BRC GLOBAL STANDARD FOR FOOD SAFETY

Issue 5

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1	**SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT**
1.0 FUNDAMENTAL Statement of Intent	**The company's senior management shall demonstrate they are fully committed to the implementation of the requirements of the Global Standard for Food Safety. This shall include provision of adequate resources, effective communication, systems of review and actions taken to effect continual improvement. Opportunities for improvement shall be identified, implemented and fully documented.**
1.1	The company's senior management shall provide the human and financial resources required to implement and improve the processes of the quality management system and the food safety plan.
1.2	There shall be clear communication and reporting channels to senior management for departments responsible for monitoring compliance with the Global Standard for Food Safety. The departments shall report regularly on effective compliance.
1.3	The company's senior management shall ensure that food safety and quality objectives are established, documented, monitored and reviewed.
1.4	The company's senior management shall ensure that there is a process to identify and address any safety or legality issue at a strategic level.
1.5	The company's senior management shall take responsibility for the review process.
1.6	The review process shall be undertaken at appropriate planned intervals, as a minimum annually, to ensure critical evaluation of the food safety plan and the HACCP system's suitability, adequacy and effectiveness.
1.7	The review process shall include the evaluation of: • internal, second party and third party audits • previous management review documents, action plans and time frames • customer performance indicators, complaints and feedback • incidents, corrective actions, out-of- specification results and non-conforming materials • process performance and deviation from defined parameters • reviews of the HACCP-based system • developments in scientific information associated with the products in scope • resource requirements.
1.8	Records of management reviews shall be comprehensively documented and retained.

1.9	The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed time scales. The records shall be updated to show when actions have been completed.
1.10	The company shall have the current issue of the Global Standard for Food Safety available.
1.11	The company shall maintain certification to the Global Standard for Food Safety by effective timescale planning to ensure that certification does not expire (refer to Section III, paragraph 12).
1.12	The most senior production or operations manager on site shall attend the opening and closing meetings of the audit for Global Standard for Food Safety certification.
1.13	The company's senior management shall ensure that non-conformities identified at the previous audit against the Standard are effectively actioned.
2	**THE FOOD SAFETY PLAN – HACCP**
2.0 FUNDAMENTAL Statement of Intent	The company's food safety plan shall be based on a HACCP system which shall be systematic, comprehensive, thorough, fully implemented and maintained. Codex Alimentarius HACCP principles shall be used and reference shall be made to relevant legislation, codes of practice or guidelines.
2.1	**The HACCP Food Safety Team – Codex Alimentarius Step 1**
2.1.1	The HACCP plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for Quality/Technical, Production Operations, Engineering and other relevant functions. The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated hazards.
2.1.2	The HACCP food safety team shall have a designated and qualified team leader who shall be able to demonstrate competence and experience of HACCP.
2.1.3	Records shall be maintained that demonstrate the HACCP food safety team has the required knowledge and understanding of HACCP. In the event of the company not having appropriate in-house knowledge, external expertise may be sought, but day-to-day management of the food safety system shall remain the responsibility of the company.
2.1.4	The company's senior management shall demonstrate commitment and support to the HACCP food safety team.
2.2	**Describe the Product – Codex Alimentarius Step 2**

2.2.1	The HACCP food safety team will define the specific products and/or processes that are the subject of the HACCP plan.
2.2.2	All relevant information needed to conduct the hazard analysis shall be collected, maintained, documented and updated. The company will ensure that the HACCP plan is based on comprehensive information sources, which are referenced and available on request. This may include the following, although this is not an exhaustive list: • the latest scientific literature • historical and known hazards associated with specific food products • relevant codes of practice • recognised guidelines • food safety legislation of products in destination countries • customer requirements.
2.2.3	A full description of the product shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list: • composition (e.g. raw materials, ingredients, recipe) • origin of ingredients • physical or chemical properties that impact food safety (e.g. pH, a_w) • treatment and processing (e.g. heating, freezing, salting) • packaging system (e.g. modified atmosphere, vacuum) • storage and distribution conditions (e.g. chilled, ambient) • target safe shelf life under prescribed storage and usage conditions • instructions for use (e.g. storage, preparation) • consideration of potential misuse (e.g. storage, preparation).
2.3	**Identify Intended Use – Codex Alimentarius Step 3**
2.3.1	The intended use of the product by the customer shall be described defining the consumer target groups, including the suitability of the product for vulnerable groups of the population, e.g. infants, elderly, allergy sufferers.
2.4	**Construct a Process Flow Diagram – Codex Alimentarius Step 4**

2.4.1	A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP scope, from raw materials selection through processing, storage and distribution. As a guide, this may include the following, although this is not an exhaustive list: • plan of premises and equipment layout • raw materials including introduction of utilities and other contact materials (e.g. water, packaging) • sequence and interaction of all process steps • outsourced processes and subcontracted work • process parameters • potential for process delay • rework and recycling • low/high risk and clean/dirty area segregation • finished products, intermediate/semi-processed products, by-products and waste.
2.5	**Verify Flow Diagram – Codex Alimentarius Step 5**
2.5.1	The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.
2.6	**List All Potential Hazards Associated with Each Process Step, Conduct a Hazard Analysis and Consider any Measures to Control Identified Hazards – Codex Alimentarius Step 6, Principle 1**
2.6.1	The HACCP food safety team shall confirm the scope of the HACCP plan and identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities which may not be controlled by existing prerequisites. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and allergen risks (refer to clause 5.2). It shall also take account of the preceding and following steps in the process chain.
2.6.2	The HACCP food safety team shall conduct a hazard analysis to identify hazards which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to the following as a minimum: • likely occurrence of hazard

2.6.3	The HACCP food safety team shall consider the control measures necessary to prevent, eliminate or reduce the hazard to acceptable levels. Consideration may be given to using more than one control measure. Justification for acceptable levels in the finished product for each hazard shall be determined and documented.
2.7	**Determine the Critical Control Points(CCP) – Codex Alimentarius Step 7, Principle 2**
2.7.1	For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. CCPs shall be those control points which are required in order to prevent, eliminate or reduce a food safety hazard to acceptable levels. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be modified at that step, or at an earlier or later step, to provide a control measure.
2.8	**Establish Critical Limits for each Critical Control Point – Codex Alimentarius Step 8, Principle 3**
2.8.1	For each CCP, the appropriate critical limits shall be defined in order to identify clearly if the process is in or out of control and if the identified acceptable level of the food safety hazard in the finished product is likely to be exceeded. Critical limits shall be measurable wherever possible (e.g. time, temperature, pH) and the rationale for their establishment clearly documented. The HACCP food safety team shall take into account relevant legislation or codes of practice when establishing critical limits.
2.8.2	Any critical limits based on subjective data (such as visual inspection) shall be supported by clear guidance or examples.
2.8.3	The HACCP food safety team shall validate each CCP. Documented evidence shall show that the control measures selected are capable of consistently controlling the hazard to the level specified by the critical limit.
2.9	**Establish a Monitoring System for each Critical Control Point – Codex Alimentarius Step 9, Principle 4**
2.9.1	The HACCP food safety team shall establish a monitoring system for each CCP to ensure compliance with critical limits.

2.9.2	Each defined CCP shall be under control. The monitoring system shall be able to detect loss of control of CCPs and wherever possible provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list: • online measurement • offline measurement • continuous measurement (e.g. thermographs) • where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.
2.9.3	Records associated with monitoring CCPs must be signed by the person responsible for the monitoring and verified, as appropriate, by an authorised person. Recorded details shall include the date and result of measurements carried out.
2.10	**Establish a Corrective Action Plan – Codex Alimentarius Step 10, Principle 5**
2.10.1	The HACCP food safety team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel with regard to any products that have been manufactured during the period when the process was out of control.
2.10.2	Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until confirmed as suitable for release.
2.11	**Establish Verification Procedures – Codex Alimentarius Step 11, Principle 6**
2.11.1	Procedures of verification shall be established to confirm that the HACCP plan is effective. Examples of verification activities are: • internal audits • review of records where acceptable limits have been exceeded • review of complaints by enforcement authorities or customers • review of incidents of product withdrawal or recall.
2.11.2	Verification results shall be recorded and communicated to the HACCP food safety team.
2.12	**HACCP Documentation and Record Keeping – Codex Alimentarius Step 12, Principle 7**

2.12.1	Documentation and record keeping shall be sufficient to assist the company to verify that the HACCP controls are in place and maintained.
2.13	**Review the HACCP Plan**
2.13.1	The HACCP food safety team shall ensure that procedures exist to review the HACCP plan prior to any changes which may affect product safety. As a guide, these may include the following, although this is not an exhaustive list: • change in raw materials or supplier of raw materials • change in ingredients/recipe • change in processing conditions or equipment • change in packaging, storage or distribution conditions • change in staff or management responsibilities • change in consumer use • developments in scientific information associated with ingredients, process or product. Appropriate changes resulting from the review shall be incorporated into the HACCP plan, fully documented and validated.
2.13.2	Irrespective of any of the above changes, the HACCP plan will be reviewed at least annually and records shall be maintained.
3.0	**FOOD SAFETY AND QUALITY MANAGEMENT SYSTEM**
3.1	**Food Safety and Quality Policy**
3.1 Statement of Intent	**The company's senior management shall develop and document a food safety and quality policy which is authorised, reviewed, signed and dated by an appropriate senior manager.**
3.1.1	The policy shall state the company's intention to meet its obligation to produce safe and legal products to the specified quality, and its responsibility to its customers. This shall include the commitment for review and continual improvement. The company's senior management shall ensure the policy is communicated to all staff involved with activities relating to product safety, legality and quality.
3.2	**Food Safety and Quality Manual**
3.2	**The company shall have a food safety and quality manual which describes how**

3.2.1	The food safety and quality manual shall contain an outline of working methods and practices or references to where such an outline is documented.
3.2.2	The food safety and quality manual shall be readily available to key staff.
3.3	**Organisational Structure, Responsibilities and Management Authority**
3.3 Statement of Intent	**The company shall have a clear organisational structure and define the responsibilities, reporting relationships and job functions of those personnel whose activities affect product safety, legality and quality.**
3.3.1	The company shall have an organisation chart demonstrating the structure of the company.
3.3.2	Documented, clearly defined responsibilities shall exist and be communicated to key staff with responsibility for product safety, legality and quality systems.
3.3.3	There shall be appropriate documented arrangements in place to cover for the absence of key staff.
3.3.4	The company's senior management shall ensure a description of general duties or work instructions are in place and communicated to all staff involved with activities relating to product safety, legality and quality.
3.3.5	The company's senior management shall have a system in place to ensure that the company is kept informed of all relevant legislative, scientific and technical developments, and industry codes of practice applicable in the country of raw material supply, production and, where known, the country where the product will be sold.
3.4	**Contract Review and Customer Focus**
3.4 Statement of Intent	**The company's senior management shall ensure that processes are in place to determine any customer requirements and expectations with regard to product safety and quality, and ensure these are fulfilled.**
3.4.1	The company shall clearly identify those individuals responsible for communication with customers and shall have an effective system for communication.
3.4.2	Customer requirements relating to the development, specification, manufacture and distribution of product shall have been agreed with the customer and, where appropriate, documented and agreed prior to order fulfilment (refer to clause 3.7.2.3).

3.4.3	Customer needs and requirements shall be reviewed on a suitable predetermined frequency. Any changes to existing agreements or contract shall be agreed, documented and communicated to appropriate departments.
3.4.4	Performance indicators shall be established relating to customer satisfaction. These shall be communicated to appropriate staff and performance reviewed against these targets.
3.5	**Internal Audit**
3.5 FUNDAMENTAL Statement of Intent	**The company shall audit those systems and procedures which cover the requirements of the Global Standard for Food Safety to ensure that they are in place, appropriate and complied with.**
3.5.1	Internal audits shall be planned and their scope and frequency shall be established in relation to the risks associated with the activity. Audits shall be scheduled so that all aspects of the food safety and quality management system are audited at least annually.
3.5.2	Internal audits shall be carried out by appropriately trained competent auditors, who are independent from the audited department.
3.5.3	Internal audit reports shall identify and verify conformity as well as non-conformity.
3.5.4	Results of the internal audit shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed.
3.5.5	The completion of corrective action shall be verified.
3.5.6	A record of all programmed internal audits and associated corrective actions shall be maintained.
3.6	**Purchasing – Supplier Approval and Performance Monitoring**
3.6 **Statement of Intent**	**The company shall control all purchasing processes which are critical to product safety, legality and quality to ensure that products and services procured conform to defined requirements.**
3.6.1	The company shall have a documented supplier approval procedure and continual assessment programme in place, based on risk assessment.

3.6.2	These procedures shall include clear criteria for ongoing assessment and standards of performance required. Ongoing assessment may take the form of monitoring performance through the following, although this is not an exhaustive list: • in-house checks • certificates of analysis • supplier audit as appropriate. Records of this monitoring shall be retained.
3.6.3	The procedures shall define how exceptions are handled, e.g. the use of products or services where audit or monitoring has not been undertaken.
3.6.4	The company shall review the performance of new suppliers against defined criteria within a specified 'trial' period and thereafter at a specified frequency to decide the level of ongoing supplier performance monitoring.
3.7.1	**Documentation Control**
3.7 Statement of Intent	**The company's senior management shall ensure that all documents, records and data critical to the management of product safety, legality and quality are in place and effectively controlled.**
3.7.1.1	All documents in use shall be properly authorised and be the correct version.
3.7.1.2	Documents shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. They shall be readily accessible to relevant staff at all times.
3.7.1.3	The reason for any changes or amendments to documents critical to product safety, legality or quality systems and procedures shall be recorded.
3.7.1.4	A procedure shall be in place to ensure obsolete documentation is rescinded, and where necessary replaced with a revised version.
3.7.2	**Specifications**
3.8 Statement of Intent	**The company shall ensure that specifications exist for raw materials including packaging, intermediate/semi-processed and finished products (where relevant), and any product or service which could affect the integrity of the finished product.**
3.7.2.1	Specifications shall be adequate and accurate and shall ensure compliance with relevant safety and legislative requirements.
3.7.2.2	Manufacturing instructions shall comply with recipes as detailed in agreed customer specifications and shall be implemented.

3.7.2.3	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that they have taken steps to ensure formal agreement is in place.
3.7.2.4	There shall be a documented procedure for the amendment and approval of specifications for all parts of the process including regular reviews to ensure adequacy and status.
3.7.2.5	Specifications and/or their contents shall be accessible to relevant staff.
3.7.3	**Record Completion and Maintenance**
3.7.3 Statement of Intent	**The company shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.**
3.7.3.1	The records shall be legible, genuine, appropriately authorised and retained in good condition for an appropriate defined time period.
3.7.3.2	Any alterations to records shall be authorised and justification for alteration shall be recorded.
3.7.3.3	The company's senior management shall ensure that procedures are operated for the collation, review, maintenance, storage and retrieval of all records relating to product safety, legality and quality.
3.7.3.4	The period of retention for records shall relate to shelf life of the product and take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer, e.g. freezing.
3.7.3.5	Any legal and customer specific requirements relevant to record retention shall be taken into account.
3.8	**Corrective and Preventive Action**
3.8 FUNDAMENTAL Statement of Intent	**The company's senior management shall ensure that procedures exist to record, investigate, analyse and correct the cause of non-conformity against standards, specifications and procedures which are critical to product safety, legality and quality.**
3.8.1	Corrective actions shall be accurately documented, assigning responsibility and accountability.
3.8.2	Corrective actions shall be undertaken as soon as possible to prevent further occurrence of non-conformity.

3.8.3	Any corrective action plan relating to food safety, legality or quality shall only be agreed by personnel who have a defined responsibility and accountability for these areas of control.
3.8.4	The completion of corrective actions shall be monitored and recorded to ensure their effectiveness and completion within an appropriate timescale.
3.9	**Traceability**
3.9 FUNDAMENTAL Statement of Intent	**The company shall have a system to identify and trace product lots and follow this through all raw materials (including primary and any other relevant packaging materials and processing aids), all stages of processing and the distribution of the finished product to the customer in a timely manner.**
3.9.1	Identification of raw materials including primary and any other relevant packaging and processing aids, intermediate/semi-processed products, part-used materials, finished products and materials pending investigation, shall be adequate to ensure traceability.
3.9.2	The company shall test the traceability system to ensure traceability can be determined from raw material to finished product and vice versa and include **quantity check/mass balance** (refer to glossary). This shall occur at a predetermined frequency and results shall be retained for inspection. The test shall take place at least annually.
3.9.3	Where there is a requirement to ensure identity preservation within the supply chain, e.g. to use a logo or to make a claim to a product characteristic or attribute, appropriate controls and testing procedures shall be in place.
3.9.4	Where rework or any reworking operation is performed, traceability shall be maintained. In addition, the company must be able to demonstrate that this does not affect the safety or legal status of the finished product, e.g. ingredient declaration, allergy information or identity preservation.
3.10	**Complaint Handling**
3.10 Statement of Intent	**The company shall have a system for the effective capture, recording and management of product complaints.**
3.10.1	All complaints shall be recorded, investigated and the results of the investigation recorded.
3.10.2	Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.

3.10.3	Complaint data shall be analysed and used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.
3.11	**Management of Incidents, Product Withdrawal and Product Recall**
3.11 Statement of Intent	**The company shall have a plan and system in place to manage incidents effectively including product withdrawal and recall procedures.**
3.11.1	The company shall have procedures designed to manage effectively incidents and potential emergency situations that impact food safety, legality or quality and have effective product withdrawal and product recall procedures in place. This may include consideration and contingency planning for business continuity and product withdrawal or recall in the event of the following, although this is not an exhaustive list: • disruption to key services such as water, energy, transport, staff availability and communications • events such as fire, flood or natural disaster • malicious contamination or sabotage.
3.11.2	The company shall provide written guidance to relevant staff regarding the type of event that would constitute an incident or emergency situation that impacts food safety, legality or quality and a documented reporting procedure shall be in place.
3.11.3	An incident management procedure shall be documented, implemented and maintained. This shall include as a minimum: • identification of key personnel constituting the incident management team with clearly identified responsibilities • an up-to-date list of key contacts, e.g. incident management team, emergency services, suppliers, customers, certification body, regulatory authority • a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner • details of external agencies providing advice and support as necessary, e.g. expert laboratories, regulatory authority and legal expertise • product withdrawal and/or recall procedures • Corrective action and business recovery.

3.11.4	The procedures relating to incident reporting, product withdrawal and product recall shall be appropriate, formalised and capable of being operated at any time, and will take into account stock reconciliation, logistics, recovery, storage and disposal. The procedures shall be regularly reviewed and, if necessary, revised.
3.11.5	The product recall and withdrawal procedures shall be regularly tested, at least annually, in a way that ensures their effective operation. Results of the test shall be retained and shall include timings of key activities.
3.11.6	The company's senior management shall ensure that results of this test shall be used to implement improvements as necessary.
3.11.7	In the event of a product recall, the certification body issuing the current certificate for the site against the Global Standard for Food Safety and the appropriate authority shall be informed in a timely manner.
4.0	**SITE STANDARDS**
4.1	**External Standards**
4.1 Statement of Intent	**The site shall be of suitable size, location, construction and design to facilitate maintenance, prevent contamination and enable the production of safe and legal finished products.**
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site from any potential contaminants, they shall be regularly reviewed to ensure they continue to be effective, e.g. dust or odours control.
4.1.2	The external areas shall be maintained in good order. Where buildings are surrounded by grassed or planted areas, they shall be regularly tended and well maintained. The condition of the site shall be included within the internal audit process.
4.1.3	Where natural drainage is inadequate, external drainage shall be installed.
4.1.4	External traffic routes, under site control, shall be suitably surfaced and maintained in good repair to avoid contamination of the product.
4.1.5	The building fabric shall be maintained to minimise potential for product contamination, e.g. pipe work shall be appropriately sealed to prevent pest entry, ingress of water and other contaminants.

4.2	**Security**
4.2 Statement of Intent	**Security shall be maintained to prevent access of unauthorised persons to production and storage areas.**
4.2.1	Access to the site by employees, contractors and visitors shall be controlled and a visitor reporting system shall be in place.
4.2.2	Staff shall be trained in site security procedures and encouraged to challenge unidentified or unknown visitors.
4.2.3	Measures shall be in place to maintain site security and to ensure only authorised staff have access to production and storage areas via designated access points. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled.
4.2.4	Based on risk assessment, procedures shall be in place to ensure the secure storage of all materials including ingredients, packaging, chemicals and equipment.
4.2.5	Procedures shall be in place to ensure that finished product is held under secure storage and transportation conditions, e.g. tamper evident packing, contractual handling agreements.
4.2.6	Where required by legislation, the site shall be registered with, or approved by, the appropriate authority.
4.3.1	**Layout, Product Flow and Segregation**
4.3.1 FUNDAMENTAL Statement of Intent	**Premises and plant shall be designed, constructed and maintained. Procedures shall be in place to control the risk of product contamination and to comply with all relevant legislation.**
4.3.1.1	The process flow from intake to dispatch shall be arranged to minimise the risk of product contamination.
4.3.1.2	Physical barriers or demonstrably effective procedures shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products with particular consideration given to handling requirements for specific materials (refer to clause 5.2).
4.3.1.3	Segregation shall take into account the flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities provision.

4.3.1.4	Based on risk assessment, the cleaning of production utensils shall be carried out in segregated areas or at specific time periods separated from the production process.
4.3.1.5	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.
4.3.1.6	Cleaning and inspection of areas and equipment shall be aided by the avoidance of obstructions and where appropriate the provision of adequate space.
4.3.1.7	Temporary structures constructed during building work or refurbishment, etc., shall be designed and located to avoid pest harbourage and potential contamination of products.
4.3.1.8	The location of all transfer points shall not compromise high-risk and low-risk segregation and practices shall be in place to minimise risk of product contamination, e.g. disinfection.
4.3.1.9	Where **high-risk products** (refer to glossary) are manufactured, there shall be physical segregation between processing and finished product handling areas. This high risk area shall be fabricated and designed to a high standard of hygiene, and practices shall be in place to control ingredients, equipment, packaging, environment and personnel to prevent product contamination.
4.3.1.10	In **high-care areas** (refer to glossary) where there is a significant risk of contamination of chilled ready to eat/heat products by pathogenic micro-organisms, the processing or handling of food in these areas shall be appropriate to minimise product contamination by such micro-organisms.
4.3.2	**Fabrication – Raw Material Handling, Preparation, Processing, Packing and Storage Areas**
4.3.2 Statement of Intent	**The fabrication of the site, buildings and facilities shall be suitable for the intended purpose.**
4.3.2.1	**Walls**
4.3.2.1.1	Walls shall be designed, constructed, finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.
4.3.2.2	**Floors**
4.3.2.2.1	Floors shall be designed to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious and maintained in good repair.
4.3.2.2.2	Drainage, including drains from laboratories, where provided, shall be sited, designed and

4.3.2.2.3	Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage.
4.3.2.3	**Ceilings**
4.3.2.3.1	Ceilings and overheads shall be designed, constructed, finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.
4.3.2.3.2	Where suspended ceilings are used, adequate access to the void shall be provided to facilitate cleaning, maintenance of utilities and inspection for pest activity.
4.3.2.4	**Windows**
4.3.2.4.1	Where there is a risk to product, windows and roof glazing which are designed to be opened for ventilation purposes shall be adequately screened to prevent the ingress of pests.
4.3.2.4.2	Where they pose a risk to product, glass windows shall be protected against breakage.
4.3.2.5	**Doors**
4.3.2.5.1	Where external doors to raw material handling, processing, packing and storage areas are opened, suitable precautions shall be taken to prevent pest ingress. Doors and dock levellers in these areas shall be close fitting or adequately proofed.
4.3.2.5.2	Doors shall be in good condition and easy to clean, where required.
4.3.2.6	**Lighting**
4.3.2.6.1	Suitable and sufficient lighting shall be provided for a safe working environment, correct operation of processes, inspection of product, and effective cleaning.
4.3.2.6.2	Where they constitute a risk to product, bulbs and strip lights, including those on electric fly-killer devices, shall be adequately protected. Where full protection cannot be provided, alternative management such as wire mesh screens or monitoring procedures shall be in place.
4.3.2.7	**Ventilation**
4.3.2.7.1	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.

4.3.2.7.2	Where the process requires screened or filtered air, the equipment used for this purpose shall be easily accessible and adequately maintained.
4.3.2.7.3	Where appropriate, positive air-pressure systems shall be in place.
4.4	**Utilities**
4.4 Statement of Intent	**All utilities to and within the production and storage areas shall be designed, constructed, maintained and monitored to control the risk of product contamination effectively.**
4.4.1	All water used as a raw material in the manufacture of processed food, the preparation of product, or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable or pose no risk of contamination according to applicable legislation, either being drawn from mains supply or suitably treated according to its source.
4.4.2	Based on risk assessment, the microbiological and chemical quality of water, steam, ice, air, compressed air or other gases that does not constitute an ingredient but comes in direct contact with food or packaging shall be regularly monitored. It shall present no risk to product safety or quality and comply with relevant legal regulations.
4.5	**Equipment**
4.5 Statement of Intent	**Equipment shall be suitably designed for the intended purpose and shall be used to minimise the risk of contamination of product.**
4.5.1	All equipment shall be properly specified before purchase, constructed of appropriate materials, be of a suitable design to ensure it can be effectively cleaned, and shall be tested and commissioned prior to use.
4.5.2	Equipment shall be positioned to give access under, inside and around it for ease of cleaning, inspection and servicing, or where permanently sited shall be properly secured and sealed to the floor.
4.5.3	Certificates of conformity or other evidence shall be available for equipment in direct contact with food to confirm its suitability for use, e.g. conveyor belts.
4.6	**Maintenance**
4.6 Statement of Intent	**A documented system of planned maintenance shall be in place, covering all items of equipment and plant which are critical to product safety, legality and quality.**

4.6.1	Equipment, including fixtures and fittings, shall be maintained in such condition as to minimise the risk of product contamination.
4.6.2	When commissioning new equipment and plant, a maintenance programme shall be established and put into place based on risk assessment.
4.6.3	The company shall ensure that the safety or legality of product is not jeopardised during maintenance and cleaning operations.
4.6.4	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment failure, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.
4.6.5	Where temporary repairs are made, these shall be controlled to ensure the safety or legality of product is not jeopardised. These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale.
4.6.6	Contractors involved in maintenance or repair activities shall be under the supervision of a nominated person.
4.6.7	Maintenance work shall be followed by a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment. On completion of any maintenance work, machinery and equipment shall be clean and free from contamination hazards.
4.6.8	Materials used for equipment and plant maintenance and that pose a risk by direct or indirect contact with raw materials, intermediate and finished products, such as lubricating oil and paints, shall be suitable for the intended use.
4.6.9	Engineering workshops shall be controlled to prevent contamination risks to the product, e.g. provision of swarf mats where workshops open directly into production areas.
4.7	**Staff Facilities**
4.7 Statement of Intent	**Staff facilities shall be sufficient to accommodate the required number of personnel, and shall be designed and operated to minimise the risk of product contamination. Such facilities shall be maintained in good and clean condition.**
4.7.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly, e.g. the provision of cleaning facilities for footwear.

4.7.2	Storage facilities of sufficient size to accommodate all reasonable personal items shall be provided for all personnel who work in raw material handling, processing, preparation, packing and storage areas.
4.7.3	Outdoor clothing and other personal items shall be stored separately from workwear within the changing facilities.
4.7.4	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-wash facilities shall provide as a minimum: ▪ sufficient quantity of water at an appropriate temperature ▪ liquid soap ▪ single use towels or suitably designed and located air driers ▪ appropriate instructions for use (including consideration of appropriate language). Where **high-risk products** (refer to glossary) are handled, the following additional requirements shall be provided: ▪ water taps with hand-free operation ▪ hand disinfection.
4.7.5	Toilets shall be adequately segregated and shall not open directly into storage, processing or production areas. Toilets shall be provided with handwashing facilities comprising: • basins with soap and water at a suitable temperature • adequate hand-drying facilities • advisory signs to prompt hand washing (including consideration of appropriate language). Where hand-washing facilities within toilets are the only ones provided before re-entering production, then the requirements of 4.7.4 shall apply.
4.7.6	Designated controlled smoking areas shall be isolated from production areas to an extent that ensures smoke cannot reach the product. Where smoking is allowed under national law, sufficient extraction to the exterior of the building shall be ensured. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations. Facilities shall be available, with adequate reminders, for hand washing after smoking.
4.7.7	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas.
4.7.8	Where catering facilities are provided, they shall be suitably controlled to prevent contamination of product.

4.7.9	Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.
4.7.10	Facilities for visitors and contractors shall be such as to enable compliance with the company's hygiene policy.
4.7.11	Where an operation involving **high-risk products** (refer to glossary) exists, personnel shall enter via a specially designated changing facility, and shall follow specified procedures for applying visually distinctive clean overalls, headwear and footwear.
4.8	**Chemical and Physical Product Contamination Control** **Raw Material Handling, Preparation, Processing, Packing and Storage Areas**
4.8 Statement of Intent	**Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.**
4.8.1	Based on risk assessment, the company shall identify, control and manage any potential risks from chemical, physical or taint contamination. This may include risks associated with the following, although this is not an exhaustive list: • storage • production operation or processes or machinery • any maintenance or building work carried out • hygiene and cleaning operations. These shall be verified through regular site audits carried out at a frequency determined by risk assessment.
4.8.2	**Chemical Control**
4.8.2.1	A chemical control procedure shall be in place which manages the use, storage and handling of non-food chemicals. This shall include as a minimum: • approved purchase • availability of material safety data sheets and specifications • where appropriate, confirmed suitability for food use • avoidance of strong scented products • identification of chemicals at all times • segregated and secure storage with restricted access to authorised personnel • use by trained personnel only.
4.8.3	**Metal Control**

4.8.3.1	There shall be a documented policy for the control of the use of sharp metal implements including knives, cutting blades on equipment, needles and wires. This shall include suitable controls both into and out of the factory, and safe disposal.
4.8.3.2	Snap-off blade knives shall not be used.
4.8.3.3	Non-production blades, equipment and tools shall not be left in a position that allows them to contaminate the product.
4.8.3.4	Where staples or other items are used which are likely to cause contamination in packaging, appropriate precautions shall be taken to minimise the risk of product contamination.
4.8.4	**Glass, Brittle and Hard Plastic, Ceramics and Similar Materials**
4.8.4.1	In areas where a risk assessment has identified a potential for product contamination from glass, the presence of glass shall be excluded. Where this cannot be avoided, but the risk is managed, glass shall be protected against breakage.
4.8.4.2	Documented procedures for handling glass, brittle or hard plastic, ceramic or other similar materials shall be in place and implemented to ensure that necessary precautions are taken. Procedures shall include as a minimum: • list of items detailing location, number, type and condition • recorded checks of condition of items carried out at a specified frequency based on risk assessment • details on cleaning or replacing items to minimise potential for product contamination.
4.8.4.3	Based on risk assessment, documented procedures detailing the action to be taken in case of breakage of glass, brittle or hard plastic, which includes glass packaging and similar material, shall be implemented and include the following: • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising to continue production • changing of workwear and inspection of footwear • specifying those staff authorised to carry out the above points • recording the breakage incident.
4.8.5	**Wood**

4.8.5.1	In areas where a risk assessment has identified the potential for product contamination from wood, the use of wood shall be excluded. Where the use of wood cannot be avoided, and the risk is managed, the condition of wood shall be regularly checked to ensure it is in good condition and clean.
4.8.6	**Other**
4.8.6.1	Filters, sieves and magnets used for foreign body control shall be regularly inspected and properly maintained. Such activities shall be recorded and investigated.
4.8.6.2	Based on risk assessment, procedures shall be implemented to minimise foreign body contamination of packaging during filling operations, e.g. covered conveyors, container inversion and foreign body removal through rinsing or air jets.
4.9	**Housekeeping and Hygiene**
4.9 **FUNDAMENTAL** **Statement of Intent**	**Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of contamination is minimised.**
4.9.1	Documented cleaning procedures shall be in place and maintained for the building, utilities, plant and all equipment. Cleaning procedures shall include the following information as a minimum: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning • cleaning materials to be used • cleaning records and responsibility for verification.
4.9.2	Cleaning-in-place (CIP) facilities shall be monitored and maintained to ensure effective operation. Consideration shall be given to frequency, cycle time, temperature, chemical concentration and spray ball location and coverage. CIP shall have adequate separation from active product lines.
4.9.3	Cleaning and housekeeping shall be carried out by trained personnel in accordance with documented procedures and records shall be maintained.

4.9.4	Cleaning chemicals and equipment shall be: • fit for purpose • suitably identified for intended use, e.g. colour coded or labelled • stored in a hygienic manner to prevent contamination.
4.9.5	The effectiveness of the cleaning and disinfection procedures shall be verified and recorded. Corrective actions shall be documented.
4.9.6	Cleaning and disinfection procedures shall be revalidated following building or maintenance work, new product introduction or changes to equipment.
4.10	**Waste/Waste Disposal**
4.10 Statement of Intent	**There shall be adequate systems for the collection, collation and disposal of waste material.**
4.10.1	Systems shall be in place to avoid the accumulation of waste in production areas, and shall prevent the use of unfit materials.
4.10.2	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal, segregated and collected in appropriate designated waste containers.
4.10.3	Waste disposal shall meet legislative requirements. Where licensing is in operation for disposal of categorised waste, it shall be removed by licensed contractors and records of disposal shall be maintained and available for audit.
4.10.4	External waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: • clearly identified • designed for ease of use and effective cleaning • well maintained to allow cleaning and where required, disinfection • emptied at appropriate frequencies • covered or doors kept closed as appropriate.
4.10.5	If substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in secure product or waste disposal and shall provide records of material destruction or disposal.
4.11	**Pest Control**

4.11 Statement of Intent	**The company shall be responsible for minimising the risk of pest infestation on the site.**
4.11.1	A preventive pest control programme shall be maintained covering all areas of the site to minimise pest infestation.
4.11.2	The company shall either contract the services of a competent pest control organisation, or shall have appropriately trained staff, for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. Where the services of a pest control contractor are employed, the service contract shall be clearly defined and reflect the activities of the site.
4.11.3	Written procedures and inspection documentation shall be maintained. This shall include as a minimum: • an up-to-date, signed and authorised site plan identifying numbered pest control device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and the contractor • details of pest control products used and instructions for their effective use.
4.11.4	Bait stations shall be robust, of tamper resistant construction, secured in place and appropriately located to prevent contamination risk to product.
4.11.5	Fly-killing devices and/or pheromone traps shall be correctly sited and operational. If there is a danger of insects being expelled from any extermination device and contaminating the product, alternative systems and equipment shall be used.
4.11.6	In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to identify, evaluate and authorise the release of any product potentially affected.
4.11.7	Detailed records of pest control inspections, recommendations and actions taken shall be maintained. It shall be the responsibility of the company to ensure all of the relevant recommendations made by their contractor or in-house expert are carried out and monitored. The completion of corrective action shall be demonstrated by documented evidence.

4.11.8	Results of pest control inspections shall be assessed and analysed for trends regularly, but as a minimum: • in the event of an infestation • annually. This shall include a catch analysis from trapping devices to identify problem areas. Any such problems shall be suitably rectified.
4.12	**Storage and Transport**
4.12 Statement of Intent	**All facilities used for the storage and transportation of product, movement around the site, and dispatch of finished product shall be suitable for the purpose, maintained in good repair and in a hygienic condition.**
4.12.1	Procedures to maintain product safety and quality during storage, loading and transportation shall be developed on the basis of risk assessment and implemented accordingly. These may include as appropriate the following, although this is not an exhaustive list: • controlling temperature • cleaning storage areas and vehicles • segregating to avoid cross contamination or taint uptake • storing materials off the floor and away from walls as appropriate • ensuring that vehicles such as bulk tankers are of hygienic design and designated for food use; putting in place procedures to prevent cross contamination from previous loads • vehicle pre-loading and unloading inspection • vehicle loading or unloading in covered bays • maintaining product security and preventing damage.
4.12.2	Where temperature control is required, the storage area or transport facility shall be capable of maintaining product temperature within specification, under minimum and maximum load and under worst case ambient temperature. Storage areas shall be dry and well ventilated.
4.12.3	Where temperature control is required, documented procedures shall be in place to ensure product temperature requirements are met. This shall include temperature data-logging devices which can be interrogated to confirm time/temperature conditions **or** a system to verify and record at predetermined frequencies the correct operation of refrigeration equipment.

4.12.4	Where storage outside is necessary, items shall be protected from contamination and deterioration.
4.12.5	Receipt documents and/or product identification shall facilitate correct stock rotation of goods in storage and ensure materials are used in the correct order and within the prescribed shelf life.
4.12.6	Where the company employs third-party contractors, all the requirements specified in this section shall be clearly defined in the contract or the company shall be certificated to the **Global Standard for Storage and Distribution**.
4.12.7	Traceability shall be ensured during storage and transportation. There shall be a clear record of dispatch and receipt of goods and materials demonstrating that sufficient checks have been completed during the transfer of goods.
4.12.8	Documented maintenance and hygiene procedures shall be maintained for all vehicles and equipment used for loading/unloading (e.g. hoses of silo installations). There shall be records of the measures taken.
4.12.9	Procedures shall, where appropriate, be in place in the case of vehicle or refrigeration equipment breakdown. All incidents of vehicle or refrigeration equipment breakdown shall be recorded and corrective action documented.
5.0	**PRODUCT CONTROL**
5.1	**Product Design/Development**
5.1 Statement of Intent	**Product design and development procedures shall be in place to ensure manufacturing processes are capable of producing a safe and legal product.**
5.1.1	A HACCP-based study shall be part of the product design and development process.
5.1.2	Production trials shall be carried out and thorough testing shall validate that product formulation and manufacturing processes are capable of producing a safe and legal product against the proposed shelf life.
5.1.3	Shelf-life trials shall be undertaken using documented protocols reflecting conditions during storage and handling throughout shelf life. Results shall be recorded and retained and shall confirm compliance with relevant microbiological, chemical and organoleptic criteria.
5.1.4	Where new products are introduced, the company shall ensure control of handling requirements for specific materials (refer to clause 5.2).

5.1.5	Procedures shall be in place to confirm that product packaging conforms to relevant food safety legislation and specification and is suitable for its intended use.
5.1.6	The company's senior management shall ensure that a system is in place to confirm that labelling of the product or other forms of customer information meets legislation for the designated country of use and in accordance with the appropriate product specification.
5.1.7	Where a product is designed to enable a claim to be made to satisfy a consumer group, e.g. a nutritional claim of reduced sugar, the company shall ensure that the product formulation and production process is fully validated to meet the stated claim.
5.1.8	The product design/development process shall be documented and effectively communicated throughout the organisation, to ensure that changes in formulation are adequately assessed for safety and legality.
5.2	**Handling Requirements for Specific Materials – Materials Containing Allergens and Identity-preserved Materials**
5.2 **FUNDAMENTAL** **Statement of Intent**	**Where raw materials and finished products require special procedures for handling specific materials (e.g. material containing allergens or the requirement for identity-preserved status such as Genetically Modified Organisms, assured organic status or special designated origin) these shall be in place to ensure that product safety, legality and quality are maintained.**
5.2.1.1	The company shall carry out risk assessment of raw materials to establish the presence and likelihood of contamination by **allergens** (refer to glossary). This shall include approval of raw material specifications. The company shall implement systems to specify the integrity of the raw material and compliance with specification throughout the purchasing and supply chain.
5.2.1.2	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, intermediate and finished products.
5.2.1.3	Risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross contamination is avoided. This shall include as appropriate: • physical or time segregation while allergen containing materials are being stored, processed or packed • use of identified, dedicated equipment for processing or cleaning • all food brought onto site including that by staff.
5.2.1.4	Where rework is used, or reworking operations carried out, procedures shall be implemented to minimise cross contamination from allergen-containing materials and ensure the safety, legality and quality of the finished product.

5.2.1.5	Where a claim is made regarding the suitability of a food for allergy or food sensitivity sufferers, the company shall ensure that the production process is fully validated to meet the stated claim. This shall be documented.
5.2.1.6	Based on risk assessment, documented equipment or area cleaning procedures shall be undertaken to remove or reduce to acceptable levels any potential cross contamination in compliance with finished product specifications. This shall include validation of cleaning methods and appropriate waste handling and spillage controls.
5.2.1.7	All relevant personnel, including temporary staff and contractors, shall be appropriately trained in allergen handling procedures prior to commencing work and shall be adequately supervised throughout the working period.
5.2.1.8	Any non-conformities relating to allergen control shall be included in the management review process (refer to clause 1.7) and may include, as appropriate, internal or external incidents and customer complaints such as labelling or cross-packing errors. The review process shall also consider updates or changes in allergen legislation or scientific information.
5.2.2	**Identity-preserved Materials**
5.2.2.1	Where an identity preserved claim is made, e.g. that a product is organic, or where products brought onto site may contain materials which require segregation, e.g. Genetically Modified Organisms, the company shall carry out a risk assessment of raw materials to specify the integrity of the raw material and compliance with specification throughout the purchasing and supply chain.
5.2.2.2	Risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross contamination is avoided and that controls are in place to maintain identity preserved status.
5.3	**Foreign Body Detection**
5.3 Statement of Intent	**The company shall have appropriate foreign body detection equipment in place and ensure its effective operation.**
5.3.1	Foreign body detection equipment shall be in place unless it can be justified as not necessary. This justification shall be documented. Detection equipment shall be situated to maximise foreign body detection within the finished product.

5.3.2	The sensitivity of detection shall be specified and best practice applied with regard to the nature of the food, the location of the detector and any other factors influencing the sensitivity of the detector.
5.3.3	The metal or foreign body detector shall incorporate the following based on best practice: • an alarm on a belt stop system • an automatic rejection device which shall either divert contaminated product out of the product flow or to a secure unit accessible only to authorised personnel • in-line detectors which identify the location of the contaminant and effectively segregate the affected product. There shall be documented procedures specifying corrective and investigative action to be taken in the event of the detection of metal or a foreign body.
5.3.4	The company shall establish and implement procedures for the operation, routine monitoring, testing and calibration of the metal or other foreign body detectors. This shall include as a minimum: • frequency and sensitivity of checks • authorisation of trained personnel to carry out specified tasks • documentation of checks.
5.3.5	The company shall establish and implement corrective action and reporting procedures in the event of the monitoring and testing procedure identifying any failure of the metal or foreign body detector. Action shall include a combination of isolation, quarantining and re-inspection of all product produced since the last acceptance test of the metal or other foreign body detector.
5.4	**Product Packaging**
5.4 Statement of Intent	**Product packaging shall be appropriate for the intended use and shall be stored under conditions to minimise contamination and deterioration.**
5.4.1	Certificates of conformity or other evidence shall be available for product packaging to confirm its suitability for use.
5.4.2	Where appropriate, packaging shall be stored away from raw materials and finished product.
5.4.3	Any part-used packaging materials suitable for use shall be effectively protected before being returned to an appropriate storage area.

5.4.4	Product contact liners (or raw material/work-in progress contact liners) shall be appropriately coloured and of sufficient gauge to prevent accidental contamination where appropriate.
5.4.5	Where packaging materials pose a product safety risk, special handling procedures shall be in place to prevent product contamination.
5.5.1	**Product Inspection and Laboratory Testing**
5.5.1 Statement of Intent	**The company shall undertake or subcontract inspection and analyses which are critical to confirm product safety, legality and quality, using appropriate procedures, facilities and standards which prevent risk to product safety.**
5.5.1.1	Based on risk assessment, testing and inspection schedules shall be established to ensure specified product requirements are met. Inspection and testing methods and frequency shall be documented.
5.5.1.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or where trends indicate unsatisfactory results.
5.5.1.3	Where validation of finished product quality attributes is required, organoleptic tests shall be carried out regularly in accordance with specifications and shall be recorded.
5.5.1.4	The company shall ensure that a system of ongoing shelf life assessment is in place. This shall be based on risk and shall include microbiological and sensory analysis as well as relevant chemical factors such as pH and a_w. Records and results from shelf life tests shall validate the minimum shelf life period indicated on the product.
5.5.2	**Laboratory Testing**
5.5.2.1	Pathogen testing shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be remote from the manufacturing site.
5.5.2.2	Where routine testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented, implemented and shall include consideration of the following: • design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • protective clothing arrangements • processes for obtaining product samples • disposal of laboratory waste.

5.5.2.3	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory, or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025. Documented justification shall be available where accredited methods are not undertaken.
5.5.2.4	Procedures shall be in place to ensure reliability of laboratory results, other than those specified in 5.5.2.3. These shall include: • use of recognised test methods, where available • documented testing procedures • ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required • use of a system to verify the accuracy of test results, e.g. ring or proficiency testing use of appropriately calibrated and maintained equipment.
5.6	**Control of Non-conforming Product**
5.6 Statement of Intent	**The company shall ensure all out-of-specification product is clearly identified, labelled and quarantined.**
5.6.1	Procedures for the control of non-conforming material, including rejection, acceptance by concession, or regrading for an alternative use, shall be in place and understood by all relevant staff. Decisions shall be approved by authorised staff.
5.6.2	Corrective actions shall be implemented to avoid recurrence of non-conformance. Details of the non-conformance and action taken shall be documented.
5.6.3	All non-conforming material shall be clearly identified and quarantined as appropriate, and handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.
5.7	**Product Release**
5.7 Statement of Intent	**The company shall ensure that finished product is not released unless all agreed procedures have been followed.**
5.7.1	A procedure shall be in place, based on risk assessment, to ensure that only products conforming to specification are dispatched, and this shall include release by authorised staff.
6.0	**PROCESS CONTROL**

6.0 Statement of Intent	**The company shall be able to demonstrate effective control of all operations undertaken.**
6.1	**Control of Operations**
6.1 FUNDAMENTAL Statement of Intent	**The company shall operate procedures that verify that the processes and equipment employed are capable of producing consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.**
6.1.1	A process shall ensure that all Critical Control Points and specified limits identified through HACCP are transferred into day-to-day production controls and are fully validated.
6.1.2	Process monitoring such as temperature, time, pressure and chemical properties shall be established and adequately controlled to ensure that product is produced within the required process specification.
6.1.3	Process monitoring shall be carried out by trained staff and shall be documented.
6.1.4	In circumstances where process parameters are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.
6.1.5	In the case of equipment failure or deviation of the process from specification, procedures shall be in place to establish the safety status of the product, prior to release.
6.1.6	Corrective action shall be taken in the event of deviation of process from specification. This shall be recorded.
6.1.7	Procedures shall be in place to ensure that products are packed into the correct packaging and correctly labelled with due consideration given to product changeover.
6.1.8	In the event of changes to product formulation, processing methods, equipment or packaging, monitoring of the specified process shall be re-established based on HACCP.
6.2	**Quantity – Weight, Volume and Number Control**
6.2 Statement of Intent	**The company shall operate a quantity control system which conforms to legal requirements and additional industry sector codes or specified customer requirement in the country where the product is sold.**
6.2.1	The frequency and methodology of quantity checking shall meet the requirements of appropriate legislation governing quantity verification.
6.2.2	Where the quantity of the product is not governed by legislative requirements (e.g. bulk quantity), the product must conform to customer requirements.

6.3	**Calibration and Control of Measuring and Monitoring Devices**
6.3 Statement of Intent	**Measuring equipment used to monitor CCPs and product safety and legality shall be identified. The identified measuring equipment shall be calibrated to a recognised national or international standard. Where a traceable calibration is not possible, the company shall demonstrate the basis by which standardisation is carried out.**
6.3.1	The company shall identify measuring equipment used to monitor CCPs and product safety and legality. This shall include as a minimum: • a documented list of equipment • equipment identified and marked in accordance with requirements (e.g. numbered, calibration due date).
6.3.2	All identified measuring devices shall be checked and where necessary adjusted: • at a predetermined frequency, based on risk assessment • by trained staff • to a defined method traceable to a recognised national or international standard where possible. Results shall be documented.
6.3.3	The prescribed measuring and monitoring devices shall be: • prevented from adjustment by unauthorised staff • protected from damage, deterioration or misuse.
6.3.4	Procedures shall be in place to record actions taken when the prescribed measuring and monitoring devices are found not to be operating within specified limits.
7.0	**PERSONNEL**
7.1	**Training – Raw Material Handling, Preparation, Processing, Packing and Storage Areas**
7.1 FUNDAMENTAL Statement of Intent	**The company shall ensure that personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.**
7.1.1	All relevant personnel, including temporary staff and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.

7.1.2	Where personnel are engaged in activities relating to Critical Control Points, relevant training and documented monitoring procedures shall be in place.
7.1.3	The company shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum: • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing and auditing the implementation and effectiveness of training and competency of the trainer • consideration of the delivery of training in the appropriate language of trainees.
7.1.4	Records of all training shall be available. This shall include as a minimum: • name of trainee and confirmation of attendance • date and duration of training • title or course contents as appropriate • training provider.
7.1.5	The company shall routinely review the competencies of staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.
7.2	**Access and Movement of Personnel**
7.2 Statement of Intent	**The company shall ensure that access and movement of personnel, visitors and contractors shall not compromise product safety.**
7.2.1	There shall be a plan of the site which defines access points for personnel, travel routes and staff facilities.
7.2.2	If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials.
7.2.3	All facilities shall be designed and positioned, where possible, so that movement of personnel is by simple, logical routes.
7.2.4	Contractors and visitors, including drivers, shall be made aware of all procedures for access to premises and the requirements of the areas they are visiting, with special reference to hazards and potential product contamination.
7.3	**Personal Hygiene – Raw Materials Handling, Preparation, Processing, Packing and Storage Areas**

7.3 Statement of Intent	**The company's personal hygiene standards shall be documented and adopted by all personnel, including contractors and visitors to the production facility. These standards shall be formulated with due regard to risk of product contamination.**
7.3.1	The requirements for personal hygiene shall be documented and communicated to all personnel. Compliance with the requirements shall be checked regularly.
7.3.2	Based on risk assessment, the company shall document its jewellery policy.
7.3.3	Watches shall not be worn. Jewellery shall not be worn, with the exception of a plain wedding ring, a wedding wristband and sleeper earrings (continuous loop). Rings and studs in exposed parts of the body, such as noses, tongues and eyebrows, shall not be worn.
7.3.4	Hand cleaning shall be performed at a frequency that is appropriate, based on risk assessment.
7.3.5	Fingernails shall be kept short, clean and unvarnished. False fingernails shall not be permitted. Where visitors cannot comply, suitable control procedures shall be in place, e.g. non-handling of product, use of gloves.
7.3.6	Excessive perfume or aftershave shall not be worn.
7.3.7	Smoking (where permitted under law), eating and drinking shall only be permitted in designated areas segregated from food-handling and storage areas.
7.3.8	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster different from the product colour (preferably blue) and containing a metal detectable strip where metal detection/X-ray equipment is in use. These shall be company issued and monitored. Where appropriate, in addition to the plaster, a finger stall shall be worn.
7.3.9	A sample from each batch of plasters shall be successfully tested through a metal detector and records shall be kept.
7.3.10	Procedures shall be in place to control the use of personal medicines to minimise the risk of contamination.
7.4	**Medical Screening**
7.4 Statement of Intent	**The company shall ensure that medical screening procedures are in place for all employees, contractors or visitors who will be working in or visiting areas where product safety could be compromised.**
7.4.1	The company shall have a procedure for the notification by employees, including temporary employees, of any relevant infections, disease or condition with which they may have been in contact or be suffering from.

7.4.2	Where there may be risk to product safety, visitors and contractors shall be required to complete a health questionnaire prior to entering the raw material, preparation, processing, packing and storage areas. Where appropriate, these persons shall undergo medical screening before permission is granted.
7.4.3	There shall be written and communicated procedures for employees, including temporary employees, contractors and visitors, on action to be taken in the case of infectious disease from which they may be suffering or have been in contact. Particular consideration should be given where product safety may be compromised. Expert medical advice shall be sought where required.
7.5	**Protective Clothing – Employees or Visitors to Production Areas**
7.5 Statement of Intent	**Suitable company issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.**
7.5.1	Based on risk assessment, the company shall document and communicate to all employees, contractors or visitors the rules regarding the wearing and changing of protective clothing in specified work areas, e.g. high-risk and low-risk areas. This shall also include policies for wearing of protective clothing away from the production environment, e.g. removal before entering toilets, use of canteen and smoking areas.
7.5.2	Protective clothing shall be available that is: • provided in sufficient numbers for each employee • of suitable design to prevent contamination of the product (as a minimum contain no external pockets or sewn on buttons).
7.5.3	Clean and dirty clothing shall be segregated and controlled to prevent cross contamination.
7.5.4	Laundering of protective clothing shall take place in-house using defined and verified criteria to validate the effectiveness of the laundering process, or by an approved contracted and audited laundry. The effectiveness of cleaning shall be monitored. Washing of workwear by the employee is exceptional but shall be deemed acceptable where, based on a detailed risk assessment, it can be confirmed there is no risk to product safety. Detailed procedures shall be in place to ensure the effectiveness of the laundering process.
7.5.5	Where there is the risk of contamination, smoking and eating while wearing protective clothing shall not be permitted.
7.5.6	All scalp hair shall be fully contained to prevent product contamination.

7.5.7	Based on risk assessment, snoods for beards and moustaches shall be worn to prevent product contamination.
7.5.8	Suitable footwear shall be worn within the production environment.
7.5.9	If gloves are used, they shall be replaced regularly. Where appropriate, gloves shall be suitable for food use; of a disposable type; of a distinctive colour (blue where possible) be intact, and not shed loose fibres.
7.5.10	For operations involving **high-risk products** (refer to glossary) all visibly distinctive protective clothing (including footwear) shall be applied when entering, and removed when leaving, the high risk area and stored in a designated changing area.