Control Units shall not be used inside food manufacturing areas where they pose a risk to the product, packaging or processing equipment.

4.1 Audit Scope

The scope of the audit is drafted at the proposal stage and then confirmed during the assessment. The audit scope outlines where the organization's responsibilities for the process begin and end. The audit scope is verified during the certification audit.

The auditor assessing the organization will have the appropriate training and experience in the products being manufactured. The scope is product and location specific. Any changes relating to the products or location of the site shall be communicated with BSI at the time the change occurs. Some changes in the scope may mean that the certificate is no longer valid and a re-audit maybe required.

4.2 Excluded Products

Products can be excluded from the scope of certification where the excluded products can be clearly segregated i.e. products are produced in a separate facility on the site OR where the products are manufactured on a different piece of equipment.

4.3 Exemptions to HACCP & GMP Criteria

Clauses of this criteria document may be excluded where an organization can demonstrate that the clause/s do not apply. Applications for exemption shall be in writing and forwarded to Compliance and Risk – Global Food for review and approval. Exemption will be granted for 12months after which a new application is will be required to be completed. Exemptions shall be provided to your auditor for review during your assessment.

A separate application for each clause shall be submitted.

Applications shall include the following information;

- Client Name
- Clause Reference
- Justification for Exemption
- Risk Assessment

Your local BSI Compliance and Risk can provide your organization with a form to assist with your application.

4.4 Extension to Scope

Once certification has been granted, any significant changes to products and processes that are included in the scope of certification shall be communicated to BSI Compliance and Risk.

A review of the significance of the changes will be carried out to determine the impact on the validity of the current certificate.

If the change is not deemed to be significant (i.e. the new products are produced on existing equipment or are an extension to an existing range) a change will be made in the certificate.

If the change is deemed to be significant then an on-site reaudit needs to occur before any changes can be made to the certificate. The expiry date of the certificate will not be changed.

Examples of a significant change include:

- An extension to the facility that was covered in the original audit
- New processing equipment and / or technology
- Introduction of new products that alter the food safety hazards on the site (i.e. packaging materials, allergens)

Depending on the nature of the change and the date of the next audit it may be decided to include the extension to scope at the next audit activity.

All non-conformances that are raised as a result of the extension to scope are required to be closed prior to issuing the updated certificate.

4.5 HACCP Only or GMP Only Certification

For organizations requiring certification to HACCP or GMP only compliance to the modules and clauses are listed in Table 1 below.

The HACCP only option is not available to manufacturers, food retailers and food service organizations.

Table 1 - HACCP & GMP Modules

HACCP & GMP	HACCP	GMP only
Module 1 Module 2 Module 3	Module 1 Module 2 Including additional elements of (but not limited to) – 3.3 Approved Supplier Program 3.4 Specifications 3.5 Labelling 3.11 Recall 3.20 Training	Module 3 (only) Including additional elements for – 1.1 Management Commitment 1.5 Document Control

4.6 Multi-Site Certification

Multi-site certification is not applicable to the BSI HACCP & GMP Certification Criteria because certification is site specific covering the product/s and process identified within the scope of the each site's Food Safety Management System.

4.7 Head Office Certification

Head office sites that require HACCP certification shall be assessed to Module 1 and 2 of the Criteria only. A HACCP (only) certificate will be issued upon gaining certification. The certified scope for head office sites is limited to those activities that are managed and controlled by the head office.

4.8 Audit Frequency

The audit frequency is determined by the outcome of the HACCP & GMP Audit (Table 2), or a GFSI standard (e.g. BRC or SQF), or as another standard requires if these audits are combined. If the frequency of a GFSI standard audit changes, the BSI HACCP & GMP certificate criteria audit frequency will reflect this change.

If an organization chooses to combine their BSI HACCP & GMP audit with a compatible supplier standard the audit frequency will be determined by the standard that requires the greater rate of audits.

In those instances where seasonality of product/production/manufacture occurs or another standard owner requirement exists, audit frequency can be reviewed on a case by case basis upon request to the BSI Compliance and Risk Department.

In the event a site requires a reaudit, BSI will suspend the HACCP & GMP certificate, and an auditor will return to the site within the timeframe stipulated (in Table 2) to conduct a reaudit of the actions and to close non-conformances.

Table 2 – Determination of audit frequency – the following combinations of non-conformances will determine the audit frequency

		Critical Non-Conformance	Major Non-Conformance	Minor Non-Conformance
Annual Audit		0	0	0 to 15
		0	1 to 2	0 to 10
6 Monthly Audits		0	Less than 3	16 to 15
		0	3 to 5	0 to 15
Reaudit	28 days	1 or more	0	0
	3 months	0	3 to 5	16 or more
	3 months	0	6 or more	0 or more

Examples - An organization that:

a) receives 0 critical, 0 major and 7 minor non-conformances will be audited in 12 months' time.
b) receives 0 critical, 2 major and 5 minor non-conformances will be audited in 12 months' time.
c) receives 0 critical, 2 major and 18 minor non-conformances will be audited in 6 months' time.
d) receives 0 critical, 4 major and 12 minor non-conformances will be audited in 6 months' time.
e) receives 1 critical non-conformance will require a reaudit within 28 days of the audit.
f) receives 0 critical, 3 major and 17 minor non-conformances will require a reaudit within 3 months of the audit.
g) receives 0 critical, 6 major and 0 minor non-conformances will require a reaudit within 3 months of the audit.

4.9 Audit Duration

The duration of a BSI HACCP & GMP Audit depends on the specific application submitted. Aspects of the activities such as organization scope, products, processes and risks are used to make this determination. It will vary with organization size and complexity. The audit duration will be established at the time the proposal is collated.

There are no audit duration calculations used to determine the audit duration. Where the HACCP & GMP Audit is being carried out combined with a GFSI or ISO standard audit, durations applied to those schemes will be adhered to. Additional time will be allocated to the audit duration associated with those schemes to cover any specific requirements in the Criteria.

4.10 Auditor Rotation

Three (3) consecutive audit visits is the maximum period an auditor shall visit the same organization without another auditor performing an audit activity at the site. Another auditor is required to conduct the fourth audit to ensure impartially of the audit process is maintained.

4.11 Audit Planning

Once the proposal has been signed the organization shall agree an audit date with BSI. An optional gap audit can be carried out to determine the readiness of the site for audit. There is no requirement for a Document Review.

Ideally at least three (3) months of production records will be available for an auditor to review to determine the implementation of the Food Safety Management System.

HACCP & GMP certification cannot be transferred from one certification body to another because the audit criteria between certification bodies are different. An audit can be carried out once the date has been agreed.

All audits need to take place when the product/s are being manufactured/produced (unless the organization is a Broker). This allows the auditor to verify the activities on the site.

4.12 Audit Reporting

BSI auditors complete a checklist while on site. This documents the objective evidence that has been sighted during the audit and provides guidance for the auditor to ensure that all areas of the standard are covered.

At the conclusion of the audit the auditor will present the findings and will leave a copy of the non-conformances on the site before they leave. This may be in either hard or soft copy.

A BSI audit report will be sent to the organization within five (5) days of the last day of the audit.

BSI undertakes an extensive technical review of audit reports and there may be occasions when the grading of a non-conformance is revised based upon discussions with the BSI Compliance and Risk Department.

4.13 Non-Conformance and Corrective Action

The level of non-conformity assigned to a finding by an auditor is based on the objective evidence and observation obtained during the audit. The following lists the rating of the findings from the audit.

Compliance
Indicates conformance to the clause/requirement within the criteria.

Observations
Observations are areas that could be considered by the organization to improve their business. These areas may be where the intent of the standard has been met however, some improvement my assist the business in achieving “best practice”.

Minor Non-Conformances
Minor non-conformances are where the requirements of the standard have partially not been met. It could be that a procedure has not been fully documented or implemented or during the premise inspection issues may have been identified that do not present a direct risk to the product.

Minor non-conformances shall be closed out within 30 days of the completion of the last day of the site audit by the auditor sighting objective evidence. Issues that are not satisfactorily addressed may be upgraded to a major non-conformity.

Initial certification will not be granted or continued until such time as the proposed corrective action has been agreed.

Major Non-Conformances
Major non-conformances are raised where the requirements of the standard have not been met. It could be that a procedure has not been documented or implemented, there have been CCP failures that have not been identified or during the premise inspection issues were identified where there is a direct risk to the product. This may be one incident or the combination of several lesser issues.

These shall be closed out or downgraded to a minor non-conformity within 14 days of completion of the on-site audit to enable certification to be granted or continued. Major non-conformances may require the auditor to return to the site to verify implementation of the organization's corrective action. A major non-conformity can only be closed out or downgraded when the auditor has seen objective evidence that the corrective action has been taken and is effective.

Critical Non-Conformances
A critical non-conformance is raised if issues directly relating to the legality of the product is identified (i.e. undeclared allergen or preservative level above the legal limit or positive pathogen result in product)

Certification will be suspended or may be cancelled pending sufficient corrective action. Depending on the nature of the non-conformity, BSI may be obliged to notify standard owners, health authorities, regulatory agencies or associated bodies. This process will be communicated with the organization to ensure that the process and the ramifications at the time of the audit are understood.

Close out of Non-Conformances:
It is the responsibility of the organization to ensure that non-conformances are closed out within the allocated time frame to avoid certification being affected.

Certification will be suspended or may be cancelled pending sufficient corrective action. The information required to demonstrate close out of the non-conformance is required to include the correction, root cause analysis and corrective action.

4.14 Certification and Use of Assurance Mark Logo

At the conclusion of the audit the auditor will make a statement in the report advising whether certification (or re-certification) is recommended. The final decision on certification is made by the BSI Compliance and Risk Department at the certification decision phase. Any changes to the audit report will be communicated to the organization by either the auditor or the Compliance and Risk Department.

Certificates will be issued three (3) yearly or when the organization details or audit scope require change.

The scope of certification and the details relating to the name of the organization will be the same as the wording in the audit report. These details shall be agreed between BSI and the organization at the commencement of each audit.

Once an organization has been certified, the organization is entitled to use the BSI Assurance Mark HACCP & GMP Logo whilst certification to this program with BSI is maintained. For a copy of the BSI HACCP & GMP Assurance Mark Logo you must contact brand@bsigroup.com

Use of the BSI HACCP & GMP Assurance Mark Logo is subject to the BSI Assurance Mark guidelines available on the BSI website.

4.15 Accreditation

The BSI HACCP & GMP Certification Criteria is not an accredited standard.

Where an organization requires an accredited standard (for example when exporting product), BSI offers a range of suitable alternative standards. These options can be discussed with BSI.

4.16 Feedback and Complaints

All complaints will be investigated and the originator of a complaint will be advised of the outcomes as appropriate.

Appeals against certification decisions and / or complaints against service delivery levels may be raised with your auditor. If you remain dissatisfied, contact your local BSI Compliance and Risk Department.