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[BRC Global Standard for Food Safety Issue 7 Draft 4 for Consultation](#)

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DRAFT FOR CONSULTATION

BRC Global Standard for Food Safety Issue 7 Draft 4 for Consultation

Requirement No	REQUIREMENT
1	Senior Management Commitment
1.1	Senior management commitment and continual improvement
FUNDAMENTAL Statement of Intent	The company's senior management shall demonstrate they are fully committed to the implementation of the requirements of the <i>Global Standard for Food Safety</i> and to processes which facilitate continual improvement of food safety and quality management.
1.1.1	<p>The company shall have a documented policy which states 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 be:</p> <ul style="list-style-type: none"> • signed by the person with overall responsibility for the site • communicated to all staff.
1.1.2	<p>The <u>company's site's</u> senior management shall ensure that clear objectives are defined to maintain and improve the safety, legality, <u>integrity</u> and quality of products manufactured, in accordance with the <u>food safety and</u> quality policy and this Standard. These objectives shall be:</p> <ul style="list-style-type: none"> • documented and include targets or clear measures of success • clearly communicated to relevant staff • monitored and results reported at least quarterly to site senior management.

1.1.3	<p>Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually as a minimum, to review the site performance against the Standard and objectives set in 1.1.2. The review process shall include the evaluation of:</p> <ul style="list-style-type: none"> • previous management review action plans and time frames • results of internal, second party and/or third party audits • customer complaints and results of any customer performance reviews<u>feedback</u> • incidents, corrective actions, out of specification results and non-conforming materials • review of the management of the HACCP system, <u>food defence and authenticity</u> • resource requirements. <p>Records of the meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed time scales.</p>
1.1.4	<p>The company shall have a demonstrable meeting programme which enables food safety, legality and quality issues to be brought to the attention of senior management at least monthly and allows for the resolution of issues requiring immediate action.</p>
1.1.5	<p>The company's senior management shall provide the human and financial resources required to produce food safely <u>and</u> in compliance with the requirements of this Standard and for the implementation of the HACCP-based food safety plan.</p>
1.1.6	<p>The company's senior management shall have a system in place to ensure that the company is kept informed of <u>and reviews</u></p> <ul style="list-style-type: none"> • <u>scientific and technical developments</u> • <u>industry codes of practice</u> • <u>Potential risks to authenticity of raw materials</u> • and all relevant legislation applicable in the country of raw material supply, production and, where known, the country where the product will be sold.
1.1.7	<p>The <u>site</u> shall have a genuine, original hard copy or electronic version of the current Standard available <u>and be aware of any changes to the Standard or Protocol that are published on the BRC website.</u></p>
1.1.8	<p>Where the company site is certificated to the Standard it shall ensure that announced recertification audits occur on or before the audit due date indicated on the certificate.</p>

1.1.9	The most senior production or operations manager on site shall attend-participate in the opening and closing meetings of the audit for Global Standard for Food Safety certification. Relevant departmental managers or their deputies shall be available as required during the audit process .
1.1.10	The company's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.
1.2	Organisational structure, responsibilities and management authority
Statement of Intent	The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality and quality.
1.2.1	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.
1.2.2	The company's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instruction.

2 The Food Safety Plan = HACCP

FUNDAMENTAL Statement of Intent	The company shall have a fully implemented and effective food safety plan based on Codex Alimentarius HACCP principles.
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 leader shall have an in-depth knowledge of HACCP and be able to demonstrate competence and experience. The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated

	<p>hazards.</p> <p>company not having appropriate in-house knowledge, external expertise may be used, but day-to-day management of the food safety system shall remain the responsibility of the company.</p>	<p>In the event of the</p>
<u>2.1.2</u>	<p><u>The scope of each HACCP plan, including the products and processes covered, shall be defined</u></p>	
2.2	<p>Prerequisite programmes</p>	
2.2.1	<p>The company shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • cleaning and sanitising • pest control • maintenance programmes for equipment and buildings • personal hygiene requirements • staff training • purchasing • transportation arrangements • processes to prevent cross-contamination • allergen controls. <p>The control measures and monitoring procedures for the prerequisite programmes must be clearly documented and shall be included within the development and reviews of the HACCP</p>	
2.3	<p>Describe the product – Codex Alimentarius Step 2</p>	
2.3.1	<p>The scope of each HACCP plan, including the products and processes covered, shall be defined. <u>A full description f</u>For each product or group of products a full description 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:</p> <ul style="list-style-type: none"> • composition, e.g. raw materials, ingredients, allergens, recipe • origin of ingredients • physical or chemical properties that impact food safety, e.g. pH, aw 	

	<ul style="list-style-type: none"> • treatment and processing, e.g. cooking, cooling • 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, and potential for known customer misuse, e.g. storage, preparation.
2.3.2	<p>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 this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • the latest scientific literature • historical and known hazards associated with specific food products • relevant codes of practice • recognised guidelines • food safety legislation relevant for the production and sale of products • customer requirements
2.4	
2.4.1	<p>The intended use of the product by the customer <u>or potential for known misuse</u>, 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).</p>
2.5	
2.5.1	<p>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 material receipt through to processing, storage and distribution. As a guide, this should include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • 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-care/high-risk area segregation

	<ul style="list-style-type: none"> finished products, intermediate/semi-processed products, by-products and waste.
2.6	
2.6.1	The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge at least annually. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.
2.7	
2.7.1	The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. 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.
2.7.2	<p>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:</p> <ul style="list-style-type: none"> likely occurrence of hazard severity of the effects on consumer safety vulnerability of those exposed survival and multiplication of micro-organisms of specific concern to the product presence or production of toxins, chemicals or foreign bodies contamination of raw materials, intermediate/semi-processed product, or finished product. <p>Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.</p>
2.7.3	The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Where the control is achieved through existing prerequisite programmes, this shall be stated and the adequacy of the programme to control the <u>specific</u> hazard validated. Consideration may be given to using more than one control measure.
2.8	

2.8.1	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 or eliminate a food safety hazard or reduce it to an acceptable level. 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 step, to provide a control measure.
2.9	
2.9.1	For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be: <ul style="list-style-type: none"> • measurable wherever possible, e.g. time, temperature, pH • supported by clear guidance or examples where measures are subjective, e.g. photographs
2.9.2	The HACCP food safety team shall validate each CCP. Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.
2.10 Establish a monitoring system for each CCP – Codex Alimentarius Step 9 Principle 1	
2.10.1	A monitoring procedure shall be established for each CCP to ensure compliance with critical limits. 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: <ul style="list-style-type: none"> • online measurement • offline measurement • continuous measurement, e.g. thermographs, pH meters etc • Where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.
2.10.2	Records associated with the monitoring of each CCP shall include the date, time and result of measurement and shall be

	signed by the person responsible for the monitoring and verified, as when appropriate, by an authorised person. Where records are in electronic form there shall be evidence that records have been checked and verified.
2.11	Establish a corrective action plan – Codex Alimentarius Step 10, Principle 5
2.11.1	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.
2.12	Establish verification procedures – Codex Alimentarius Step 11, Principle 6
2.12.1	<p>Procedures of verification shall be established to confirm that the HACCP plan, including controls managed by prerequisite programmes, are effective. Examples of verification activities include:</p> <ul style="list-style-type: none"> • 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. <p>Results of verification shall be recorded and communicated to the HACCP food safety team.</p>
2.13	HACCP documentation and record keeping – Codex Alimentarius Step 12, Principle 7
2.13.1	Documentation and record keeping shall be sufficient to enable the company to verify that the HACCP controls, including controls managed by prerequisite programmes, are in place and maintained.
2.14	Review the HACCP plan
2.14.1	<p>The HACCP food safety team shall review the HACCP plan and prerequisite programmes at least annually and prior to any changes which may affect product safety. As a guide, these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • change in raw materials or supplier of raw materials • change in ingredients/recipe

	<ul style="list-style-type: none"> • change in processing conditions, <u>process flow</u> or equipment • change in packaging, storage or distribution conditions • change in consumer use • <u>emergence of a new risk</u>, for example <u>known</u> adulteration of an ingredient • <u>an incident or recall</u> • developments in scientific information associated with ingredients, process or product. <p>Appropriate changes resulting from the review shall be incorporated into the HACCP plan and/or prerequisite programmes, fully documented and validation recorded.</p>
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3. Food safety and quality management system	
3.1	Food safety and quality manual
Statement of Intent	The company's processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe product.
3.1.1	The company's documented procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual.
3.1.2	The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to <u>key-relevant</u> staff.
3.1.3	All procedures and work instructions shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. This shall include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language).
3.2	Documentation control
Statement of Intent	The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use.

3.2.1	<p>The company shall have a procedure to manage documents which form part of the food safety and quality system. This shall include:</p> <ul style="list-style-type: none"> • a list of all controlled documents indicating the latest version number • the method for the identification and authorisation of controlled documents • a record of the reason for any changes or amendments to documents • the system for the replacement of existing documents when these are updated.
3.3	Record completion and maintenance
Statement of Intent	The company shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.
3.3.1	Records shall be legible, retained <u>maintained</u> in good condition and retrievable. Any alterations to records shall be authorised and justification for alteration shall be recorded. Where records are in electronic form these shall be suitably backed up to prevent loss.
3.3.2	<p>Records shall be retained for a defined period with consideration given to</p> <ul style="list-style-type: none"> • <u>any legal or customer requirements</u> • and to <u>the shelf life of the product or where an ingredient, the likely shelf life of products manufactured from the ingredient where known.</u> <p>This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing). As a minimum, records shall be retained for the shelf life of the product plus 12 months.</p>
3.4	Internal audit
FUNDAMENTAL Statement of Intent	The company shall be able to demonstrate it verifies the effective application of the food safety plan and the implementation of the requirements of the Global Standard for Food Safety.
3.4.1	There shall be a scheduled <u>planned</u> programme of internal audits <u>throughout the year</u> with a scope which covers the

	implementation of the HACCP programme, prerequisite programmes and procedures implemented to achieve this Standard. The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance; all activities shall be covered at least annually.
3.4.2	Internal audits shall be carried out by appropriately trained, competent auditors. <u>Auditors shall be independent i.e. not audit their own work.</u> , who are independent from the audited department.
3.4.3	The internal audit programme shall be fully implemented. Internal audit reports shall identify conformity as well as non-conformity and the results shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.
3.4.4	In addition to the internal audit programme there shall be a programme of documented inspections to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production. These inspections shall include: <ul style="list-style-type: none"> • hygiene inspections to assess cleaning and housekeeping performance • fabrication inspections to identify risks to the product from the building or equipment. The frequency of these inspections shall be based on risk but will be no less than once per month in open product areas.
	* FUNDAMENTAL
3.5	Supplier and raw material approval and performance monitoring
3.5.1	Management of suppliers of raw materials and packaging
Statement of Intent	The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including packaging) to the safety, <u>integrity</u> , legality and quality of the final product are understood and managed.
3.5.1.1	The company shall undertake a documented risk assessment of each raw material or group of raw materials to identify potential risks to product safety, legality and quality. This shall take into account the potential for: <ul style="list-style-type: none"> • allergen contamination • foreign body risks • microbiological contamination • chemical contamination. • <u>Substitution or fraud (see clause 5.4.2)</u>

	<p>Consideration shall also be given to the significance of a raw material to the quality of the final product. The risk assessment shall form the basis for the raw material acceptance and testing procedure and for the processes adopted for supplier approval and monitoring. <u>The risk assessments shall be reviewed at least annually.</u></p>
3.5.1.2	<p>The company shall have a documented supplier approval and ongoing monitoring procedure to ensure that <u>all suppliers of raw materials and packaging are manufacturing products under hygienic conditions</u>, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval and monitoring procedure shall be based on <u>risk and include</u> one or a combination of:</p> <ul style="list-style-type: none"> • certification, e.g. to BRC Global Standards • supplier audits <u>with a scope to include product safety, traceability, HACCP review and good manufacturing practices undertaken by an experienced and demonstrably competent product safety auditor - Or for suppliers assessed as low risk only</u> ——— • supplier questionnaires. <p>Where approval is based on questionnaires, these shall be reissued at least every three years and suppliers required to notify the site of any significant changes in the interim. <u>The site shall have an up to date list of approved suppliers.</u></p>
<u>3.5.1.3</u> NEW	<p><u>Where raw materials are purchased from agents or brokers the site shall know the identity of the last manufacturer or packer or for bulk commodity products consolidation place of the raw material. Procedures shall be in place for the approval of the manufacturer or packer as in 3.5.1.2 above.</u></p>
<u>3.5.1.34</u>	<p>The procedures shall define how exceptions are handled (e.g. where raw material suppliers are prescribed by a customer or where products are purchased from agents and direct audit or monitoring has not been undertaken).</p>
3.5.2	Raw material and packaging acceptance and monitoring procedures
Statement of Intent	<p>Controls on the acceptance of raw materials <u>and packaging</u> shall ensure that <u>raw materials these</u> do not compromise the safety, legality, <u>integrity</u> or quality of products.</p>
3.5.2.1	<p>The company shall have a documented procedure for the acceptance of raw materials and packaging on receipt based upon the risk assessment (3.5.1). Raw material <u>including packaging</u> acceptance and its release for use shall be based on one or a combination of:</p> <ul style="list-style-type: none"> • <u>product sampling and testing</u> • visual inspection on receipt

	<ul style="list-style-type: none"> • certificates of conformance — specific to each consignment • certificates of analysis — specific to the consignment • certificates of conformance — specific to each consignment product sampling and testing. <p>A list of raw materials <u>including packaging</u> and the requirements to be met for acceptance shall be available. The parameters for acceptance and frequency of testing shall be clearly defined, <u>implemented and reviewed</u>.</p>
3.5.2.2	The procedures shall be fully implemented and records maintained to demonstrate the basis for acceptance of each batch of raw materials.
3.5.3	Management of suppliers of services
Statement of Intent	The company shall be able to demonstrate that where services are outsourced, the service is appropriate and any risks presented to food safety, <u>legality, integrity and quality</u> have been evaluated to ensure effective controls are in place.
3.5.3.1	<p>There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services shall include as appropriate:</p> <ul style="list-style-type: none"> • pest control • laundry services • contracted cleaning • contracted servicing and maintenance of equipment • transport and distribution • off-site storage of ingredients, packaging or products • laboratory testing • catering services • waste management.
3.5.3.2	Contracts or formal agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential food safety risks associated with the service have been addressed.
3.5.4	Management of outsourced processing <u>and packing</u>
Statement of Intent	Where any <u>intermediate</u> process steps in the manufacture <u>or packing</u> of a product which is included within the scope of certification is subcontracted to a third party or undertaken at another company site, this shall be managed to ensure this does

	not compromise the safety, legality, <u>integrity</u> or quality of the product.
3.5.4.1	The company shall be able to demonstrate that where part of the production process is outsourced and undertaken off site, this has been declared to the brand owner and, where required, approval granted.
3.5.4.2	The company shall ensure that subcontractors are approved and monitored by successful completion of either <ul style="list-style-type: none"> • <u>certification to the</u> -BRC Global Standard for Food Safety or other GFSI-recognised Standard (see Glossary) <u>or</u> <ul style="list-style-type: none"> • <u>a documented site audit with a scope to include product safety, traceability, HACCP review and good manufacturing practices by an experienced and demonstrably competent product safety auditor.</u>
3.5.4.3	Any outsourced processing <u>or packing</u> operations shall: <ul style="list-style-type: none"> • be undertaken in accordance with established contracts which clearly define any processing <u>and or packing</u> requirements and product specification • maintain product traceability.
3.5.4.4	The company shall establish inspection and test procedures for outsourced product on return, including visual, chemical and/or microbiological testing, dependent on risk assessment.
3.6	Specifications
Statement of Intent	Specifications shall exist for raw materials including packaging, finished products and any product or service which could affect the integrity of the finished product.
3.6.1	Specifications for raw materials and packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements. The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological or physical standards).
3.6.2	Manufacturing instructions and process specifications shall comply with recipes and quality criteria as detailed in agreed customer specifications.

3.6.3	Accurate, up to date s Specifications shall be available for all finished products. These shall either be in the agreed format of the customer or, in the case of branded products, include key data to meet <u>customer and</u> legal requirements and assist the customer consumer in the safe usage of the product.
3.6.4	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 it has taken steps to ensure formal agreement is in place.
3.6.5	Specifications shall be reviewed whenever products change (e.g. ingredients, processing method) or at least every three years. The date of review and the approval of any changes shall be recorded.
3.7	Corrective action
FUNDAMENTAL Statement of Intent	The company shall be able to demonstrate that they use the information from identified failures in the food safety and quality management system to make necessary corrections and prevent recurrence.
3.7.1	<u>The company shall have a documented procedure for handling non-conformities identified within the scope of this Standard and their correction.</u>
3.7.12	<p>Where a non conformity places the safety, legality or quality of products at risk records shall to include:</p> <ul style="list-style-type: none"> • clear documentation of the non-conformity • assessment of consequences by a suitably competent and authorised person • identification of the corrective action to address the immediate issue • identification of an appropriate timescale for correction • identification of personnel with appropriate authority responsible for corrective action • verification that the corrective action has been implemented and is effective • identification of the root cause of the non-conformity and implementation of any necessary corrective actions <u>to prevent re-occurrence.</u>
3.8	Control of non-conforming product
Statement of Intent	The company shall ensure that any out-of-specification product is effectively managed to prevent <u>unauthorised</u> release.

3.8.1	<p>There shall be documented procedures for managing non-conforming products which include:</p> <ul style="list-style-type: none"> the requirement for staff to identify and report potentially non-conforming product clear identification of non-conforming product, e.g. direct labelling or the use of IT systems secure storage to prevent accidental release, e.g. isolation areas referral to the brand owner where required defined responsibilities for decision making on the use or disposal of products appropriate to the issue, e.g. destruction, reworking, downgrading to an alternative label or acceptance by concession records of the decision on the use or disposal of the product records of destruction where product is destroyed for food safety reasons.
3.8.2 NEW	<p><u>Where customer branded products not meeting specification are sold to staff or passed on to charities or other organisations this shall be with the prior consent of the brand owner. Processes shall be in place to ensure the products are fit for consumption and meet legal requirements.</u></p>
3.9	Traceability
FUNDAMENTAL Statement of Intent	<p>The company <u>site</u> shall be able to trace all raw material product lots (including packaging) from their supplier through all stages of processing and despatch to their customer and vice versa.</p>
3.9.1	<p>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.</p>
3.9.2	<p>The site <u>company</u> shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material <u>including packaging</u> to finished product and vice versa, including quantity check/mass balance. This shall occur at a predetermined frequency, <u>as a minimum annually</u> and results shall be retained for inspection. The test shall take place at least annually. Full traceability should be achievable within four hours.</p>
3.9.3 NEW	<p><u>The company shall verify that their raw material suppliers have an effective traceability system in place. Where the supplier approval process is based on questionnaires, instead of audit or certification, the raw material suppliers traceability system shall be tested as part of the approval process and then routinely, as an extension of the traceability test 3.9.2. above and at a frequency of at least once every 3 years.. The additional information demonstrating the suppliers ability to trace products may</u></p>

	<u>exceed the 4 hour target for traceability.</u>
3.9.3 4	Where rework or any reworking operation is performed, traceability shall be maintained.
3.10	Complaint handling
Statement of Intent	Customer complaints shall be handled effectively and information used to reduce recurring complaint levels.
3.10.1	All complaints shall be recorded, investigated and the results of the investigation and root cause of the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.
3.10.2	Complaint data shall be analysed for significant trends. <u>Where there has been a significant increase in a complaint or a serious complaint and root cause analysis shall be</u> 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
Statement of Intent	The company shall have a plan and system in place to effectively manage incidents and enable the effective withdrawal and recall of products should this be required.
3.11.1	<p>The company shall have documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality. This shall include consideration of contingency plans to maintain business continuity <u>product safety, integrity, quality and legality</u>. Incidents may include:</p> <ul style="list-style-type: none"> • disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications • events such as fire, flood or natural disaster • malicious contamination or sabotage. <p>Where products which have been released from the site may be affected by an incident, consideration shall be given to the need to withdraw or recall products.</p>

3.11.2	<p>The company shall have a documented product withdrawal and recall procedure. This shall include as a minimum:</p> <ul style="list-style-type: none"> • identification of key personnel constituting the recall management team, with clearly identified responsibilities • guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained • an up-to-date list of key contacts (<u>including out of hours contact details</u>) or reference to the location of such a list, e.g. recall 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. specialist laboratories, regulatory authority and legal expertise • a plan to handle the logistics of product traceability, recovery or disposal of affected product and stock reconciliation. <p>The procedure shall be capable of being operated at any time.</p>
3.11.3	<p>The product recall and withdrawal procedures shall be 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. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary.</p>
3.11.4	<p>In the event of a product recall, the Certification Body issuing the current certificate for the site against this Standard shall be informed within three working days of the decision to issue a recall.</p>
<u>3.12</u>	<u>Customer focus and communication</u>
<u>NEW</u>	<u>The company shall understand, implement and clearly communicate any specific requirements of their customers to relevant staff and where appropriate suppliers of raw materials, packaging and services.</u>
<u>3.12.1</u> <u>NEW</u>	<u>Where there are specific customer requirements, codes of practice, methods of working etc these shall be made known to relevant staff within the company and implemented.</u>
<u>3.12.2</u> <u>NEW</u>	<u>Effective processes shall be in place for communicating customer specific requirements to the suppliers of raw materials and services as applicable.</u>

4. Site Standards	
4.1	External standards
Statement of Intent	The production site shall be of suitable size, location, construction and <u>maintained design</u> to reduce the risk of contamination and facilitate 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 potential contaminants, flooding etc.), they shall be reviewed in response to any changes.
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. External traffic routes under site control shall be suitably surfaced and maintained in good repair to avoid contamination of the product.
4.1.3	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).
4.2	Security
Statement of Intent	Security systems shall ensure that products are protected from theft or malicious contamination whilst under the control of the site.
4.2.1	The company shall undertake a documented assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements <u>to reduce risks</u> shall be implemented and reviewed at least annually.
4.2.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained

	in site security procedures and encouraged to report unidentified or unknown visitors.
4.2.3	External storage tanks, silos and any intake pipes with an external opening shall be locked when not in use
4.2.34	Where required by legislation, the site shall be registered with, or be approved by, the appropriate authority.
4.3	Layout, Product Flow and Segregation
FUNDAMENTAL Statement of Intent	The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with relevant legislation.
4.3.1	<p>There shall be a planmap of the site which designates areas where product is at different levels of risk from contamination; that is:</p> <ul style="list-style-type: none"> • high-risk areas • high-care areas • Ambient High Care • low-risk areas • enclosed product areas • non-product areas <p>See Appendix 2 for guidance.</p> <p>This shall be taken into account when determining the prerequisite programmes for the particular areas of the site.</p>
4.3.2	<p>The site planmap(s) shall define:</p> <ul style="list-style-type: none"> • access points for personnel • access points for ingredients and raw materials (including packaging) • and travel routes routes of movement for personnel

	<ul style="list-style-type: none"> • routes of movement for ingredients and raw materials • routes for the removal of waste • routes for the movement of rework • location of <u>any</u> staff facilities and routes to the facilities from places of work including changing rooms, toilets, canteens and smoking areas • production process flow <p>If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials. All facilities shall be designed and positioned, where possible, so that movement of personnel is by simple, logical routes. The movement of waste and rework shall not compromise the safety of products.</p>
4.3.3	<p>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. Contractors involved in maintenance or repair activities shall be <u>working in product processing or storage areas shall be under the supervision responsibility</u> of a nominated person.</p>
4.3.4	<p>The movement of personnel, raw materials, rework and/or waste shall not compromise the safety of products. In low-risk areas <u>the</u> The process flow together with the use of 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.</p>
4.3.65	<p>Where high-risk areas are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials (<u>including packaging</u>), equipment, personnel, waste, airflow, air quality and utilities provision (<u>including drains</u>). The location of transfer points shall not compromise the segregation between high-risk areas and other areas of the factory. Practices shall be in place to minimise risk of product contamination (e.g. the disinfection of materials on entry).</p>
4.3.56	<p>Where high-care areas are part of the manufacturing site there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials (<u>including packaging</u>), equipment,</p>

	<p>personnel, waste, airflow, air quality and utilities provision <u>(including drains)</u>. Where physical barriers are not in place, the site shall have undertaken a full <u>documented, risk assessment evaluation</u> of the <u>potential risks of</u> cross-contamination and alternative <u>effective, - validated</u> processes shall be in place to protect products from contamination.</p>
<p>4.3.7 New</p>	<p>For ready to eat, ambient products that may be susceptible to the survival of pathogens <u>Where ambient high care areas are required, a documented risk assessment shall be completed to determine the risk of cross-contamination with pathogens. The risk assessment shall take into account the potential sources of microbiological contamination and include:</u></p> <ul style="list-style-type: none"> • <u>the raw materials and products</u> • <u>flow of raw materials, products, equipment, personnel and waste</u> • <u>airflow and air quality</u> • <u>utilities (including drains)</u> <p><u>Effective processes shall be in place to protect the final product from this contamination. These processes may include segregation, management of process flow or other controls.</u></p>
4.3.78	<p>Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.</p>
4.3.89	<p>Temporary structures constructed during building work or refurbishment, etc. shall be designed and located to avoid pest harbourage and ensure the safety and quality of products.</p>
4.4	<p>Building fabric Raw material handling, preparation, processing, packing and storage areas</p>
Statement of Intent	<p>The fabrication of the site, buildings and facilities shall be suitable for the intended purpose.</p>

4.4.1	Walls shall be constructed , finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.
4.4.2	Floors shall be suitably hard wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious and maintained in good repair <u>and facilitate cleaning</u> .
4.4.3	Drainage, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety. Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain. 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.
4.4.4	Where sites include high- care risk or high-risk care facilities, there shall be a <u>map/plan</u> of the drains for these areas which shows the direction of flow and location of any equipment fitted to prevent the back up of waste water. <u>The</u> flow of drains shall not present a risk of contamination of the high-risk/care area.
4.4.5	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.
4.4.6	Where suspended ceilings or roof voids are present, adequate access to the void shall be provided to facilitate inspection for pest activity, unless the void is fully sealed.
4.4.7	Where there is a risk to product, windows, and roof glazing which is designed to be opened for ventilation purposes, shall be adequately screened to prevent the ingress of pests.
4.4.8	Where they pose a risk to product, glass windows shall be protected against breakage.
4.4.9	Doors shall be maintained in good condition. <ul style="list-style-type: none"> • External doors and dock levellers shall be close fitting or adequately proofed. • External doors to open product areas shall not be opened during production periods except in emergencies. Where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.

4.4.10	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.
4.4.11	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.
4.4.12	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.
4.4.13	High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.
4.5	Utilities – water, ice, air and other gases
Statement of Intent	Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination.
4.5.1	All water used as a raw material in the manufacture of processed food, the preparation of product, <u>hand washing</u> or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use or pose no risk of contamination according to applicable legislation. The microbiological and chemical quality of water shall be analysed at least annually. The sampling points and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage.
4.5.2	An up-to-date <u>planschematic diagram</u> shall be available of the water distribution system on site, including holding tanks, water treatment and water recycling as appropriate. The plan shall be used as a basis for water sampling and the management of water quality.
4.5.3	Where legislation specifically permits the use of water which may not be potable for initial product cleaning (e.g. for the storage/washing of fish), the water shall meet the designated legal requirement for this operation.

4.5.4	Air, other gases and steam used directly in contact with or as an ingredient in products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.
4.6	Equipment
Statement of Intent	All food processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.
4.6.1	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.
4.6.2	Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.
4.7	Maintenance
Statement of Intent	An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns.
4.7.1	There shall be a documented planned maintenance schedule or condition monitoring system which includes all plant and processing equipment. The maintenance requirements shall be defined when commissioning new equipment.
4.7.2	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment damage, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.
4.7.3	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.

4.7.4	The company shall ensure that the safety or legality of product is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work shall be followed by a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment.
4.7.5 NEW	<u>Maintenance activities undertaken in high risk and high care areas shall respect the segregation requirements of the area. Where ever possible tools and equipment shall be dedicated for use in the area and be retained in the area.</u>
4.7.56	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, shall be food grade <u>and of a known allergen status.-</u>
4.7.67	Engineering workshops shall be kept clean and tidy and controls shall be in place to prevent <u>transfer of engineering debris to production or storage areas.</u> contamination risks to the product (e.g. provision of swarf mats at the entrance/exit of workshops).
4.8	Staff facilities
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. The facilities shall be maintained in good and clean condition.
4.8.1	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).
4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material handling, preparation, processing, packing and storage areas.

4.8.3	<p>Outdoor clothing and other personal items shall be stored separately from production clothingworkwear within the changing facilities. Facilities shall be available to separate clean and dirty workwear<u>production clothing</u>.</p>
4.8.54	<p>Where an operation includes a high-risk area, personnel shall enter via a specially designated changing facility at the entrance to the high-risk area. The changing facilities shall include the following requirements:</p> <ul style="list-style-type: none"> • clear instructions for the order of changing into <u>and out of</u> dedicated protective clothes to prevent the contamination of clean clothing • dedicated footwear shall be provided to be worn in the high-risk area • an effective system shall be provided to segregate areas for wearing high-risk and other footwear, ie a barrier or bench system • protective clothing shall be visually distinctive from that worn in other areas and shall not be worn outside of the high-risk area • hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing <u>(ie hand-washing after hair covering and footwear has been put on, but before handling clean protective clothing)</u> • prior to entry to high-risk areas, hand-washing and/or disinfection shall be provided <u>and used.</u> • dedicated footwear shall be provided to be worn in the high-risk area with an effective system to segregate areas for wearing high-risk and other footwear, ie a barrier or bench system. By exception the use of boot wash facilities are accepted where these demonstrably provide an effective control of foot wear to prevent the introduction of pathogenic material into high risk areas. <p><u>. A programme of environmental monitoring shall be established to assess the effectiveness of foot wear controls</u></p>
4.8.45	<p>Where an operation includes a high-care area, personnel shall enter via a specially designated changing facility with arrangements to ensure that protective clothing will not be contaminated before entry to the high-care area. The changing facilities shall incorporate the following requirements:</p> <ul style="list-style-type: none"> • clear instructions for the order of changing into <u>and out of</u> dedicated protective clothes to prevent the contamination of clean

	<p>clothing</p> <ul style="list-style-type: none"> • company provided dedicated footwear which shall not be worn outside the factory, by exception shoe coverings shall be provided for visitors only to be worn in the high-care area • an effective system shall be provided to segregate areas for wearing high-care from other footwear (e.g. a barrier or bench system) or there shall be an effective boot wash on entrance to the high-care area • protective clothing shall be visually distinctive from that worn in lower risk areas and shall not be worn outside of the high-care area • hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing • <u>on entry to high-care areas, hand-washing and disinfection shall be provided and used.</u> <p><u>There shall be an effective control of foot wear to prevent the introduction of pathogens into high care areas. This may be by a controlled change of foot wear before entering the area or by the use of controlled and managed boot wash facilities.</u></p> <p><u>A programme of environmental monitoring shall be established to assess the effectiveness of foot wear controls</u></p>
4.8.6	<p>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:</p> <ul style="list-style-type: none"> • <u>advisory signs to prompt hand-washing</u> sufficient quantity of water at a suitable temperature • <u>water taps with hand-free operation</u> • Liquid/<u>foam</u> soap • single use towels or suitably designed and located air driers • water taps with hand-free operation • advisory signs to prompt hand-washing.
4.8.7	<p>Toilets shall be adequately segregated and shall not open directly into production <u>or</u>, packing and storage areas. Toilets shall be provided with hand-washing facilities comprising:</p> <ul style="list-style-type: none"> • basins with soap and water at a suitable temperature • adequate hand-drying facilities • advisory signs to prompt hand-washing. <p>Where hand-washing facilities within toilet facilities are the only facilities provided before re-entering production, the requirements of 4.8.6 shall apply and signs shall be in place to direct people to hand-wash facilities before entering production.</p>

4.8.8	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations.
4.8.9	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. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.
4.8.10	Where catering facilities are provided on the premises, they shall be suitably controlled to prevent contamination of product (e.g. as a source of food poisoning or introduction of allergenic material to the site).
4.9	Chemical and physical product contamination control Raw material handling, preparation, processing, packing and storage areas
Statement of Intent	Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.
4.9.1	Chemical control
4.9.1.1	Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include as a minimum: <ul style="list-style-type: none"> • an approved list of chemicals for purchase • availability of material safety data sheets and specifications • confirmation of suitability for use in a food processing environment • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • designated storage area with restricted segregated and secure storage with restricted access to authorised personnel

	<ul style="list-style-type: none"> • use by trained personnel only.
4.9.1.2	Where strongly scented or taint-forming materials have to be used, for instance for building work, procedures shall be in place to prevent the risk of taint contamination of products.
4.9.2	Metal control
4.9.2.1	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 a record of inspection for damage and the investigation of any lost items. Snap-off blade knives shall not be used.
4.9.2.2	The purchase of ingredients and packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided. Staples and paper clips and drawing pins shall not be used in open product areas. Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.
4.9.3	Glass, brittle plastic, ceramics and similar materials
4.9.3.1	Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination.
4.9.3.2	Documented procedures for handling glass and other brittle materials (<u>other than product packaging</u>) shall be in place <u>where open products are handled or there is a risk of product contamination. These p-and implemented to ensure that necessary precautions are taken. P</u> procedures shall include as a minimum: <ul style="list-style-type: none"> • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise potential for product contamination.
4.9.3.3	Documented procedures detailing the action to be taken in case of breakage of glass or other brittle items shall be implemented and include the following: <ul style="list-style-type: none"> • quarantining the products and production area that were potentially affected

	<ul style="list-style-type: none"> • 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.
4.9.3.4	Products packed into glass or other brittle containers
4.9.3.4.1	The storage of the containers shall be segregated from the storage of raw materials, product or other packaging.
4.9.3.4.2	<p>Systems shall be in place to manage container breakages between the container cleaning/inspection point and container closure. This shall include, as a minimum, documented instructions which ensure:</p> <ul style="list-style-type: none"> • the removal and disposal of at-risk products in the vicinity of the breakage; this may be specific for different equipment or areas of the production line. • the effective cleaning of the line or equipment which may be contaminated by fragments of the container. Cleaning shall not result in the further dispersal of fragments, for instance by the use of high pressure water or air. • the use of dedicated, clearly identifiable cleaning equipment (e.g. colour coded) for removal of container breakages. Such equipment shall be stored separately from other cleaning equipment. • the use of dedicated, accessible lidded waste containers for the collection of damaged containers and fragments. • a documented inspection of production equipment is undertaken following the cleaning of a breakage to ensure cleaning has effectively removed any risk of further contamination. • authorisation is given for production to re-start following cleaning. • the area around the line is kept clear of broken glass.
4.9.3.4.3	Records shall be maintained of all container breakages on the line. Where no breakages have occurred during a production period, this shall also be recorded. This record shall be reviewed to identify trends and potential line or container improvements.
4.9.4	Wood
4.9.4.1	Wood should not be used in open product areas except where this is a process requirement (e.g. maturation of products in wood). Where the use of wood cannot be avoided, the condition of wood shall be continually monitored to ensure it is in good condition and free from damage or splinters which could contaminate products.
4.10	Foreign body detection and removal equipment

Statement of Intent	The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies.
4.10.1	Foreign body detection and removal equipment
4.10.1.1	<p>A documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign body contamination. Typical equipment to be considered may include:</p> <ul style="list-style-type: none"> • filters • sieves • metal detection • magnets • optical sorting equipment • X-ray detection equipment • other physical separation equipment e.g. gravity separation, fluid bed technology.
4.10.1.2	The type, location and sensitivity of the detection and/or removal method shall be specified as part of the company's documented system. Industry best practice shall be applied with regard to the nature of the ingredient, material, product and/or the packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified.
4.10.1.3	<p>The company shall ensure that the frequency of the testing of the foreign body detection and/or removal equipment is defined and takes into consideration:</p> <ul style="list-style-type: none"> • specific customer requirements • the company's ability to identify, hold and prevent the release of any affected materials, should the equipment fail.
4.10.1.4	Where foreign material is detected or removed by the equipment, the source of any unexpected material shall be investigated. Information on rejected materials shall be used to identify trends and where possible instigate preventive action to reduce the occurrence of contamination by the foreign material.
4.10.2	Filters and sieves
4.10.2.1	Filters and sieves used for foreign body control shall be of a specified mesh size or gauge and designed to provide the maximum

	practical protection for the product. Material retained or removed by the system shall be examined and recorded to identify contamination risks.
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage on a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified this shall be recorded and the potential for contamination of products investigated and appropriate action taken.
4.10.3	Metal detectors and X-ray equipment
4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve the protection of final products from metal contamination. Where metal detectors are not used justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective, method of protection (e.g. use of X-ray, fine sieves or filtration of products).
4.10.3.2	Where metal detectors or X-ray equipment is used, this shall be situated at the latest practical step in the process flow and, wherever possible, after the product has been packaged.
4.10.3.32	The metal detector or X-ray equipment shall incorporate one of the following: <ul style="list-style-type: none"> • an automatic rejection device, for continuous in-line systems, which shall either divert contaminated product out of the product flow or to a secure unit accessible only to authorised personnel • a belt stop system with an alarm where the product cannot be automatically rejected, e.g. for very large packs • in-line detectors which identify the location of the contaminant shall be operated to allow effective segregation of the affected product.
4.10.3.43	The company shall establish and implement documented procedures for the operation and testing of the metal or X-ray equipment. This shall include as a minimum: <ul style="list-style-type: none"> • responsibilities for the testing of equipment • the operating effectiveness and sensitivity of the equipment and any variation to this for particular products

	<ul style="list-style-type: none"> the methods and frequency of checking the detector recording of the results of checks.
4.10.3.564	<p>Metal detector checking procedures shall be based on <u>best good</u> practice and shall as a minimum include:</p> <ul style="list-style-type: none"> use of test pieces incorporating a sphere of metal of a known diameter <u>selected on the basis of risk</u>. The test pieces shall be marked with the size and type of test material contained. tests carried out using separate test pieces containing ferrous metal, stainless steel and typically non-ferrous metal <u>;</u>, unless the product is within a foil container <u>where Ferrous only may be applicable</u>. a test that both the detection and rejection mechanisms are working effectively under normal working conditions. checks that test the memory/reset function of the metal detector by passing successive test packs through the unit <u>at typical line operating speed</u>. <p>In addition, where metal detectors are incorporated on conveyors:</p> <p>the test piece shall be passed as close as possible to the centre of the metal detector aperture and wherever possible be carried out by inserting the test piece within a clearly identified sample pack of the food being produced at the time of the test.</p> <p>Where in-line metal detectors are used the test piece shall be placed in the product flow wherever this is possible <u>and the correct timing of the rejection system to remove identified contamination shall be validated.</u></p>
4.10.3.65	The company shall establish and implement corrective action and reporting procedures in the event of the testing procedure identifying any failure of the foreign body detector. Action shall include a combination of isolation, quarantining and re-inspection of all product produced since the last successful test.
4.10.4	Magnets
4.10.4.1	The type, location and the strength of magnets shall be fully documented. Documented procedures shall be in place for the inspection, cleaning, strength testing and integrity checks. Records of all checks shall be maintained.
4.10.5	Optical sorting equipment
4.10.5.1	Each unit shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.

4.10.6	Container cleanliness – glass jars, cans and other rigid containers
4.10.6.1	Based on risk assessment, procedures shall be implemented to minimise foreign body contamination originating with the packaging container (e.g. jars, cans and other preformed rigid containers). This may include the use of covered conveyors, container inversion and foreign body removal through rinsing with water or air jets.
4.10.6.2	The effectiveness of the container cleaning equipment shall be checked and recorded during each production. Where the system incorporates a rejection system for dirty or damaged containers, the check shall incorporate a test of both the detection and effective rejection of the test container.
4.11	Housekeeping and hygiene
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 product contamination is minimised.
<u>4.11.1</u> <u>NEW</u>	<u>The premises and equipment shall be maintained in a clean and hygienic condition</u>
<u>4.11.12</u>	<p>Documented cleaning procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures <u>for processing equipment and food contact surfaces</u> shall as a minimum include the:</p> <ul style="list-style-type: none"> • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning, including dismantling equipment for cleaning purposes where required • cleaning chemicals and concentrations • cleaning materials to be used • cleaning records and responsibility for verification. <p>The frequency and methods of cleaning shall be based on risk. <u>This shall include the risk from cleaning chemical residues on food contact surfaces.</u></p> <p>The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.</p>

4.11.23	<p><u>As a minimum for food contact surfaces and processing equipment</u> Limits of acceptable and unacceptable cleaning performance shall be defined <u>This shall be</u>, based on the potential hazards (e.g. microbiological, allergen, or foreign body contamination <u>or product to product contamination</u>). Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see Glossary), microbiological testing or chemical testing as appropriate. <u>Where cleaning procedures are part of a defined pre-requisite plan to control the risk of a specific hazard</u> tThe cleaning and disinfection procedures and frequency shall be validated and records maintained.</p>
4.11.34	<p>The resources for undertaking cleaning shall be available. Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled and, where necessary, planned for non-production periods. Cleaning staff shall be adequately trained or engineering support provided where access within equipment is required for cleaning.</p>
4.11.45	<p>The cleanliness of equipment shall be checked before equipment is released back into full production. The results of checks on cleaning, including visual, analytical and microbiological checks, shall be recorded and used to identify trends in cleaning performance and instigate improvements where required.</p>
4.11.56	<p>Cleaning equipment shall be:</p> <ul style="list-style-type: none"> • hygienically designed and fit for purpose • suitably identified for intended use, e.g. colour coded or labelled • cleaned and stored in a hygienic manner to prevent contamination. <p>Equipment used for cleaning in high-care and high-risk areas <u>shall be visually distinctive and</u> shall be dedicated for use in that area.</p>
4.11.67	<p>Cleaning in place (CIP)</p>
4.11.67.1	<p>Cleaning-in-place (CIP) facilities, where used, shall be monitored and maintained to ensure their effective operation.</p>
4.11.67.2	<p>A schematic <u>plan diagram</u> of the layout of the CIP system shall be available. There shall be an inspection report or other <u>verification-validation</u> that:</p> <ul style="list-style-type: none"> • systems are hygienically designed with no dead areas, limited interruptions to flow streams and good system drain ability. • scavenge pumps are operated to ensure that there is no build-up of cleaning fluids in the vessels. • spray balls effectively clean vessels by providing full surface coverage and are periodically inspected for blockages. Rotating spray devices should have a defined operational time.

	<ul style="list-style-type: none"> CIP equipment has adequate separation from active product lines, e.g. through the use of double seat valves, manually controlled links or blanks in pipework. <p>The system shall be revalidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.</p>
4.11.67.3	<p>The CIP equipment shall be operated to ensure effective cleaning is carried out:</p> <ul style="list-style-type: none"> The process parameters, time, detergent concentrations, flow rate and temperatures shall be defined to ensure removal of the appropriate target hazard, e.g. soil, allergens, vegetative microorganisms, spores. This shall be validated and records of the validation maintained. Detergent concentrations shall be checked routinely. Process verification shall be undertaken by analysis of rinse waters and/or first product through the line for the presence of cleaning fluids or by tests of ATP (bioluminescence techniques) allergens or micro-organisms as appropriate. Detergent tanks shall be kept stocked up and a log maintained of when these are filled and emptied. Recovered pre-rinse solutions shall be monitored for a build-up of carry-over from the detergent tanks. Filters, where fitted, shall be cleaned and inspected at a defined frequency.
4.12	Waste/waste disposal
Statement of Intent	Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.
4.12.1	Where licensing is required <u>by law</u> for the disposal-removal of categorised waste, it shall be removed by licensed contractors and records of disposal-removal shall be maintained and available for audit.
4.12.2	By-products and downgraded/surplus products intended for Food products intended to be supplied for animal feed shall be segregated from waste and <u>protected from contamination during storage. Products for animal feed shall be</u> managed in accordance with relevant legislative requirements.
4.12.3	<p>External waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be:</p> <ul style="list-style-type: none"> clearly identified designed for ease of use and effective cleaning well-maintained to allow cleaning and, where required, disinfection emptied at appropriate frequencies

	<ul style="list-style-type: none"> covered or doors kept closed as appropriate.
4.12.4	If unsafe products or 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 which includes the quantity of waste collected for destruction or disposal.
4.12.5 NEW	<u>Surplus customer branded products shall be disposed of in accordance with customer specific requirements. Customer brand names shall be removed from packed surplus products under the control of the factory before product enters the supply chain unless authorised by the customer.</u>
4.13	Pest control
Statement of Intent	The whole site shall have an effective preventive pest control programme in place to minimise the risk of infestation and there shall be the resources available to rapidly respond to any issues which occur to prevent risk to products.
4.13.1 NEW	<u>Any pest infestation shall not present a risk of contamination to products, raw materials or packaging. The presence of any pests on site shall be identified in pest control records and be part of an effective pest management programme to eliminate the pest.</u>
4.13.42	The company site 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.
4.13.23	Where a company site undertakes its own pest control, it shall be able to effectively demonstrate that: <ul style="list-style-type: none"> pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site sufficient resources are available to respond to any infestation issues there is ready access to specialist technical knowledge when required legislation governing the use of pest control products is understood dedicated locked facilities are used for the storage of pesticides.

4.13.34	<p>Pest control documentation and records shall be maintained. This shall include as a minimum:</p> <ul style="list-style-type: none"> • an up-to-date plan of the full site identifying numbered pest control device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and for the contractor • details of pest control products used, including instructions for their effective use and action to be taken in case of emergencies • any observed pest activity • details of pest control treatments undertaken.
4.13.45	<p>Bait stations <u>or other rodent control devices</u> shall be robust, of tamper resistant construction, secured in place and appropriately located <u>and maintained</u> to prevent contamination risk to product. Missing bait boxes shall be recorded, reviewed and investigated. Toxic rodent baits shall not be used within production areas or storage areas where open product is present except when treating an active infestation. <u>Where toxic baits are used these shall be secured.</u></p> <p><u>Any missing baits shall be recorded reviewed and investigated.</u></p>
4.13.56	<p>Fly-killing devices and/or pheromone traps shall be correctly sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used.</p>
4.13.67	<p>In the event of infestation, or evidence of pest activity, immediate action shall be taken to eliminate the hazard. Any potentially affected products should be subject to the non-conforming product procedure.</p>
4.13.78	<p>Records of pest control inspections, pest proofing and hygiene 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 in a timely manner.</p>
4.13.89	<p>An in-depth, documented pest control survey shall be undertaken at a frequency based on risk, but <u>as a minimum annually typically quarterly</u>, by a pest control expert to review the pest control measures in place. <u>The survey shall</u></p>

	<ul style="list-style-type: none"> • <u>Review the existing pest control measures in place and make any recommendations for change</u> • <u>Provide an indepth inspection of the facility for pest activity</u> The timing of the survey shall be such as to allow access to equipment for inspection where a risk of stored product insect infestation exists.
4.13.910	<p>Results of pest control inspections shall be assessed and analysed for trends on a regular basis, but as a minimum:</p> <ul style="list-style-type: none"> • in the event of an infestation • annually. <p>This shall include a catch analysis from trapping devices to identify problem areas. The analysis shall be used as a basis for improving the pest control procedures.</p>
4.13.11 NEW	<u>Employees shall be aware of the need to report any evidence of pest activity to a designated manager.</u>
4.14	Storage facilities
Statement of Intent	All facilities used for the storage of <u>ingredientsraw materials, packaging</u> , in-process product and finished products shall be suitable for its purpose.
4.14.1	<p>Documented procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment, understood by relevant staff and implemented accordingly. These may include as appropriate:</p> <ul style="list-style-type: none"> • managing chilled and frozen product transfer between temperature controlled areas • segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake • storing materials off the floor and away from walls • specific handling or stacking requirements to prevent product damage.
5.4.2 4.14.2	<u>Where appropriate, packaging shall be stored away from raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified before being returned to an appropriate storage area. Obsolete packaging shall be stored in a separate area and systems shall be in place to prevent accidental use.</u>
4.14.23	Where temperature control is required, the storage area shall be capable of maintaining product temperature within specification

	and operated to ensure specified temperatures are maintained. Temperature recording equipment with suitable temperature alarms shall be fitted to all storage facilities or there shall be a system of recorded manual temperature checks, typically on at least a four-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products.
4.14.34	Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions.
4.14.45	Where storage outside is necessary, items shall be protected from contamination and deterioration. <u>Items shall be checked for suitability before being brought into the factory.</u>
4.14.56	Receipt documents and/or product identification <u>The site</u> shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life.
4.15	Despatch and transport
Statement of Intent	Procedures shall be in place to ensure that the management of despatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety, security or quality of the products.
4.15.1	Documented procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include as appropriate: <ul style="list-style-type: none"> • controlling temperature of loading dock areas • the use of covered bays for vehicle loading or unloading • securing loads on pallets to prevent movement during transit • inspection of loads prior to despatch.

4.15.2	Traceability shall be ensured during 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.
4.15.3	All vehicles or containers used for the de ispatch of products shall be inspected prior to loading to ensure that they are fit for purpose. This shall ensure that they are: <ul style="list-style-type: none"> • in a suitably clean condition • free from strong odours which may cause taint to products • suitably maintained to prevent damage to products during transit • equipped to ensure any temperature requirements can be maintained. Records of inspections shall be maintained.
4.15.4	Where temperature control is required, the transport shall be capable of maintaining product temperature within specification, under minimum and maximum load. Temperature data-logging devices which can be interrogated to confirm time/temperature conditions or a system to verify <u>monitor</u> and record at predetermined frequencies the correct operation of refrigeration equipment shall be used and records maintained.
4.15.5	Maintenance systems and documented cleaning procedures shall be maintained for all vehicles and equipment used for loading/unloading (e.g. hoses connecting to silo installations). There shall be records of the measures taken.
4.15.6	The company shall have documented procedures for the transport of products, which shall include: <ul style="list-style-type: none"> • any restrictions on the use of mixed loads • requirements for the security of products during transit, particularly when vehicles are parked and unattended • clear instructions in the case of vehicle breakdown, accident or failure of refrigeration systems which ensure the safety of the products is assessed and records maintained.
4.15.7	Where the company employs third-party contractors, all the requirements specified in this section shall be clearly defined in the contract and verified or the contracted company shall be certificated to the Global Standard for Storage and Distribution or similar internationally <u>GFSI</u> recognised Standard.

5. Product control	
5.1	Product design/development
Statement of Intent	Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced.
5.1.1	The company shall provide clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards which would be unacceptable to the company or customers (e.g. the introduction of allergens, glass packaging or microbiological risks).
5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or authorised HACCP committee member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.
5.1.3	Trials using production equipment shall be carried out where it is necessary to validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.
5.1.4	Shelf-life trials shall be undertaken using documented protocols reflecting conditions experienced during storage, <u>transport</u> and handling. Results shall be recorded and retained and shall confirm compliance with relevant microbiological, chemical and organoleptic criteria. Where shelf-life trials prior to production are impractical, for instance for some long-life products, a

	documented science-based justification for the assigned shelf life shall be produced.
5.2	<u>Product Labelling</u>
NEW	<u>Product labelling shall comply with the appropriate legal requirements and contain information to enable the safe handling, display, storage and preparation of the product within the food supply chain or by the customer</u>
5.4-5.2.1	All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer. There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe <u>and ingredient specifications</u> .
5.2.2 NEW	<u>There shall be effective processes in place to ensure that labelling information is reviewed whenever changes occur to</u> <ul style="list-style-type: none"> • <u>the product recipe,</u> • <u>raw materials</u> • <u>supplier of raw materials</u> • <u>legislation</u> • <u>Country of origin (when identified on labels)</u>
5.4-6.2.3	Where a product is designed to enable a claim to be made to satisfy a consumer group (e.g. a nutritional claim, <u>'free from'</u> , reduced sugar), the company shall ensure that the product formulation and production process is fully validated to meet the stated claim.
5.2.4 NEW	<u>Where the label information is the responsibility of a customer or a nominated third party the company shall provide</u> <ul style="list-style-type: none"> • <u>Information to enable the the label information to be accurately created</u> • <u>Information when ever a change occurs which may affect the label information.</u>

5.2—3	Management of allergens
FUNDAMENTAL Statement of Intent	The company shall have a developed system for the management of allergenic materials which minimises the risk of allergen contamination of products and meets legal requirements for labelling <u>in the country of sale</u> .
5.23.1	The company shall carry out an assessment of raw materials to establish the presence and likelihood of contamination by allergens (refer to glossary). This shall include review of raw material specifications and, where required, obtain additional information from suppliers, for example through questionnaires to understand the allergen status of the raw material, its ingredients and the factory in which it is produced.
5.23.2	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products and any new product development ingredients or products. <u>A list shall also be available of products which do not contain allergens and therefore need to be protected from contamination</u>
5.23.3	A documented 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: <ul style="list-style-type: none"> • consideration of the physical state of the allergenic material, i.e. powder, liquid, particulate • identification of potential points of cross-contamination through the process flow • assessment of the risk of allergen cross-contamination at each process step • identification of suitable controls to reduce or eliminate the risk of cross-contamination.
5.23.4	Documented procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination into products not containing the allergen. This shall include as appropriate: <ul style="list-style-type: none"> • physical or time segregation whilst allergen-containing materials are being stored, processed or packed • the use of separate or additional protective over clothing when handling allergenic materials • use of identified, dedicated equipment and utensils for processing • scheduling of production to reduce changes between products containing an allergen and products not containing the allergen

	<ul style="list-style-type: none"> • systems to restrict the movement of airborne dust containing allergenic material • waste handling and spillage controls • restrictions on food brought onto site by staff, visitors, contractors and for catering purposes.
5.23.5	Where rework is used, or reworking operations carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.
5.23.6	Where the nature of the production process is such that cross-contamination from an allergen cannot be prevented, a warning shall <u>should</u> be included on the label. National guidelines or codes of practice shall be used when making such a warning statement.
5.23.7	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.
5.23.8	Equipment or area cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination by allergens. The cleaning methods shall be validated to ensure they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use.
5.2.9	All relevant personnel, including engineers, temporary staff and contractors, shall have received general allergen awareness training and be trained in the company's allergen handling procedures.
5.2.10	An effective system of documented checks shall be in place at line start-up, following product changeover and changes in batches of packaging to ensure that the labels applied are correct for the products packed.
5.3—4	Product Authenticity, Claims and Chain of custody Provenance, assured status and claims of identity preserved materials
Statement of Intent	Systems shall be in place to minimise the risk of purchasing fraudulent or adulterated raw materials and ensure that all product descriptions and claims are legal accurate and verified. <u>of traceability, identification and segregation of raw materials, intermediate and finished products shall be in place to ensure that all claims relating to provenance or assured status can be</u>

	substantiated.
<u>5.4.1</u> <u>NEW</u>	<p><u>The company shall have processes in place to access information on historical and developing threats to the supply chain which may present a risk of adulteration or substitution of raw materials e.g.</u></p> <ul style="list-style-type: none"> <u>• trade associations</u> <u>• government sources</u> <u>• private resource centres.</u>
<u>5.4.2</u> <u>NEW</u>	<p><u>A documented vulnerability assessment shall be carried out of all raw materials to assess the potential risk of adulteration or substitution. This shall take into account</u></p> <ul style="list-style-type: none"> <u>• historical evidence of substitution or adulteration</u> <u>• economic factors</u> <u>• ease of access to raw materials through the supply chain</u> <u>• sophistication of routine testing to identify adulterants.</u> <u>• Nature of the raw material</u> <p><u>The vulnerability assessment shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risk. It shall be formally reviewed annually</u></p>
<u>5.4.3</u> <u>NEW</u>	<u>Where raw materials are identified as being at particular risk of adulteration or substitution appropriate assurance and/or testing processes shall be in place to reduce the risk.</u>
<u>5.4.4</u>	<p>Where <u>products are labelled or</u> claims are to be made on finished packs about the<u>including</u></p> <ul style="list-style-type: none"> <u>• Specific provenanceorigin</u> <u>• Breed/variety claims</u> <u>• Assured status</u> <u>• Genetically Modified Origin (GMO) status</u> <p>, assured or 'identity preserved' status (see Glossary) of raw materials used, the status of each batch of the raw material</p>

	shall be verified and records maintained.
5.4.5 NEW	<u>Where claims are made about the methods of production for example Organic, Halal, the site shall maintain the necessary certification status in order to make such a claim.</u>
5. 34.26	Where a claim is made relating to the provenance/ <u>origin</u> , assured or identity preserved status of a product or ingredient, the facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The company shall undertake documented mass balance tests at least every six months and at a frequency to meet the particular scheme requirements.
5. 43.31	The process flow for the production of products where claims are made shall be documented and potential areas for contamination or loss of identity identified. Appropriate controls shall be established to ensure the integrity of the product claims.
5.4—5	Product Packaging
Statement of Intent	Product packaging shall be appropriate for the intended use and shall be stored under conditions to <u>minimise-prevent</u> contamination and <u>minimise</u> deterioration.
5. 45.1	When purchasing or specifying food contact packaging the supplier of packaging materials shall be made aware of any particular characteristics of the food (e.g. high fat content, pH or usage conditions such as microwaving) which may affect packaging suitability. Certificates of conformity or other evidence shall be available for product packaging to confirm it conforms to relevant food safety legislation and is suitable for its intended use.
5.4.2	Where appropriate, packaging shall be stored away from raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified before being returned to an appropriate storage area. Obsolete packaging shall be stored in a separate area and systems shall be in place to prevent accidental use.

5.45.32	Product liners and bags purchased by the company for use directly with ingredients, or work in process which may come into contact with Product contact liners (or raw material/work-in-progress contact liners) purchased by the company shall be appropriately coloured and resistant to tearing to prevent accidental contamination.
5.5-6	Product inspection and laboratory testing
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.
5.56.1	Product inspection and testing
5.56.1.1	There shall be a scheduled programme of testing covering products and the processing environment which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, frequency and specified limits shall be documented.
5.56.1.2	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 trends.
5.56.1.3	The company shall ensure that a system of on-going shelf-life assessment is in place. This shall be based on risk and shall include microbiological <u>where applicable</u> and sensory analysis as well as relevant chemical factors such as pH and aw. Records and results from shelf life tests shall validate-verify the shelf life period indicated on the product.
5.56.2	Laboratory testing
5.56.2.1	Pathogen testing shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be fully segregated from the manufacturing site <u>production and storage areas</u> and have operating procedures to prevent any risk of product contamination.

5.56.2.2	<p>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:</p> <ul style="list-style-type: none"> • 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.
5.56.2.3	<p>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. <u>The results of external testing shall be formally reviewed.</u></p>
5.56.2.4	<p>Procedures shall be in place to ensure reliability of laboratory results, other than those critical to safety and legality specified in 5.5.2.3. These shall include:</p> <ul style="list-style-type: none"> • 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.
5.6-7	Product release
Statement of Intent	The company shall ensure that finished product is not released unless all agreed procedures have been followed.
5.67.1	<p>Where products require positive release, procedures shall be in place to ensure that release does not occur until all release criteria have been completed and release authorised.</p>

6. Process Control	
6.1	Controls of operations
FUNDAMENTAL Statement of Intent	The company shall operate to documented procedures and/or work instructions that ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.
6.1.1	<p>Documented process specifications and work instructions shall be available for the key processes in the production of products to ensure product safety, legality and quality. The specifications as appropriate shall include:</p> <ul style="list-style-type: none"> • recipes – including identification of any allergens • mixing instructions, speed, time • equipment process settings • cooking times and temperatures • cooling times and temperatures • labelling instructions • coding and shelf life marking • any additional critical control points identified in the HACCP plan. <p><u>Process specifications shall be in accordance with the agreed finished product specification</u></p>
6.1.2	Process monitoring, such as of temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification.
6.1.3	In circumstances where process parameters <u>or product quality</u> are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.
6.1.4	Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts,

	ovens and processing vessels; temperature distribution in freezers and cold stores).
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 and quality of the product to determine the action to be taken.
	<u>FUNDAMENTAL</u>
<u>6.2</u>	<u>Labelling and Pack control</u>
<u>6.2.2</u> <u>1</u>	Where appropriate, packaging shall be stored away from raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified before being returned to an appropriate storage area. Obsolete packaging shall be stored in a separate area and systems shall be in place to prevent accidental use.
<u>6.2.3</u> <u>2</u> <u>NEW</u>	<u>There shall be a formal process for the allocation of packaging materials to packing lines which ensures that only the packaging for immediate use is available at the packaging machines.</u> <u>Where off line coding or printing of packaging materials occur, checks shall be in place that only correctly printed material is available at the packaging machines.</u>
<u>6.4.2</u> <u>6.4.3</u>	Documented checks of the production line shall be carried out before commencing production and following changes of product. These shall ensure that lines have been suitably cleaned and are ready for production. Documented checks shall be carried out at product changes to ensure all products and packaging from the previous production have been removed from the line before changing to the next production.
<u>6.4.2.754</u>	Documented procedures shall be in place to ensure that products are packed into the correct packaging and correctly labelled. These shall include <ul style="list-style-type: none"> • <u>checks at the start of packing,</u> • <u>-during the packaging run,</u> • <u>When changing batches of packaging materials</u>

	<ul style="list-style-type: none"> • <u>At the end of each production run, following packaging changes and</u>, in order to ensure that correct packaging materials are used. The <u>checks procedures</u> shall also include verification of any <u>code information or other</u> printing carried out at the packing stage. <u>including as appropriate</u> • <u>Date coding</u> • <u>Batch coding</u> • <u>Quantity indication</u> • <u>Pricing information</u> • <u>Bar coding</u> • <u>Country of origin</u>
6.2.65 NEW	<u>Where on line vision equipment is used to check product labels and printing; procedures shall be in place to ensure that the system is correctly set up and capable of alerting or rejecting product when packaging information is out of specification.</u>
6.23	Quantity-weight, volume and number control
Statement of Intent	The company shall operate a quantity control system which conforms to legal requirements in the country where the product is sold and any additional industry sector codes or specified customer requirement.
6.23.1	The frequency and methodology of quantity checking shall meet the requirements of appropriate legislation governing quantity verification, and records of checks shall be <u>maintained-retained</u>
6.23.2	Where the quantity of the product is not governed by legislative requirements (e.g. bulk quantity), the product must conform to customer requirements and records shall be maintained.
6.34	Calibration and control of measuring and monitoring devices

Statement of Intent	The company shall be able to demonstrate that measuring and monitoring equipment is sufficiently accurate and reliable to provide confidence in measurement results.
6.34.1	<p>The company shall identify and control measuring equipment used to monitor CCPs, product safety and legality. This shall include as a minimum:</p> <ul style="list-style-type: none"> • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration or misuse.
6.34.2	<p>All identified measuring devices, including new equipment, shall be checked and where necessary adjusted:</p> <ul style="list-style-type: none"> • at a predetermined frequency, based on risk assessment • to a defined method traceable to a recognised national or international Standard where possible. <p>Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform.</p>
6.34.3	<p>Reference measuring equipment shall be calibrated and traceable to a recognised national or international Standard and records maintained. <u>The uncertainty of calibration shall be considered when equipment is used to assess critical limits.</u></p>
6.34.4	<p>Procedures shall be in place to record actions to be taken when the prescribed measuring and monitoring devices are found not to be operating within specified limits. Where the safety or legality of products is based on equipment found to be inaccurate, action shall to be taken to ensure at-risk product is not offered for sale.</p>

7. Personnel	
7.1	Training Raw material handling, preparation, processing, packing and storage areas
FUNDAMENTAL Statement of Intent	The company shall ensure that all 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 <u>Agency</u> , 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 competency assessment 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: <ul style="list-style-type: none"> • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training • the delivery of training in the appropriate language of trainees.
7.1.4	All relevant personnel, including engineers, temporary-Agency and temporary staff and contractors, shall have received general allergen awareness training and be trained in the company's allergen-handling procedures
7.1.45	Records of all training shall be available. This shall include as a minimum: <ul style="list-style-type: none"> • the name of the trainee and confirmation of attendance • the date and duration of the training • the title or course contents, as appropriate • the training provider.

	Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
7.1.56	The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.
7.2	Personal hygiene Raw material handling, preparation, processing, packing and storage areas
Statement of Intent	The company's personal hygiene standards shall be appropriate to the products produced, documented, and adopted by all personnel, including agency staff, contractors and visitors to the production facility.
7.2.1	<p>The requirements for personal hygiene shall be documented and communicated to all personnel. This shall include as a minimum the following requirements :</p> <ul style="list-style-type: none"> • Watches shall not be worn. • Jewellery shall not be worn, with the exception of a plain wedding ring or wedding wristband. • Rings and studs in exposed parts of the body, such as ears, noses, tongues and eyebrows, shall not be worn. • Fingernails shall be kept short, clean and unvarnished. False fingernails shall not be permitted. • Excessive perfume or aftershave shall not be worn. <p>Compliance with the requirements shall be checked routinely.</p>
7.2.2	Hand cleaning shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.
7.2.3	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue) and containing a metal detectable strip. These shall be company issued and monitored. Where appropriate, in addition to the plaster, a glove shall be worn.
7.2.4	Where metal detection equipment is used, a sample from each batch of plasters shall be successfully tested through the

	equipment and records shall be kept.
7.2.5	Processes and written instructions for staff shall be in place to control the use and storage of personal medicines, so as to minimise the risk of product contamination.
7.3	Medical screening
Statement of Intent	The company shall ensure that procedures are in place to ensure that employees, agency staff, contractors or visitors are not a source of transmission of food-borne diseases to products.
7.3.1	<u>The company shall make employees aware of the types of infection, disease or condition which would prevent a person working with open food.</u> The company shall have a procedure which enables notification by employees, including temporary employees, of any relevant infection, disease or condition with which they may have been in contact or be suffering from.
7.3.2	Where there may be a risk to product safety, visitors and contractors shall be <u>made aware of the types of infection, disease or condition which would prevent a person visiting areas with open food.</u> Where permitted by law visitors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from a condition which may put product safety at risk, prior to entering the raw material, preparation, processing, packing and storage areas.
7.3.3	There shall be documented procedures for employees, contractors and visitors, relating to action to be taken where they may be suffering from or have been in contact with an infectious disease. Expert medical advice shall be sought where required.
7.4	Protective clothing Employees or visitors to production areas

Statement of Intent	Suitable company-issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.
7.4.1	The company shall document and communicate to all employees <u>(including agency and temporary personnel)</u> , contractors or visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. high-care or low-risk areas). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, use of canteen and smoking areas).
7.4.2	Protective clothing shall be available that: <ul style="list-style-type: none"> • is provided in sufficient numbers for each employee • is of suitable design to prevent contamination of the product (as a minimum containing no external pockets above the waist or sewn on buttons) • fully contains all scalp hair to prevent product contamination • includes snoods for beards and moustaches where required to prevent product contamination.
7.4.3	<p><u>Laundering of protective clothing shall take place by an approved contracted or in-house laundry using defined and verified criteria to validate the effectiveness of the laundering process. The laundry must operate procedures which ensure:</u></p> <ul style="list-style-type: none"> • <u>adequate segregation between dirty and cleaned clothes</u> • <u>effective cleaning of the protective clothing</u> • <u>protective clothing for high-risk or high-care areas are commercially sterile following the washing and drying process</u> • <u>cleaned clothes are protected from contamination until use e.g. by the use of covers or bags</u> <p>Washing of workwear by the employee is exceptional but shall be acceptable where the protective clothing is to protect the employee from the products handled and the clothing is worn in enclosed product or low-risk areas only.</p>
7.4.4	<p>Where protective clothing for high-care or high-risk areas <u>Where protective clothing is cleaned</u> provided by a contracted laundry, this shall be audited either directly or by a third party, or <u>The frequency of these audits should be based on risk.</u> should have a relevant certification.</p> <p>The laundry must operate procedures which ensure:</p>

	<p>effective cleaning of the protective clothing clothes are commercially sterile following the washing and drying process adequate segregation between dirty and cleaned clothes <u>Cleaned protective clothinges shall be</u> protected from contamination until delivered to the site, e.g. by the use of covers or bags.</p>
<u>New 7.4.5</u>	<u>Protective clothing shall be changed at an appropriate frequency, based on risk. For high risk and high care areas the protective clothing shall be changed at least daily.</u>
<u>7.4.56</u>	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.
<u>7.4.67</u>	Where items of personal protective clothing that are not suitable for laundering are provided (such as chain mail, gloves and aprons), these shall be cleaned and sanitised at a frequency based on risk.

DRAFT FOR CONSULTATION

Guidelines on Defining Production Risk Zones

The Standard identifies a number of different risk zones within the processing and storage facilities, with corresponding levels of hygiene and segregation to reduce the potential for product contamination. The decision tree (Section 4) provides a guide to defining the risk zones. These are classified as:

- High Risk (Chilled & Frozen)
- High Care (Chilled & Frozen)
- **Ambient High Care**
- Low Risk
- Enclosed Product Areas (e.g. warehouses & storerooms)
- Non-Product Areas (e.g. canteens, laundries and offices)

The food safety controls operated within the factory areas shall be appropriate to the product. The expectations for factory hygiene, finish of buildings, equipment, protective clothing and staff hygiene should reflect the potential risks to the product. Identifying areas of different risk helps to ensure the appropriate food safety controls are in place and identify any need to restrict movement of personnel and materials between areas.

1 Open Product Areas

Wherever ingredients, intermediates or finished products are not protected from the factory environment there is a potential risk of product contamination by foreign bodies, allergenic material or micro-organisms in the environment.

The significance of the risk of microbiological contamination will depend upon the susceptibility of the product to support the growth or survival of pathogens and the expected storage conditions, shelf life and further treatment of the product at the factory or by the consumer.

In determining the zones particular consideration shall be given to the risks presented by pathogens. It should be recognised that some products considered as low risk on this basis will nevertheless require high standards of microbiological control because spoilage organisms present a significant risk (e.g. yeasts in yoghurt or moulds on hard cheese).

1.1 High Risk (Chilled & Frozen)

A physically segregated area⁽¹⁾, designed to a high hygiene standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to *prevent* contamination by pathogenic micro-organisms. Products which require handling in a high risk area meet all of the following:

- The finished products require chilling or freezing during storage to preserve food safety
- All components have received a full cook⁽²⁾ process, to a minimum of 70°C for 2 minutes or equivalent before entry to the area
- Vulnerable to the growth and/or **survival** of pathogens, for example, *Listeria* species
- The finished products are ready to eat⁽³⁾ or reheat⁽⁴⁾ or, on the basis of known consumer use, are likely to be eaten without adequate cooking

Examples of products considered as high risk include cooked sliced meats and fully cooked prepared meals.

It should be noted that where the product has cooking instructions for the consumer that are equivalent to a full cook⁽²⁾ then the product may be considered as low risk if the product is no longer ready to eat or reheat. However, in these situations the site is expected to have a full validation, which the auditor can refer to, demonstrating that the cooking instructions are appropriate and that the product will achieve the correct temperature/time when the cooking instructions are used. However, this activity must not compromise the safety of other products in the area.

- (1) The purpose of physical segregation is to provide a self-contained area where uncovered (i.e. unprotected) high risk products are handled after the microbiological kill step (e.g. thermal processing) until fully protected, usually by means of packaging.

The segregating barrier must be capable of preventing the risk of cross contamination from:

- pathogens which may be present in a low risk environment or on products or ingredients that have not received a full cook
- All people moving between the high risk area and other areas except through designated changing areas
- The movement of all equipment, utensils or materials into the high risk area except through designated ports with sanitising controls in place.
- Water or other liquids on the floor, washing into the high risk area
- Airborne contaminants e.g. dust particles or water droplets

The ideal barrier is a full wall separating the high risk area from other areas. In assessing the suitability of the segregating barrier a risk assessment must have been carried out and documented.

It is expected that newly built factories will employ full wall separation where high risk facilities are required.

Time segregation is not an acceptable alternative to physical segregation for high risk areas, except for transfer points noted in the current BRC position statement.

(2) Cook – is a thermal process which is designed to achieve typically a 6 log reduction in *Listeria monocytogenes* equivalent to 70°C for 2 minutes. Alternative cooking processes may be accepted where these meet recognised national guidelines and are validated by scientific data.

(3) Ready to Eat Food – is food intended, by the manufacturer, for direct human consumption without the need for cooking or other processing, effective to eliminate or reduce to an acceptable level, micro-organisms of concern.

(4) Reheat – products that are designed to be safe to be consumed without the need for a full cook; the reheating of the product is intended to make the product more palatable and is not a microbiological kill step (i.e. not a 6 log reduction).

1.2 High Care (Chilled & Frozen)

This is an area designed to a high standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to *minimise* product contamination by pathogenic micro-organisms. Segregation⁽¹⁾ of the high care area and access arrangements to the area shall minimise the risk of product contamination. Products which require handling in a high care area meet all of the following:

- The finished products require chilling or freezing during storage
- All microbiologically susceptible components have received a process to reduce the microbiological contamination to acceptable levels (typically 1 – 2 log reduction of micro-organisms, for example, *Listeria* species) before entry to the area
- Vulnerable to the growth and/or **survival** of pathogens
- The finished products are ready to eat⁽²⁾ or reheat⁽³⁾ or, on the basis of known consumer use, are likely to be eaten without adequate cooking

Although all vulnerable products have, before entry to the high care area, received a process to reduce pathogenic bacteria to a level to make them safe to eat, spoilage organisms will be present and shall be controlled by temperature and shelf life. Examples of products considered as high care include sandwiches and prepared salads.

Products produced in high care areas may themselves present hazards to other products; for instance the use of salad products, even when processed by rinsing in chlorine solution to reduce microbial load, may still present an increased risk, and this needs to be taken into account when planning hygiene regimes and production controls within the high care area.

- (1) It is important that the high care area is effectively protected from recontamination from the low risk zones. This segregation is most effectively achieved by full physical segregation by means of walls which separate the high care area from other factory areas.

The segregating barrier must be capable of preventing the risk of cross contamination from:

- pathogens which may be present in a low risk environment or on products or ingredients that have not received a full cook
- all people moving between the high risk area and other areas except through designated changing areas
- the movement of all equipment, utensils or materials into the high risk area except through designated ports with sanitising controls in place
- water or other liquids on the floor, washing into the high risk area
- airborne contaminants e.g. dust particles or water droplets

In assessing the suitability of the segregating barrier a risk assessment must have been carried out and documented. Alternative controls may be accepted where all the objectives above can be met.

It is expected that newly built factories will employ full wall separation where high risk facilities are required.

(2) Ready to Eat Food – is food intended, by the manufacturer, for direct human consumption without the need for cooking or other processing, effective to eliminate or reduce to an acceptable level micro-organisms of concern.

(3) Reheat – products that are designed to be safe to be consumed without the need for a full cook; the reheating of the product is intended to make the product more palatable and is not a microbiological kill step (i.e. not a 6 log reduction).

1.3 Ambient High Care

This is an area designed to a high standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to *minimise* product contamination by pathogenic micro-organisms. Ambient products that are handled in these areas are vulnerable; as the pathogens are known to survive on the product (i.e. this area is different from low risk areas because products handled in low risk either intrinsically, or by design, do not support the growth or survival of pathogens).

Products which require handling in this area meet all of the following:

- the finished products are stored at ambient temperatures (i.e. greater than 5°C)
- the finished products are ready to eat⁽¹⁾ or reheat⁽²⁾ or, on the basis of known consumer use, are likely to be eaten without adequate cooking
- Vulnerable to pathogen survival

Examples of products considered as ambient, ready to eat but susceptible to pathogen survival include chocolate, baby formula and milk powder.

The site will need to assess the level of risk that these products represent and introduce appropriate risk based controls to minimise the potential for cross-contamination. Depending on the product these controls may be similar to those for high risk or high care. The controls used and the risk assessment demonstrating these are appropriate must be documented.

(1) Ready to Eat Food – is food intended, by the manufacturer, for direct human consumption without the need for cooking or other processing, effective to eliminate or reduce to an acceptable level micro-organisms of concern.

(2) Reheat – products that are designed to be safe to be consumed without the need for a full cook; the reheating of the product is intended to make the product more palatable and is not a microbiological kill step (i.e. not a 6 log reduction).

1.4 Low Risk

The significance to human health of microbiological contamination in low risk areas is reduced because the products either:

- do not support the growth or survival of pathogens (either intrinsically or by design of the product)
- are designed to undergo a later validated kill step that ensures the product is safe to eat

The hygiene standards in such areas generally require greater emphasis on preventing foreign body and allergen contamination but good manufacturing practices, including good process flow are still expected.

Products manufactured in this area include the following:

- products which will always require cooking by the consumer before consumption e.g. raw meat and fish, where instructions require products to be fully cooked
- where the products are processed within the final container e.g. canned
- products unsuitable for the growth and/or survival of pathogens and are stored and distributed as ambient products e.g. preserves, pH controlled products such as pickles, low Aw foods such as dried pasta and sugar confectionary

- ready to eat products stored chilled or frozen to preserve the quality of the product, but which have other controls to prevent the growth of pathogens e.g. hard cheese
- production areas where processes are undertaken prior to the transfer point into high risk or high care areas

Examples of products considered as low risk include raw meat.

2 Enclosed Product Areas

An enclosed product area is defined as an area of the factory where all of the products are fully enclosed and therefore not vulnerable to environmental contamination (e.g. foreign bodies or micro-organisms). This includes areas where:

- The product is fully enclosed within packaging e.g. raw material and finished product storage and dispatch areas
- The product is fully enclosed within equipment shielding the product from physical or microbiological contamination from the production equipment during production. This may include enclosure within transfer pipework and fully enclosed equipment, and also where the equipment maintains its own environment to protect the product e.g. aseptic filling equipment.

Whenever product lines are entered, for example for cleaning, maintenance or sampling, documented processes must be in place to ensure that the potential for contamination is minimised and the line is returned to the correct standard to maintain the enclosed product status.

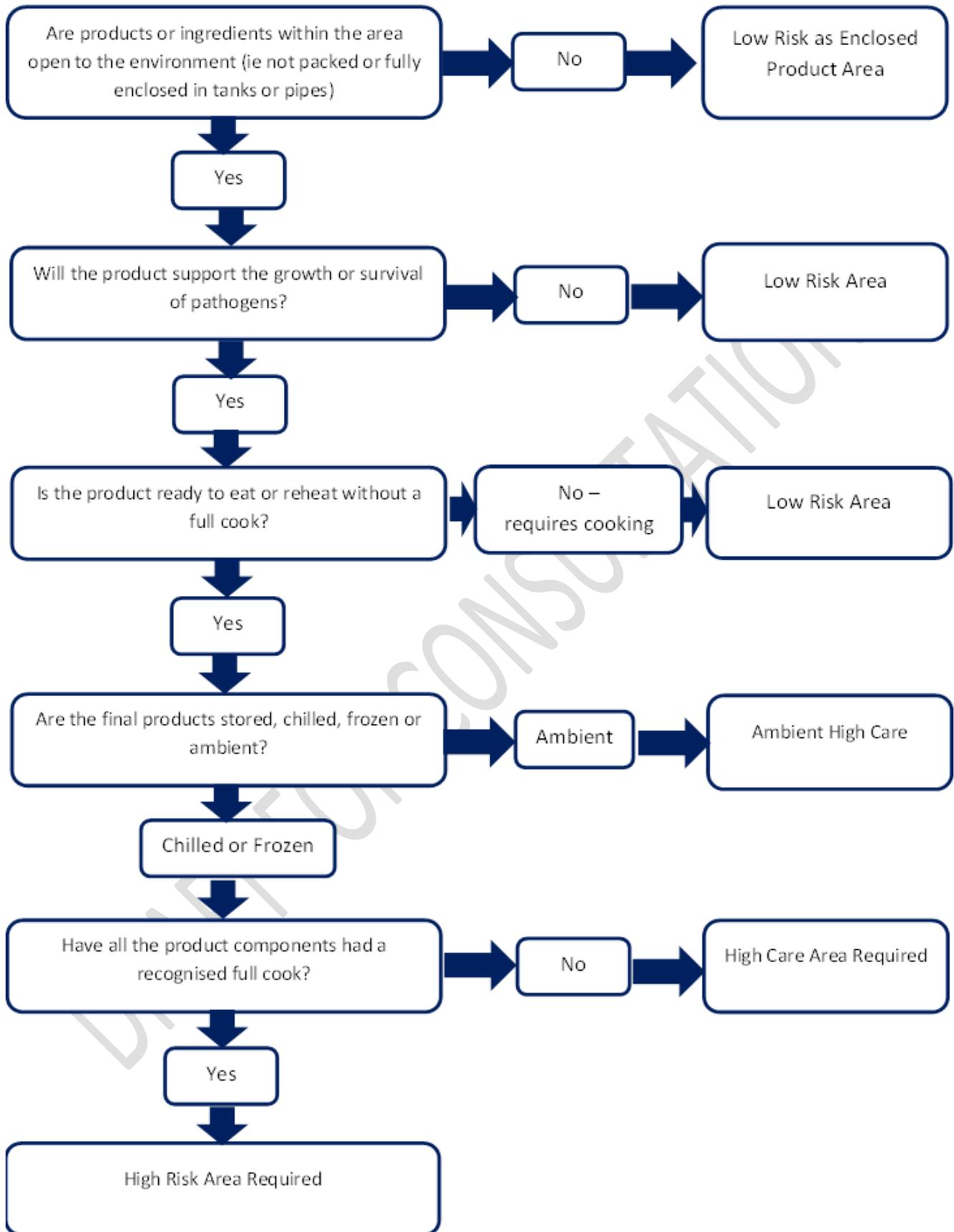
3 Non-Product Areas

Manufacturing sites will have some non-product areas i.e. those parts of the site where products are never taken (e.g. canteens, offices or laundries). These areas often operate to different standards than those required in production and storage areas.

Procedures are required to ensure that the activities in these areas cannot result in the subsequent contamination of production areas, for example, by removing protective clothing when leaving production areas, hand washing on entry on open product areas, etc.

4 Production Area Decision Tree

This decision tree below provides a guide to the categorisation of production areas and cannot take account of specific product characteristics (e.g. pH or Aw) or the vulnerability of particular products to pathogens or spoilage that may result in exceptions. A detailed risk assessment should be undertaken where necessary to support the decision.



BRC Global Standards Protocol

The following changes have been proposed for the operating Protocol for issue 7 and are published for comment.

1. Grading

New grade barriers and nomenclature

Objective is to drive behaviour to capture detail of more relevant non-conformities and to make the top grade more exclusive.

The top grade would be based on achieving less than 4 minor non-conformities.

The second grade boundaries would be widened to 4 to 20 minor non-conformities.

The 3rd grade would remain the same at 20 to 30 minor non-conformities.

It is proposed to change the grading terminology to avoid direct comparisons to current A and B grades and grade as Excellent, Good, Satisfactory and un-certificated with a + symbol to designate unannounced audits

2. Exclusions from Scope

Proposal

- Limit exclusions to
 - Products which are clearly differentiated from products included within scope
 - AND the products are produced in a separate area of the factory.
- Introduce a box within the audit report where the reasons for any exclusions are clearly justified
- Remove the ability to exclude products produced on different production equipment but within the same production area
- Remove the use of the word 'minority' as this leads to wide interpretation and is not clearly understood

3. Additional voluntary Modules

Proposal to allow the addition of modules to the core standard. The modules would be voluntary and could be added to during the life of the Standard to react to regional requirements e.g. Food defense, emerging issues e.g. Food Fraud, or customer demand e.g. Animal Feed.

Modules would be audited as part of the core standard and would operate to the same protocol as the core standard except that

- Non conformities raised would not count towards the grading of the main core Standard
- All non-conformities would need to be closed to achieve the module.

- Modules would be shown within the scope of the report and certificate as certificated or not certificated.

Reports would include additional sections demonstrating compliance.

4. Small Suppliers and Developing sites - Redevelopment of the Enrolment Programme

The proposal is to offer audits at 3 levels

Basic – closely aligned to the GFSI Global Markets requirements

Intermediate – closely aligned to the GFSI Global markets intermediate level

Full BRC Certification

Audits at Basic and Intermediate level would operate under similar rules to the full assessment except that

- The audit will be restricted to the clauses applicable at that level
- The audit duration will be shorter reflecting the reduced number of requirements being audited
- 90 days will be allowed for the closure on non-conformities (28 days for re-approval audits)
- There will be no grading – simply pass or fail
- The audit report will clearly differentiate from a Full BRC audit report
- A statement of compliance will be provided but clearly differentiated from the BRC certificate.
- Recognition on the searchable BRC Directory but in a different area from certificated sites

The positioning of Basic and Intermediate level awards to be clearly differentiated from full certification terminology is still to be defined.