Global Standard Food Safety Issue 9
Draft for Industry Consultation (December 2021)

Document Scope:

Draft of Issue 9 of the Global Standard Food Safety for industry consultation.

On conclusion of the consultation (refer to Part I Introduction) comments received will be review by the BRCGS Technical Working Group and where applicable, the draft Standard updated prior to publication of the final text. This document shall therefore only be considered a draft document and not the final definitive text or normative version of the Standard.

Change log:

Version no.	Date	Description
1	6/12/2021	First draft of BRCGS Standard Food Safety Issue 9 for industry consultation.

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How this publication is organised?

This publication sets out the draft requirements for auditing and certification of food manufacturers to achieve certification for the *Global Standard Food Safety Issue 9*.

The document consists of the following sections:

Part I - Introduction

Provides an introduction to this document and the consultation process.

Part II - Requirements

Details the proposed requirements of the Standard with which a company must comply to gain certification.

Part III - Summary of the Audit Protocol

Provides a summary of the key changes to the audit protocol.

Part I – Introduction

The information included in this consultation document has been developed and reviewed by a working group made up of international stakeholders representing food manufacturers, retailers, food service companies, certification bodies and independent technical experts.

An important next step in the development of the Global Standard Food Safety Issue 9 is an extensive consultation to understand stakeholders' requirements and views on the draft proposals.

This document therefore contains the proposals for Issue 9 and is structured as follows:

- Section II – full details of the proposed requirements for Issue 9
- Section III – a summary of the key changes to the audit protocol

Stakeholders are encouraged to consider the details within this document and provide feedback on both the proposed requirements and the audit protocol, by email, to enquiries@brcgs.com using the feedback form provided.

The closing date for submission of feedback is **12th January 2022.**

This draft is for the purposes of consultation only and the requirements and protocol are subject to change.

Effective Date of Issue 9

As with all revisions of the Global Standards, there must be a transition period between consultation, publication of the complete, finalised Standard and full implementation of the Standard. Therefore:

- Issue 9 will be published in August 2022
- Certification against Issue 9 will commence in audits from 1st February 2023.

All certificates issued against audits carried out prior to this date will be against Issue 8 and be valid for the period specified on the certificate.

Part II - Requirements

How the requirements are set out

Each main section or subsection of the requirements in the Standard begins with a statement of intent. This sets out the expected outcome of compliance with the requirements of that section. This forms part of the audit and all companies must comply with the statements of intent.

Below the statements of intent in the tables are more specific and detailed requirements (clauses) that, if applied appropriately, will help to achieve the stated objective of the requirement. All of the requirements shall form part of the audit.

Colour coding of requirements

Production processes represent the key activities on site. The audit process therefore gives specific emphasis to the practical implementation of food safety procedures within the factory and general good manufacturing practices. Auditing these areas forms a significant proportion of the audit (around 50% of the audit time is spent auditing production and site facilities, interviewing staff, observing processes and reviewing documentation in production areas with the relevant staff).

Production areas include factory production, storage, dispatch, engineering, on-site laboratory facilities and external areas such as site security.

As an aid to this process, the requirements within the Standard have been colour coded. This shows the activities that would usually be audited as part of the assessment of the production areas and facilities and those that would form part of an audit of records, systems and documentation.

Key to colour coding of requirements

Audit of production facilities and good manufacturing practice	
Audit of records, systems and documentation	
Requirements assessed in both	

Issue 9 has, for the first time, introduced a blended audit option into the Food Standard (see Part III – Summary of the Audit Protocol). This audit option uses ICT (Information and Communication Technology) to remotely audit documentation, prior to an onsite audit of production facilities and good manufacturing practice. The colour coding of the requirements therefore also acts as an indication of the clauses which may be audited remotely. (It must be noted that whether a specific clause is actually audited remotely or onsite, during a blended audit, is subject to several considerations, including the certification body risk assessment. Therefore, the green colour coding is indicative of the maximum number of clauses which may be audited remotely and not an indication of those which will always be audited remotely during a blended audit).

Fundamental requirements

Within the Standard certain requirements have been designated as 'fundamental' requirements. These are marked with the word 'FUNDAMENTAL' and denoted with the

following symbol ☆. These requirements relate to systems that are crucial to the establishment and operation of an effective food quality and safety operation. The requirements deemed fundamental are:

- Senior management commitment and continual improvement (1.1)
- The food safety plan – HACCP (2)
- Internal audits (3.4)
- Management of suppliers of raw materials and packaging (3.5.1)
- Corrective and preventive actions (3.7)
- Traceability (3.9)
- Layout, product flow and segregation (4.3)
- Housekeeping and hygiene (4.11)
- Management of allergens (5.3)
- Control of operations (6.1)
- Labelling and pack control (6.2)
- Training: raw material handling, preparation, processing, packing and storage areas (7.1)

Failure to comply with the statement of intent of a fundamental requirement (i.e. a major non-conformity) leads to non-certification at an initial audit or withdrawal of certification at subsequent audits. This will require a further full audit to establish demonstrable evidence of compliance.

Additional requirements

The requirements in sections 1 – 7 shall be applied to **all** operations, except for section 5.8 which only applies to sites manufacturing, processing or packing pet food or animal feed, and section 5.9 which only applies to animal primary conversion.

Where products require high risk, high care or ambient high care production facilities (as defined in appendix 2 of the Standard), these requirements are listed in section 8. Any site that requires high risk, high care or ambient high care facilities is required to meet the requirements in section 8.

Where a site also handles traded products (traded products are defined as food products, that would normally fall within the scope of the Standard and are stored at the site's facilities, but that are not manufactured, processed, reworked or packed at the site being audited) the site can opt to include these products within the scope of their BRCGS audit. The requirements for traded products are detailed in section 9.

Documented procedures

In many instances, the Standard specifically states that requirements shall be satisfied by documented procedures, processes, plans or records, in others, this is implied. However, the definitions in the Standard glossary (e.g. procedure) clearly indicate that a documented system is required in these situations, as the company needs to be able to demonstrate that systems are in place, working consistently and that documents are available for reference when required.

Any policies and documents must be written in sufficient detail to satisfy their purpose and must reflect the activities that happen in practice.

These documents can be hard copy (i.e. paper-based) or electronic.

Layout of the requirements

1 Senior management commitment

1.1 Senior management commitment and continual improvement

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1Senior management commitment

1.1Senior management commitment and continual improvement

☆ FUNDAMENTAL

The site's senior management shall demonstrate they are fully committed to the implementation of the requirements of the Global Standard for Food Safety and to processes which facilitate continual improvement of food safety, ~~and~~ quality management and the site's food safety and quality culture.

Clause	Requirements
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe, legal and authentic products to the specified quality, and its responsibility to its customers. This shall be: • signed by the person with overall responsibility for the site • communicated to all staff • include commitment to improve the site's food safety and quality culture
1.1.2	The site's senior management shall define and maintain a clear plan for the development and continuing improvement of a food safety and quality culture. The plan shall also include behaviours needed to achieve the intended positive culture change. This shall include: • defined activities involving all sections of the site that have an impact on product safety. As a minimum, these activities shall be designed around: o clear and open communication on product safety o training o feedback from employees o behaviour changes required to improve product safety processes o performance measurement on product safety, authenticity, legality and quality related activities • an action plan indicating how the activities will be undertaken and measured, and the intended timescales • a review of the effectiveness of completed activities. The plan shall be reviewed and updated, at least annually at a minimum.
1.1.3	The site's senior management shall ensure that clear objectives are defined to maintain and improve the safety, authenticity, legality and quality of products manufactured, in accordance with the food safety and quality policy and this Standard. These objectives shall be: • 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 and all staff.
1.1.4	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually at a minimum, to review the site performance against the Standard and objectives set in clause 1.1.3. The review process shall include the evaluation of: • previous management review action plans and timeframes

		• the results of internal, second-party and/or third-party audits • any objectives that have not been met, to understand the underlying reasons. This information shall be used when setting future objectives and to facilitate continual improvement • any customer complaints and the results of any customer feedback • any incidents (including both recalls and withdrawals), corrective actions, out-of-specification results and non-conforming materials • the effectiveness of the systems for HACCP, food defence and authenticity, food safety and quality culture plan • resource requirements. Records of the meeting shall be documented and used to revise the objectives thereby encouraging continual improvement. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.
1.1.5		The site shall have a demonstrable meeting programme which enables food safety, authenticity, legality, ~~integrity~~ and quality issues to be brought to the attention of senior management. These meetings shall occur at least monthly. ~~Employees shall be aware of the need to report any evidence of unsafe or out-of-specification product or raw materials, to a designated manager to enable the resolution of issues requiring immediate action.~~
1.1.6		The company shall have a confidential reporting system to enable staff to report concerns relating to product safety, authenticity, ~~integrity,~~ quality and legality. The mechanism (e.g. the relevant telephone number) for reporting concerns ~~must~~ shall be clearly communicated to staff. The company's senior management shall have a process for assessing any concerns raised. Records of the assessment and, where appropriate, actions taken, shall be documented.
1.1.7		The company's senior management shall provide the human and financial resources required to produce ~~food~~ safe, authentic, legal products to the specified quality and in compliance with the requirements of this Standard.
1.1.8		The company's senior management shall have ~~a~~ systems in place to ensure that the site is kept informed of and reviews: • scientific and technical developments • industry codes of practice • new risks to authenticity of raw materials • all relevant legislation in the country where the product will be sold (where known).
1.1.9		The site shall have a genuine, original hard copy or electronic version of the current Standard available and be aware of any changes to the Standard or protocol that are published on the BRCGS ~~Global Standards~~ website.
1.1.10		Where the 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.
1.1.11		The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for certification to the Standard. Relevant departmental managers or their deputies shall be available as required during the audit.

		Site's senior manager shall be available during the audit for a discussion on effective implementation of the food safety and quality culture plan.
1.1.12		The site's senior management shall ensure that the root causes of any non-conformities against the Standard identified at the previous audit have been effectively addressed to prevent recurrence.
1.1.13		The BRCGS ~~Global Standards~~ logo and references to certification status shall only be used in accordance with the conditions of use detailed in the audit protocol section (Part III, section ~~5.~~6.7) of the Standard.

1.2Organisational structure, responsibilities and management authority

The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, authenticity, legality and quality.

Clause	Requirements
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, ~~integrity~~authenticity, 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 site's senior management shall ensure that all employees are aware of their responsibilities and demonstrate that work is carried out in accordance with~~Where~~ documented site policies, procedures, work instructions and existing practices ~~exist~~ for activities undertaken.~~the~~ All ~~relevant~~ employees shall have access to relevant documentation ~~these~~ and be able to request an assessment of training needs for activities undertaken to maintain product safety, authenticity, legality and quality ~~demonstrate that work is carried out in accordance with the instructions.~~
1.2.3	Employees shall be aware of the need to report any evidence of unsafe or out-of-specification product or raw materials, to a designated manager to enable the resolution of issues requiring immediate action.
1.2.4	In the event of the site not having the appropriate in-house food safety, authenticity, legality or quality knowledge, external expertise (e.g. food safety consultants) may be used, but day-to-day management of the food safety systems shall remain the responsibility of the company.

2The food safety plan – HACCP

☆ FUNDAMENTAL

The company shall have a fully implemented and effective food safety plan incorporating the Codex Alimentarius HACCP principles.

2.1The HACCP food safety team (equivalent to Codex Alimentarius Step 1)

Clause	Requirements
2.1.1	The HACCP or food safety plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for quality assurance, technical management, production operations~~, engineering~~ and other relevant functions (e.g. engineering, hygiene). The team leader shall have an in-depth knowledge of Codex HACCP principles (or equivalent) and be able to demonstrate competence, experience and training. Where there is a legal requirement for specific training, this shall be in place. The team members shall have specific knowledge of HACCP and relevant knowledge of products, processes and associated hazards. ~~In the event of the site not having the 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.~~
2.1.2	The scope of each HACCP or food safety plan, including the products and processes covered, shall be defined.

2.2Prerequisite programmes

Clause	Requirements	
2.2.1		The site 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: • cleaning and sanitising (e.g. procedures to comply with section 4.11) • pest management (e.g. procedures to comply with section 4.14) • maintenance programmes for equipment and buildings (e.g. procedures to comply with sections 4.4 and 4.6) • personal hygiene requirements (e.g. procedures to comply with section 7.2) • staff training (e.g. procedures to comply with section 7.1) • supplier approval and purchasing (e.g. procedures to comply with section 3.5.1) • transportation arrangements (e.g. procedures to comply with section 4.16) • processes to prevent cross-contamination (e.g. procedures to comply with sections 4.9 and 4.10) • allergen ~~controls~~management (e.g. procedures to comply with section 5.3).

		The prerequisite programmes for the particular areas of the site shall take into account the production risk zoning (see clause 4.3.1). The control measures and monitoring procedures for the prerequisite programmes ~~must~~shall be clearly documented and shall be included within the development and reviews of the HACCP or food safety plan.

2.3Describe the product (equivalent to Codex Alimentarius Step 2)

Clause	Requirements
2.3.1	A full description for each product or group of products shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list: • composition (e.g. raw materials, ingredients, allergens, recipe) • origin of ingredients • physical or chemical properties that impact food safety (e.g. pH, a_w) • treatment and processing (e.g. cooking, cooling) • packaging system (e.g. modified atmosphere, vacuum) • storage and distribution conditions (e.g. chilled, ambient) • maximum safe shelf life under prescribed storage and usage conditions.
2.3.2	All relevant information needed to conduct the hazard analysis shall be collected, maintained, documented and updated. The company will ensure that the HACCP or food safety plan is based on comprehensive information sources, which are referenced and available on request. As a guide, this may include the following, although this is not an exhaustive list: • the latest scientific literature • historical and known hazards associated with specific food products • relevant codes of practice • recognised guidelines • food safety legislation relevant for the production and sale of products • customer requirements~~.~~ • a copy of any existing site HACCP plans (e.g. for products already in production at the site) • a map of the premises and equipment layout (see clause 4.3.2) • a water distribution diagram for the site (see clause 4.5.2) • indication of any areas (zones) where high-risk, high-care or ambient high-care production facilities are required (see clause 4.3.1)

2.4Identify intended use (equivalent to Codex Alimentarius Step 3)

Clause	Requirements
2.4.1	The intended use of the product by the customer, and ~~any known~~expected alternative uses, shall be described, defining the consumer target groups, including the suitability of the product for vulnerable groups of the population (e.g. infants, elderly, allergy sufferers).

2.5Construct a process flow diagram (equivalent to Codex Alimentarius Step 4)

Clause		Requirements
2.5.1		A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP or food safety plan 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: • ~~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 • potential for process delay • rework and recycling • low-risk/high-risk/high-care area segregation • finished products, intermediate/semi-processed products, by-products and waste.

2.6Verify flow diagram (equivalent to Codex Alimentarius Step 5)

Clause		Requirements
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 and whenever there are changes which may affect food safety. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.

2.7List all potential hazards associated with each process step, conduct a hazard analysis and consider any measures to control identified hazards (equivalent to Codex Alimentarius Step 6, Principle 1)

Clause	Requirements
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 consideration of the following types of hazard: • microbiological • physical contamination • chemical and radiological contamination • fraud (e.g. substitution or deliberate/intentional adulteration) (see section 4.2) • malicious contamination of products (see section 5.4) • allergen risks (see ~~clause~~section 5.3). It shall also take account of the preceding and following steps in the process chain.
2.7.2	The HACCP food safety team shall conduct a hazard analysis to identify the significant hazards (i.e. those hazards that are reasonably likely to occur at an unacceptable level),

		which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to the following: • 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. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.
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 specific hazard validated.~~ Consideration may be given to using more than one control measure.
2.7.4		Where the control of a food safety hazard is achieved through prerequisite programmes (refer to section 2.2) or controls other than CCPs (refer to clause 2.8.1), this shall be stated and the adequacy of the programme to control the specific hazard validated.

2.8Determine the critical control points (CCPs) (equivalent to Codex Alimentarius Step 7, Principle 2)

Clause	Requirements
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. Critical control points (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.

2.9Establish validated critical limits for each CCP (equivalent to Codex Alimentarius Step 8, Principle 3)

Clause	Requirements
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: • 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.

2.10Establish a monitoring system for each CCP (equivalent to Codex Alimentarius Step 9, Principle 4)

Clause		Requirements
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: • 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, when appropriate, by a suitably competent and authorised person. Where records are in electronic form, there shall be evidence that records have been checked and verified.

2.11Establish a corrective action plan (equivalent to Codex Alimentarius Step 10, Principle 5)

Clause	Requirements
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.

2.12Validation of the HACCP Plan and ~~E~~establish verification procedures (equivalent to Codex Alimentarius Step 11, Principle 6)

Clause	Requirements
2.12.1	HACCP or food safety plans shall be validated before implementation or prior to any changes which may affect product safety, to ensure that the plan will effectively control the identified hazards. For existing HACCP or food safety plans this may be achieved using the established processes detailed in clauses 2.12.2 and 2.12.3.

2.12.2	Procedures of verification shall be established to confirm that the HACCP or food safety plan, including controls managed by prerequisite programmes, continues to be effective. Examples of verification activities include: • 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. Results of verification shall be recorded and communicated to the HACCP food safety team.
2.12.3	The HACCP food safety team shall review the HACCP or food safety plan and prerequisite programmes at least annually and prior to any changes which may affect food safety. As a guide, these may include the following, although this is not an exhaustive list: • change in raw materials or supplier of raw materials • change in ingredients/recipe • change in processing conditions, process flow or equipment • change in packaging, storage or distribution conditions • change in consumer use • emergence of a new risk (e.g. known adulteration of an ingredient or other relevant, published information, such as the recall of a similar product) • review following a significant product safety incident (e.g. a product recall) • new developments in scientific information associated with ingredients, process or product. Appropriate changes resulting from the review shall be incorporated into the HACCP or food safety plan and/or prerequisite programmes, fully documented and the validation recorded. Where appropriate, the changes shall also be reflected in the company's product safety policy and food safety objectives.

2.13HACCP documentation and record-keeping (equivalent to Codex Alimentarius Step 12, Principle 7)

Clause	**Requirements**
2.13.1	Documentation and record-keeping shall be sufficient to enable the site to verify that the HACCP and food safety controls, including controls managed by prerequisite programmes, are in place and maintained.

~~2.14Review the HACCP plan~~

~~**Clause**~~	~~**Requirements**~~
~~2.14.1~~	~~The HACCP food safety team shall review the HACCP or food safety plan and prerequisite programmes at least annually and prior to any changes which may affect food safety. As a guide, these may include the following, although this is not an exhaustive list:~~ ~~• change in raw materials or supplier of raw materials~~

	• change in ingredients/recipe • change in processing conditions, process flow or equipment • change in packaging, storage or distribution conditions • change in consumer use • emergence of a new risk (e.g. known adulteration of an ingredient or other relevant, published information, such as the recall of a similar product) • review following a recall • new developments in scientific information associated with ingredients, process or product. Appropriate changes resulting from the review shall be incorporated into the HACCP or food safety plan and/or prerequisite programmes, fully documented and the validation recorded. Where appropriate, the changes shall also be reflected in the company's product safety policy and food safety objectives.

3Food safety and quality management system

3.1Food safety and quality manual

The company's processes and procedures to meet the requirements of this Standard shall be documented to allow effective, consistent application, facilitate training, and support due diligence in the production of a safe product.

Clause		Requirements
3.1.1		The site's 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 relevant 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~~ should 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).

3.2Document control

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.

Clause	Requirements
3.2.1	The company shall have a procedure to manage documents which form part of the food safety and quality system. This shall include: • 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. Where documents are stored in electronic form these shall also be: • stored securely (e.g. with authorised access, control of amendments, or password protected) • backed up to prevent loss.

3.3Record completion and maintenance

The site shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.

Clause	Requirements
3.3.1	Records shall be legible, maintained in good condition and retrievable. Any alterations to records shall be authorised and justification for the alteration shall be recorded. Where records are in electronic form these shall also be: • stored securely (e.g. with authorised access, control of amendments, or password protected) • suitably backed up to prevent loss.
3.3.2	Records shall be retained for a defined period with consideration given to: • any legal or customer requirements • the shelf life of the product. 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). At a minimum, records shall be retained for the shelf life of the product plus 12 months.

3.4 Internal audits

☆ FUNDAMENTAL

The company shall be able to demonstrate that it verifies the effective application of the food safety plan and the implementation of the requirements of the Global Standard ~~for~~ Food Safety and the site's food safety and quality management system.

Clause	Requirements
3.4.1	There shall be a scheduled programme of internal audits. At a minimum, the programme shall include at least four different audit dates spread throughout the year. The frequency at which each activity is audited shall be established in relation to the risks associated with the activity and previous audit performance. All activities relevant to food safety, authenticity, legality and quality shall be covered at least once each year. ~~At a minimum, t~~The scope of the internal audit programme shall include, but is not limited to ~~the~~: • HACCP or food safety plan, including the activities to implement it (e.g. supplier approval, corrective actions and verification) • prerequisite programmes (e.g. hygiene, pest control) • food defence and food fraud prevention plans • procedures implemented to achieve the Standard • ~~product~~food safety and quality culture plan • assessment of the site's conformity with their food safety and quality management systems.

	Each internal audit within the programme shall have a defined scope and consider a specific activity or a section of the HACCP or food safety plan.
3.4.2	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be independent (e.g. not audit their own work).
3.4.3	The internal audit programme shall be fully implemented. Internal audit reports shall identify conformity as well as non-conformity and include objective evidence of the findings. The results shall be reported to the personnel responsible for the activity audited. Corrective and preventive actions, and timescales for their implementation, shall be agreed and their completion verified. The minimum expectations for handling non-conformities identified in the internal audit programme are detailed in the requirements in section 3.7. As a minimum a summary of the results shall be reviewed in the management review meetings (see clause 1.1.4).
3.4.4	In addition to the internal audit programme, there shall be a separate programme of documented inspections to ensure that the factory environment and processing equipment are maintained in a suitable condition for food production. At a minimum, these inspections shall include: • hygiene inspections to assess cleaning and housekeeping performance • fabrication inspections (e.g. doors, walls, facilities and equipment) to identify risks to the product from the building or equipment. The frequency of these inspections shall be based on risk and on any changes that may affect food safety but will be no less than once per month in open product areas. The results shall be reported to the personnel responsible for the activity or area audited. Corrective actions, and timescales for their implementation, shall be agreed and their completion verified. As a minimum a summary of the results shall be reviewed in the management review meetings (see clause 1.1.4).

3.5Supplier and raw material approval and performance monitoring

3.5.1Management of suppliers of raw materials and packaging

☆ FUNDAMENTAL

The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including primary packaging) to the safety, authenticity, legality and quality of the final product are understood and managed.

Clause	Requirements
3.5.1.1	The company shall undertake a documented risk assessment of each raw material or group of raw materials including primary packaging to identify potential risks to product safety, authenticity, legality and quality. This shall take into account the potential for:

	• allergens (allergen content and potential contamination) • foreign-body risks • microbiological contamination • chemical contamination • variety or species cross-contamination • substitution or fraud (see clause 5.4.2) • any risks associated with raw materials which are subject to legislative control or customer requirements. 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. The risk assessment for a raw material shall be updated: • when there is a change in a raw material, the processing of a raw material, or the supplier of a raw material • if a new risk emerges • following a product recall or withdrawal, where a specific raw material has been implicated • at least every 3 years.
3.5.1.2	The company shall have a documented supplier approval procedure to ensure that all suppliers of raw materials, including primary packaging, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval procedure shall be based on risk and include either one or a combination of: • a valid certification to the applicable BRCGS ~~Global~~ Standard or GFSI-benchmarked standard. The scope of the certification shall include the raw materials purchased **or** • supplier audits, with a scope to include product safety, traceability, HACCP review, the product security and food defence plan, the product authenticity plan and good manufacturing practices.~~,~~ The audit shall ensure that these plans form part of the supplier's product safety management system and that any resultant actions are implemented. The supplier audit shall be undertaken by an experienced and demonstrably competent product safety auditor. Where the supplier audit is completed by a second or third party, the company shall be able to: • demonstrate the competency of the auditor • confirm that the scope of the audit includes product safety, product security and food defence plan, product authenticity, traceability, HACCP review and good manufacturing practices • obtain and review a copy of the full audit report **or** • where a valid risk-based justification is provided and the supplier is assessed as low risk only, a completed supplier questionnaire may be used for initial approval. As a minimum, ~~T~~the questionnaire shall have a scope that includes product safety, product security and food defence, product authenticity, traceability, HACCP review and good manufacturing practices.~~, and it~~The

	questionnaire shall have been reviewed and verified by a demonstrably competent person.
3.5.1.3	There shall be a documented process for ongoing supplier performance review, based on risk and defined performance criteria. The process shall be fully implemented. Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status. Records of the review shall be kept.
3.5.1.4	The site shall have an up-to-date list or database of approved suppliers. This may be on paper (hard copy) or it may be controlled on an electronic system. The list or relevant components of the database shall be readily available to the relevant staff (e.g. at goods receipt).
3.5.1.5	Where raw materials (including primary packaging) are purchased from companies that are not the manufacturer, packer or consolidator (e.g. purchased from an agent, broker or wholesaler), the site shall know the identity of the last manufacturer or packer, or for bulk commodity products the consolidation place of the raw material. Information to enable the approval of the manufacturer, packer or consolidator, as in clauses 3.5.1.1 and 3.5.1.2, shall be obtained from the agent/broker or directly from the supplier, unless the agent/broker is themselves certificated to a BRCGS Standard (e.g. ~~BRC~~ Global Standard for Agents and Brokers) or a standard benchmarked by GFSI.
3.5.1.6	The company shall ensure that its suppliers of raw materials (including primary packaging) have an effective traceability system. Where a supplier has been approved based on a questionnaire instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least every 3 years. This may be achieved by a traceability test. Where a raw material is received directly from a farm or fish farm, further verification of the farm's traceability system is not mandatory.
3.5.1.7	The procedures shall define how exceptions to the supplier approval processes in clause 3.5.1.2 are handled (e.g. where raw material suppliers are prescribed by a customer) or where information for effective supplier approval is not available (e.g. bulk agricultural commodity products) and instead product testing is used to verify product quality and safety. When a site produces customer-branded product, the customer shall be made aware of the relevant exceptions.

3.5.2Raw material and packaging acceptance, monitoring and management procedures

Controls on the acceptance of raw materials (including primary packaging) shall ensure that these do not compromise the safety, legality or quality of products and where appropriate any claims of authenticity.

Clause		Requirements
3.5.2.1		The company shall have a procedure for the acceptance of raw materials and primary packaging on receipt based upon the risk assessment (clause 3.5.1.1). Acceptance of raw materials (including primary packaging) and their release for use shall be based on either one or a combination of: • product sampling and testing • visual inspection on receipt • certificates of analysis (specific to the consignment) • certificates of conformance. A list of raw materials (including primary packaging) and the requirements to be met for acceptance shall be available. The parameters for acceptance and frequency of testing shall be clearly defined, implemented and reviewed.
3.5.2.2		Procedures shall be in place to ensure that approved changes to raw materials (including primary packaging) are communicated to goods receipt personnel and that only the correct version of the raw material is accepted. For example, when labels or printed packaging have been amended, only the correct version should be accepted and released into production.

3.5.3Management of suppliers of services

The company shall be able to demonstrate that where services are outsourced, the service is appropriate and any risks presented to food safety, authenticity, legality and quality have been evaluated to ensure effective controls are in place.

Clause	Requirements
3.5.3.1	There shall be a procedure for the approval and monitoring of suppliers of services. Such services shall include, as appropriate: • pest control • laundry services • contracted cleaning • contracted servicing and maintenance of equipment • transport and distribution • off-site storage of ingredients or, packaging ~~or products~~ (other than at the supplier's facilities) prior to delivery to the site • off-site packing of products • laboratory testing • catering services • waste management • product safety consultants. This approval and monitoring process shall be risk-based and take into consideration:

	• risk to the safety and quality of products • compliance with any specific legal requirements • potential risks to the security of the product (i.e. risks identified in the vulnerability and food defence assessments).
3.5.3.2	Contracts or formal agreements shall exist with the suppliers of services that clearly define service expectations and ensure that the potential food safety risks associated with the service have been addressed.
3.5.3.3	There shall be a documented process for ongoing performance review of suppliers of services, based on risk and defined performance criteria. The process shall be fully implemented. Records of the review shall be kept.

3.5.4Management of outsourced processing

Outsourced processing (also referred to as subcontracted processing) is defined as where intermediate production, processing, storage or a step in the manufacture of a product is completed at another company or another site.

It should be noted that outsourced processing refers to an intermediate step, therefore during outsourced processing the product or partly processed product, leaves the site being audited for the completion of the outsourced processing, before returning to the site. The audited site may or may not complete additional packing or processing steps on the product.

Where raw materials receive additional storage or processing prior to their initial arrival onsite, this is not considered outsourced processing, but should be managed by the site using supplier approval, raw material risk assessments and raw material specifications.

Where a product leaves the site, and does not return to the site, this is not outsourced processing and the activities completed off-site are outside the scope of the audit.

~~Where any process step in the manufacture of a product is outsourced to a third party or undertaken at another site, this shall be managed to ensure it does not compromise the safety, legality, quality or authenticity of the product.~~

Where any intermediate process step (including production, processing or storage) in the manufacture of a product is outsourced to a third party or undertaken at another site, and subsequently returned to the site, this shall be managed to ensure it does not compromise the product safety, authenticity, legality or quality.

Clause	Requirements
3.5.4.1	The company shall be able to demonstrate that, where part of the production process (i.e. any intermediate process step) is outsourced, ~~or any part of the final packing is outsourced and~~ undertaken off-site and subsequently returned to the site, this has been declared to the customer~~brand owner~~ and, where required, approval granted.
3.5.4.2	The company shall ensure that outsourced processors are approved and monitored, to ensure that they effectively manage risks to product safety and quality and are operating effective traceability processes.

	The approval and monitoring procedure shall be based on risk and include either one or a combination of: • a valid certification to the applicable BRCGS ~~Global~~ Standard or GFSI-benchmarked standard. The scope of the certification shall include the ~~raw materials~~ activities completed for the site~~purchased~~ **or** • supplier audits, with a scope to include product safety, traceability, HACCP review, product security and food defence plan, product authenticity plan and good manufacturing practices. The audit shall ensure that these plans form part of the supplier's product safety management system and that any resultant actions are implemented.~~,~~ The supplier audit shall be undertaken by an experienced and demonstrably competent product safety auditor. Where this supplier audit is completed by a second or third party, the company shall be able to: • demonstrate the competency of the auditor • confirm that the scope of the audit includes product safety, traceability, HACCP review, product security and food defence plan, product authenticity plan and good manufacturing practices • obtain and review a copy of the full audit report. There shall be a documented process for ongoing supplier performance review, based on risk and defined performance criteria. The process shall be fully implemented. Records of the review shall be kept.
3.5.4.3	Where any processes are outsourced, including production, manufacture, processing or storage, the risks to the product safety, authenticity, legality and quality shall form part of the site's food safety plan (HACCP plan).
3.5.4.4	Clear specifications shall be agreed for all outsourced processing.
3.5.4.5	Any outsourced processing operations shall: • be undertaken in accordance with established contracts which clearly define any processing ~~and/or packing~~ requirements ~~and product specification~~ • maintain product traceability.
3.5.4.6	The company shall establish inspection and test procedures for products where part of the processing has been outsourced, including visual, chemical and/or microbiological testing. The frequency and methods of inspection or testing shall depend on risk assessment.

3.6Specifications

Specifications shall exist for raw materials (including primary packaging), finished products and any product or service which could affect the integrity of the finished product.

Clause	**Requirements**
3.6.1	Specifications for raw materials and primary 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 or allergen standards).
3.6.2	Accurate, up-to-date specifications shall be available for all finished products. These may be in the form of a printed or electronic document, or part of an online specification system. They shall include key data to meet customer and legal requirements and assist the user in the safe usage of the product.
3.6.3	Where the company is manufacturing customer-branded products, it shall seek formal agreement of the finished product specifications. 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.
3.6.4	Specification review shall be sufficiently frequent to ensure that data is current or at a minimum every 3 years, taking into account product changes, suppliers, regulations and other risks. Reviews and changes shall be documented.

3.7Corrective and preventive actions

☆ FUNDAMENTAL

The site shall be able to demonstrate that it uses the information from identified failures in the food safety and quality management system (e.g. non-conforming products, internal audits, complaints, product recalls, product testing, second- and third-party audits and online reviews) to complete~~make~~ necessary corrective actions~~ons~~ and prevent recurrence.

Clause		Requirements
3.7.1		The site shall have a procedure for handling and correcting failures identified in the food safety and quality management system. The site procedures shall include the completion of root cause analysis and handling of preventive action.
~~3.7.2~~		~~Where a non-conformity places the safety, legality or quality of products at risk, this shall be investigated and recorded including:~~ • ~~clear documentation of the non-conformity~~ • ~~assessment of consequences by a suitably competent and authorised person~~ • ~~the action to address the immediate issue – review this clause as per feedback.~~ • ~~an appropriate timescale for correction and preventive action?~~ • ~~the person responsible for correction~~ • ~~verification that the correction has been implemented and is effective.~~
3.7.2		Where a non-conformity places the safety, authenticity or legality of a product at risk, or where there is an adverse trend in quality, this shall be investigated and recorded including: • clear documentation of the non-conformity • assessment of consequences by a suitably competent and authorised person • the corrective action to address the immediate issue

		• completion of root cause analysis to identify the fundamental cause (root cause) of the non-conformity • appropriate timescales for corrective and preventive actions • the person(s) responsible for corrective and preventive actions • verification that the corrective and preventive actions have been implemented and are effective. Root cause analysis shall also be used to prevent recurrence of non-conformities and to implement ongoing improvements when analysis of non-conformities for trends shows there has been a significant increase in a type of non-conformity.
~~3.7.3~~		~~The site shall have a procedure for the completion of root cause analysis. At a minimum root cause analysis shall be used to implement ongoing improvements and to prevent recurrence of non-conformities when:~~ • ~~analysis of non-conformities for trends shows there has been a significant increase in a type of non-conformity~~ • ~~a non-conformity places the safety, legality or quality of a product at risk.~~

3.8Control of non-conforming product

The site shall ensure that any out-of-specification product is effectively managed to prevent unauthorised release.

Clause		Requirements
3.8.1		There shall be procedures for managing non-conforming products. These procedures shall include: • the requirement for staff to identify and report a potentially non-conforming product • clear identification of a non-conforming product (e.g. direct labelling or the use of IT systems) • secure storage to prevent accidental release (e.g. physical or computer-based isolation) • management of any product returned to the site • 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 a product is destroyed for food safety reasons.

3.9Traceability

☆ FUNDAMENTAL

The site shall be able to trace all raw material product lots (including primary packaging) from its suppliers through all stages of processing and dispatch to its customers and vice versa.

Clause	Requirements

3.9.1	The site shall have a documented traceability procedure designed to maintain traceability throughout the site's processes. At a minimum this shall include: • how the traceability system works • the labelling and records required. Where applicable, the traceability system shall meet the legal requirements in the country of sale or intended use.
3.9.2	Identification of raw materials (including primary packaging), intermediate/semi-processed products, part-used materials, finished products and materials pending investigation shall be adequate to ensure traceability.
3.9.3	The site shall test the traceability system across the range of product groups to ensure traceability can be determined from the supplier of raw material (including primary packaging) to the finished product and vice versa. ~~,~~ For food raw materials and finished products (i.e. excluding primary packaging) the test of the traceability system shall include~~ing~~ a quantity check/mass balance. The traceability test shall include a summary of the documents that should be referenced during the test, and clearly show the links between them. The test shall occur at a predetermined frequency, at a minimum annually, and results shall be retained for inspection. Traceability should be achievable within 4 hours.
3.9.4	Where rework or any reworking operation is performed, traceability shall be maintained.

3.10Complaint-handling

Customer complaints shall be handled effectively and information used to reduce recurring complaint levels.

Clause	**Requirements**
3.10.1	All complaints shall be recorded, investigated and the results of the investigation 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. Where there has been a significant increase in a complaint or a serious complaint, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.

3.11Management of incidents, product withdrawal and product recall

The company shall have a plan and system in place to manage incidents effectively and enable the withdrawal and recall of products should this be required.

Clause	**Requirements**
3.11.1	The company shall have procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, authenticity, legality or

	quality. This shall include consideration of contingency plans to maintain product safety, quality and legality. Incidents may include: • 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 • product contamination indicating a product may be unsafe or illegal • failure of, or attacks against, digital cyber-security. 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.
3.11.2	The company shall have a documented product withdrawal and recall procedure. This shall include, at a minimum: • 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 (including out-of-hours contact details) 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 • a plan to record timings of key activities • a plan to conduct root cause analysis and to implement ongoing improvements, to avoid recurrence. The procedure shall be capable of being operated at any time.
3.11.3	The incident management procedures (including those for 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.
3.11.4	In the event of a significant food safety, authenticity or legality incident, including a product recall, ~~or~~ regulatory food safety non-conformity (e.g. a regulatory enforcement notice) or food safety related withdrawal, BRCGS ~~the certification body issuing the current certificate for the site against this Standard~~ shall be informed within 3 working days using the BRCGS Directory. The company shall provide sufficient information to enable the certification body to assess any effects of the incident on the ongoing validity of the current certificate (as detailed in the audit protocol, Part III, section 7.1). As a minimum, this will include corrective action, root cause analysis and a preventive action plan.

4Site standards

4.1External standards and site security

The production site shall be of suitable size, location and construction, and be maintained to reduce the risk of contamination and facilitate the production of safe and legal finished products.

Clause	Requirements
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 grassed or planted areas are located near buildings, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to mitigate the risk of 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).
4.1.4	Policies and systems shall be in place to ensure that access to the site by employees, contractors and visitors is controlled. A visitor recording system shall be in place. Contractors and visitors, including drivers, shall be made aware of the procedures for access to the site. Only authorised personnel have access to production and storage areas. Contractors working in product processing or storage areas shall be the responsibility of a nominated person. Staff shall be trained in site security procedures.

4.2~~Site security and f~~Food defence

Systems shall protect products, premises and brands from malicious actions while under the control of the site.

Clause	Requirements
4.2.1	Where personnel are engaged in threat assessments and food defence plans, the individual or team responsible shall understand potential food defence risks at the site. This shall include knowledge of both the site and the principles of food defence. Where there is a legal requirement for specific training, this shall be in place.
4.2.2	The company shall undertake a documented risk assessment (threat assessment) of the potential risks to products from any deliberate attempt to inflict contamination or damage. This threat assessment shall include both internal and external threats.

	The output from this assessment shall be a documented food defence ~~threat assessment~~ plan. This plan shall be kept under review to reflect changing circumstances and market intelligence. It shall be formally reviewed at least annually and whenever: • a new risk emerges (e.g. a new threat is publicised or identified) • an incident occurs, where product security or food defence is implicated. Where applicable, the food defence plan shall meet the legal requirements in the country of sale or intended use.
4.2.3	Where raw materials or products are identified as being at particular risk, the ~~threat assessment~~food defence plan shall include controls to mitigate these risks. Where prevention is not sufficient or possible, systems shall be in place to identify any tampering. These controls shall be monitored, the results documented, and the controls reviewed at least annually.
4.2.4	Areas where a significant risk is identified shall be defined in the food defence plan, monitored and controlled. These shall include external storage and intake points for products and raw materials (including packaging). ~~Policies and systems shall be in place to ensure that only authorised personnel have access to production and storage areas, and that access to the site by employees, contractors and visitors is controlled. A visitor recording system shall be in place.~~ Staff shall be trained in ~~site security procedures and~~ food defence procedures.
4.2.5	Where required by legislation, the site shall maintain appropriate registrations with the relevant authorities.

4.3Layout, product flow and segregation

☆ FUNDAMENTAL

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.

Clause	Requirements
4.3.1	The site shall assess the production risk zones required for the products manufactured, processed or packed at the site, using the definitions in appendix 2 of the Standard.
4.3.2	There shall be a map of the site. At a minimum, this map shall define: • production risk zones, where product is at different levels of risk from pathogen contamination, for example, high-risk, high-care, low-risk and enclosed product areas (see clause 4.3.1 and appendix 2 for guidelines on defining the production risk zones) • access points for personnel • access points for raw materials (including packaging), semi-finished products and open products • routes of movement for personnel • routes of movement for raw materials (including packaging) • routes for the removal of waste

	• routes for the movement of rework • location of any staff facilities, including changing rooms, toilets, canteens and smoking areas • production process flows. • any areas where time segregation is used to complete different activities (for example, time segregation for high-care areas)
4.3.3	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 working in product processing or storage areas shall be the responsibility of a nominated person.~~
4.3.4	The movement of personnel, raw materials, packaging, rework and/or waste shall not compromise the safety of products. 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.
4.3.5	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.
4.3.6	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.

4.4Building fabric, raw material handling, preparation, processing, packing and storage areas

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

Clause	Requirements
4.4.1	Walls shall be 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, be maintained in good repair and facilitate cleaning.
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	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.
4.4.5	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.
4.4.6	Where elevated walkways or mezzanine floors are adjacent to or pass over production lines which have open products, they shall be:

	• designed to prevent contamination of products and production lines • easy to clean • correctly maintained.
4.4.7	Where there is a risk to product, windows and roof glazing which are designed to be opened for ventilation purposes shall be adequately screened to prevent the ingress of pests.
4.4.8	Doors (both internal and external) shall be maintained in good condition. At a minimum: • 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.
4.4.9	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.
4.4.10	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.
4.4.11	Where plastic strip curtains are present, these shall be maintained in good condition to prevent pest ingress.

4.5Utilities – water, ice, air and other gases

Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination.

Clause	Requirements
4.5.1	All water (including ice and steam) used as a raw material in the manufacture of processed food, the preparation of product, hand-washing or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use, fit for purpose or pose no risk of contamination according to applicable legislation. Where water is stored and handled onsite (e.g. holding tanks) these shall be managed to minimise food safety risks. The microbiological and chemical quality of water shall be analysed at least annually. The sampling points, scope of the test 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 schematic diagram shall be available of the water distribution system on site, including water source, holding tanks, water treatment and water recycling as appropriate. The diagram shall be used as a basis for water sampling and the management of water quality.
4.5.3	Air and other gases used as an ingredient or that are in direct contact with products shall be monitored to ensure this does not represent a contamination risk. Compressed air that is in direct contact with the product shall be filtered at point of use.

~~4.6Equipment~~

~~All food-processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.~~

~~Clause~~	~~Requirements~~
~~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 that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.~~

4.6Equipment

All production and product handling equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.

4.6.1	There shall be a documented purchase specification for any new equipment detailing the site requirements for the equipment. This may, for example, include: • any relevant legislation • where applicable, requirements for food contact surfaces to meet legal requirements • details of intended use of the equipment and the type of materials it will be handling The supplier should provide evidence that equipment meets these site requirements prior to supply.
4.6.2	A documented, risk-based, commissioning procedure shall be in place to ensure that food safety and integrity is maintained during the installation of new equipment. Installation work shall be followed by a documented hygiene clearance procedure. New equipment shall be inspected by an authorised member of staff, before being accepted into operation. The commissioning procedure shall include the update of any other site procedures that are affected by the new equipment, for example, training, operating procedures, cleaning, environmental monitoring, maintenance schedules or internal audits. The design and placement of equipment shall ensure that it can be effectively cleaned and maintained.
4.6.3	The design and construction of equipment shall be based on risk, to prevent product contamination. For example the use of the correct seals, impervious surfaces or smooth welds and joints, where they are exposed to product and could otherwise result in foreign-body, microbiological or allergen contamination of the product. Equipment that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.
4.6.4	A procedure shall be in place to manage the movement of static equipment in production areas.

4.6.5	Equipment which is not used or taken out of service shall be cleaned and stored in a manner which does not pose a risk to the product. Equipment stored in internal production and storage areas shall be kept clean. Food contact equipment which has been stored but is not in daily use shall be cleaned and, where necessary disinfected, prior to use.
4.6.6	Mobile equipment (e.g. fork-lift trucks, pallet trucks, scissor lifts and ladders) used in open product areas shall not pose a risk to the product. Where the use of mobile equipment in external areas cannot be avoided, the equipment shall be cleaned and disinfected prior to entering production areas.
4.6.7	Battery charging equipment shall not be stored in open product areas (unless the batteries are fully sealed/maintenance free) or where there is a risk to products.

4.7Maintenance

An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns.

Clause	Requirements
4.7.1	There shall be a planned, preventive maintenance schedule or condition monitoring system which includes all plant, ~~and~~ processing equipment and mobile 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, the inspection results documented and appropriate action taken.
4.7.3	Where temporary repairs are made, these shall be documented and controlled to ensure that the safety or legality of products is not jeopardised. These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale.
4.7.4	The site shall ensure that the safety or legality of products is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work shall be followed by a documented hygiene clearance procedure. Equipment and machinery shall be inspected by an authorised member of staff to confirm the removal of contamination hazards, before being accepted back into operation.
4.7.5	Materials and parts used for equipment and plant maintenance shall be of an appropriate grade or quality. Those materials (such as lubricating oil) that pose a risk by direct or indirect contact with raw materials (including primary packaging), intermediate products and finished products shall be food grade and of a known allergen status.
4.7.6	Engineering workshops shall be kept clean and tidy, and controls shall be in place to prevent transfer of engineering debris to production or storage areas.

4.8Staff facilities

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.

Clause	Requirements
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	Outdoor clothing and other personal items shall be stored separately from production clothing within the changing facilities. Facilities shall be available to separate clean and dirty production clothing.
4.8.4	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-washing facilities shall provide, at a minimum: • advisory signs to prompt hand-washing • a sufficient quantity of water at a suitable temperature • water taps with hands-free operation • liquid/foam soap • single-use towels or suitably designed and located air driers.
4.8.5	Toilets shall be adequately segregated and shall not open directly into production or packing areas. Toilets shall be provided with hand-washing facilities comprising: • basins with soap and water at a suitable temperature • adequate hand-drying facilities • advisory signs to prompt hand-washing. Where hand-washing facilities within toilet facilities are the only facilities provided before re-entering production, the requirements of clause 4.8.4 shall apply and signs shall be in place to direct people to hand-washing facilities before entering production.
4.8.6	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. Electronic cigarettes shall not be permitted to be used or brought into production or storage areas.
4.8.7	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.
4.8.8	Where catering facilities (including vending machines) are provided on the premises, they shall be suitably controlled to prevent contamination of products (e.g. as a source of

		food poisoning, ~~or~~ the use of allergenic ingredients or introduction of new allergenic material to the site).

4.9Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.

4.9.1Chemical control

Clause		Requirements
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, at a minimum: • 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 • a designated storage area (separate from chemicals used as raw materials in products) with restricted access to authorised personnel • use by trained personnel only. • procedures to manage any spills • procedures for the safe, legal disposal or return, of obsolete or out-of-date chemicals and empty chemical containers
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.

4.9.2Metal control

Clause	Requirements
4.9.2.1	There shall be a documented policy for the controlled use and storage 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, 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.

4.9.3Glass, brittle plastic, ceramics and similar materials

Clause	Requirements
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	Procedures for handling glass and other brittle materials (other than product packaging) shall be in place where open products are handled or there is a risk of product contamination. These procedures shall include, at a minimum: • a list of items detailing location, number, type and condition • recorded checks of the 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 the potential for product contamination.
4.9.3.3	Procedures detailing the action to be taken in case of breakage of glass or other brittle items shall be implemented and include the following: • training of staff in the correct procedure • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising production to continue • changing of workwear and inspection of footwear • specifying those staff authorised to carry out the above points • recording the breakage incident • safely disposing of contaminated product.
4.9.3.4	Where they pose a risk to product, glass windows shall be protected against breakage.
4.9.3.5	Where they pose 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.

4.9.4Products packed into glass or other brittle containers

Clause	Requirements
4.9.4.1	The storage of the containers shall be segregated from the storage of raw materials, product or other packaging.
4.9.4.2	Systems shall be in place to manage container breakages between the container cleaning/inspection point and container closure. This shall include, at a minimum, documented instructions which ensure: • 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 restart following cleaning • the area around the line is kept clear of broken glass.
4.9.4.3		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.

4.9.5Wood

Clause	Requirements
4.9.5.1	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 on a risk-based frequency to ensure it is in good condition and free from damage or splinters which could contaminate products. Wood used for food contact purposes shall be fit for purpose (e.g. free from damage or splinters, free from taint, and wood treatments where used, are only used in accordance with legislation and approved for food use).

4.9.6Other physical contaminants

Clause		Requirements
4.9.6.1		Procedures shall be in place to prevent physical contamination of raw materials by raw material packaging (e.g. during debagging and deboxing procedures to remove the packaging).
4.9.6.2		~~Pens used in open product areas shall be controlled to minimise the risk of physical contamination (e.g. designed without small external parts and detectable by foreign body detection equipment).~~ Pens and similar portable items used in open product areas shall be controlled by the site to minimise the risk of physical contamination (e.g. excluding non-approved items, restricting use to site issued equipment, pens designed without small external parts and detectable by foreign-body detection equipment or use in designated areas where contamination is prevented).
4.9.6.3		Based on risk, procedures shall be implemented to minimise other types of foreign-body contamination (i.e. types of contamination that are different from those detailed in section 4.9).

4.10Foreign-body detection and removal equipment

The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies.

4.10.1Selection and operation of foreign-body detection and removal equipment

Clause	Requirements
4.10.1.1	A documented assessment in association with the ~~HACCP study~~food safety plan (see section 2) 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: • filters and sieves ~~sieves~~ • metal detection and x-ray detection equipment • 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 site'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	The site shall ensure that the frequency of the testing of the foreign-body detection and/or removal equipment is defined and takes into consideration: • specific customer requirements • the site's ability to identify, hold and prevent the release of any affected materials, should the equipment fail. The site shall establish and implement corrective action and reporting procedures in the event of a failure of the foreign-body detector and/or removal equipment. Action shall include a combination of isolation, quarantining and re-inspection of all products produced since the last successful test or inspection.
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.

4.10.2Filters and sieves

Clause	Requirements
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.
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage at 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.

4.10.3Metal detectors and X-ray equipment

Clause	Requirements
4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve food safety~~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	The metal detector or X-ray equipment shall incorporate one of the following: • 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 to allow effective segregation of the affected product.
4.10.3.3	The site shall establish and implement procedures for the operation and testing of the metal detection or X-ray equipment. This shall include, at a minimum: • responsibilities for the testing of equipment • the operating effectiveness and sensitivity of the equipment and any variation to this for particular products • the methods and frequency of checking the detector • recording of the results of checks.
4.10.3.4	Metal detector testing procedures shall, at a minimum, include: • use of test pieces incorporating a sphere of metal of a known diameter selected on the basis of risk. 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, unless the product is within a foil container where a ferrous-only test may be applicable • a test to prove that both the detection and rejection mechanisms are working effectively under normal working conditions • tests of the metal detector by passing successive test packs through the unit at typical line operating speed • checks of failsafe systems fitted to the detection and rejection systems. In addition, where metal detectors are incorporated on conveyors, the test piece shall be passed as close as possible to the least sensitive area of the metal detector (usually the centre of the metal detector aperture). Wherever possible, the test piece shall be inserted within a clearly identified sample pack of the food being produced at the time of the test. Where in-line metal detectors are used, the test piece shall be placed in the product flow wherever this is possible and the correct timing of the rejection system to remove identified contamination shall be validated. Testing of in-line metal detectors shall be completed during both line start-up and at the end of the production period.

4.10.3.5	X-ray equipment testing procedures shall, at a minimum, include: • use of test pieces incorporating a sphere of suitable material (e.g. a typical contaminant) of a known diameter selected on the basis of risk. The test pieces shall be marked with the size and type of test material contained • tests carried out using separate test pieces • a test to prove that both the detection and rejection mechanisms are working effectively under normal working conditions • tests of the X-ray detector by passing successive test packs through the unit at typical line operating speed • checks of failsafe systems fitted to the detection and rejection systems. In addition, where X-rays are incorporated on conveyors, the test piece shall be passed as close as possible to the least sensitive area of the X-ray (e.g. this may be close to the X-ray source or close to the X-ray detector). Wherever possible, the test piece shall be inserted within a clearly identified sample pack of the food being produced at the time of the test. Where in-line X-ray detectors are used, the test piece shall be placed in the product flow wherever this is possible and the correct timing of the rejection system to remove identified contamination shall be validated. Testing of in-line detectors shall be completed during both line start-up and at the end of the production period.

4.10.4Magnets

Clause		Requirements
4.10.4.1		The type, location and strength of magnets shall be fully documented. Procedures shall be in place for the inspection, cleaning, strength testing and integrity checks of magnets used for final product testing. Records of all checks shall be maintained.

4.10.5Optical sorting equipment

Clause	Requirements
4.10.5.1	Optical testing equipment used for final product testing ~~Each unit~~ shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.

4.10.6Container cleanliness – glass jars, cans and other rigid containers

Clause	Requirements
4.10.6.1	Based on risk assessment, procedures shall be implemented to minimise foreign-body contamination originating from the packaging container (e.g. jars, cans and other pre-formed 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.

4.10.7 Other foreign-body detection and removal equipment

Clause	Requirements
4.10.75.1	Other foreign-body detection and removal equipment, such as gravity separation, fluid bed technology or aspirators, shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.

4.11Housekeeping and hygiene

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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.

Clause	Requirements
4.11.1	The premises and equipment shall be maintained in a clean and hygienic condition.
4.11.2	Documented cleaning and disinfection procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures for the processing equipment and food contact surfaces shall, at a minimum, include: • 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 (including records for completion and sign-off) and responsibility for verification. The frequency and methods of cleaning shall be based on risk. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.
4.11.3	Limits of acceptable and unacceptable cleaning performance shall be defined for food contact surfaces and processing equipment. These limits shall be based on the potential hazards relevant to the product or processing area (e.g. microbiological, allergen, foreign-body contamination or product-to-product contamination). Therefore, acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing, allergen testing or chemical testing as appropriate.

	The site shall define the corrective action to be taken when monitored results are outside of the acceptable limits. Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard, the cleaning and disinfection procedures and their frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.
4.11.4	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.
4.11.5	The cleanliness of equipment shall be checked before equipment is released back into 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 to instigate improvements where required.
4.11.6	Cleaning equipment shall be: • 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.

4.11.7Cleaning in place (CIP)

Clause	**Requirements**
4.11.7.1	All CIP equipment shall be designed and constructed to ensure effective operation. This shall include: • validation confirming the correct design and operation of the system • an up-to-date schematic diagram of the layout of the CIP system • where rinse solutions are recovered and reused, an assessment of the risk of cross-contamination (e.g. due to the re-introduction of allergen or the existence of different production risk zones within the site). Alterations or additions to the CIP system shall be authorised by a suitably competent individual before changes are made. A record of changes shall be maintained. The system shall be revalidated at a frequency based on risk, and following any alteration or addition.
4.11.7.2	Limits of acceptable and unacceptable performance for key process parameters shall be defined to ensure the removal of target hazards (e.g. soil, allergens, micro-organisms, spores). At a minimum these parameters shall include: • times for each stage • detergent concentrations • flow rate and pressure • temperatures. These shall be validated and records of the validation maintained.

4.11.7.3	The CIP equipment shall be maintained by suitably trained staff to ensure effective cleaning is carried out. This shall include: • detergent concentrations shall be checked routinely • recovered post-rinse solutions shall be monitored for build-up of carry-over from the detergent tanks • filters, where fitted, shall be cleaned and inspected at a defined frequency • where used, flexible hoses shall be stored hygienically when not in use, and inspected at a defined frequency to ensure that they are in good condition.
4.11.7.4	CIP facilities, where used, shall be monitored at a defined frequency based on risk. This may include: • monitoring of process parameters defined in clause 4.11.7.2 • ensuring correct connections, piping and settings are in place • confirming the process is operating correctly (e.g. valves opening/closing sequentially, spray balls are operating correctly) • ensuring effective completion of the cleaning cycle • monitoring for effective results, including draining where required. Procedures shall define the action to be taken if monitoring indicates that processing is outside the defined limits.

4.11.8Environmental monitoring

Risk-based environmental monitoring programmes shall be in place for pathogens or spoilage organisms. At a minimum, these shall include all production areas with open and/or ready-to-eat products.

Clause		Requirements
4.11.8.1		The design of the environmental monitoring programme shall be based on risk, and at a minimum include: • sampling procedures • identification of sample locations • frequency of tests • target organism(s) (e.g. pathogens, spoilage organisms and/or indicator organisms) • test methods (e.g. settle plates, rapid testing and swabs) • recording and evaluation of results. The programme and its associated procedures shall be documented.
4.11.8.2		Appropriate control or action limits shall be defined for the environmental monitoring programme. The company shall document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate an upward trend of positive results (i.e. a trend towards a control or action limit).
4.11.8.3		The company shall review the environmental monitoring programme at least annually and whenever there are: • changes in processing conditions, process flow or equipment which could impact the environmental monitoring programme

	• new developments in scientific information– (e.g. new pathogens of concern) • failures of the programme to identify a significant issue (e.g. regulatory authority tests identifying positive results which the site programme did not) • product failures (products with positive tests) • consistently negative results (e.g. a site with a long history of negative results should review its programme to consider whether the correct parts of the factory are being tested, whether the testing is being conducted correctly, whether the tests are for the appropriate organisms, etc.).

4.12Waste/waste disposal

Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.

Clause	Requirements
4.12.1	Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and records of removal shall be maintained and available for audit.
4.12.2	Internal and external waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: • clearly identified • designed for ease of use and effective cleaning • well maintained to allow cleaning and, where required, disinfection • emptied at appropriate frequencies. External waste containers shall be covered or doors kept closed as appropriate.
4.12.3	Waste disposal from open product areas shall be managed to ensure that it does not compromise product safety.
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 include the quantity of waste collected for destruction or disposal.

4.13Management of surplus food and products for animal feed

Effective processes shall be in place to ensure the safety and legality of by-products of the primary processing activity of the site.

Clause	Requirements
4.13.1	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 the product enters the supply chain, unless otherwise authorised by the customer.

4.13.2	Where customer-branded products which do not meet specifications 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 that all products (own-branded and customer-branded) which are sold to staff or passed on to charities or other organisations are fit for consumption, ~~and~~ meet legal requirements and maintain traceability. .
4.13.3	By-products and downgraded/surplus products intended for animal feed shall be segregated from waste and protected from contamination during storage. Products for animal feed shall be managed in accordance with the relevant legislative requirements.

4.14Pest management

The whole site shall have an effective preventive pest management programme in place to minimise the risk of ~~infestation~~pest presence and resources shall be available to respond rapidly to any issues which occur to prevent risk to products.

Pest management programmes shall comply with all applicable legislation.

Clause	Requirements
4.14.1	If pest activity is identified, it shall not present a risk of contamination to products, raw materials or packaging. The presence of any infestation on site shall be documented in pest management records and be part of an effective pest control programme to eliminate or manage the infestation so that it does not present a risk to products, raw materials or packaging.
4.14.2	The site shall either contract the services of a competent pest management organisation or 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. The risk assessment shall be reviewed whenever: • there are changes to the building or production processes which could have an impact on the pest management programme • there has been a significant pest issue. Where the services of a pest management contractor are employed, the service scope shall be clearly defined and reflect the activities of the site. Service provision regardless of the source shall meet with all applicable regulatory requirements.
4.14.3	Where a site undertakes its own pest management, it shall be able to effectively demonstrate that: • pest management 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 • staff undertaking pest management activities meet any legal requirements for training or registration

	• 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 and complied with • dedicated locked facilities are used for the storage of pesticides.
4.14.4	Pest management documentation and records shall be maintained. At a minimum, this shall include: • an up-to-date plan of the full site, identifying pest control devices and their locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for the site management and 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. Records may be on paper (hard copy) or controlled on an electronic system (e.g. an online reporting system).
4.14.5	Bait stations or other rodent monitoring or control devices shall be appropriately located and maintained to prevent contamination risk to product. Toxic rodent baits shall not be used within production or storage areas where open product is present except when treating an active infestation. Where toxic baits are used, these shall be secured. Any missing bait stations shall be recorded, reviewed and investigated.
4.14.6	Insect-killing devices, pheromone traps and/or other insect monitoring devices shall be appropriately 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.
4.14.7	The site shall have adequate measures in place to prevent birds from entering buildings or roosting above loading or unloading areas.
4.14.8	In the event of infestation, or evidence of pest activity, immediate action shall be taken to identify at-risk products and to minimise the risk of product contamination. Any potentially affected products should be subject to the non-conforming product procedure.
4.14.9	Records of pest management inspections, pest proofing and hygiene recommendations and actions taken shall be maintained. It shall be the responsibility of the site to ensure that all of the relevant recommendations made by its contractor or in-house expert are carried out in a timely manner.
4.14.10	An in-depth, documented pest management ~~survey~~assessment shall be undertaken at a frequency based on risk, but at least annually, by a pest management ~~control~~ expert to review the pest management measures in place. The assessment~~survey~~ shall: • include~~provide~~ an in-depth inspection of the site, equipment and facilities~~y~~ for pest activity • review the existing pest management measures in place and make any recommendations for change. The ~~survey~~ assessment shall be timed to allow access to equipment for inspection where a risk of stored product insect infestation exists.

4.14.11		Results of pest management inspections shall be assessed and analysed for trends on a regular basis. At a minimum, results of inspections shall be analysed: • annually or • in the event of an infestation. The analysis shall include results from trapping and monitoring devices to identify problem areas. The analysis shall be used as a basis for improving the pest management procedures.
4.14.12		Employees shall understand the signs of pest activity and be aware of the need to report any evidence of pest activity to a designated manager.

4.15Storage facilities

All facilities used for the storage of raw materials, packaging, in-process products and finished products shall be suitable for purpose.

Clause	Requirements
4.15.1	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: • 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.
4.15.2	Where appropriate, packaging shall be stored away from other raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified to maintain traceability before being returned to an appropriate storage area.
4.15.3	Where temperature control is required (e.g. for raw materials, semi-finished materials or final products), 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 4-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products.
4.15.4	Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions.
4.15.5	Where storage outside is necessary, items shall be protected from contamination and deterioration. Items shall be checked for suitability before being brought into the factory.

4.15.6	The site shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure that materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life.

4.16Dispatch and transport

Procedures shall be in place to ensure that the management of dispatch 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.

Clause	Requirements
4.16.1	Procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include, as appropriate: • controlling temperature of loading dock areas and vehicles • the use of covered bays for vehicle loading or unloading • securing loads on pallets to prevent movement during transit • inspection of loads prior to dispatch.
4.16.2	All vehicles or containers used for the transport of raw materials and the dispatch of products shall be fit for purpose. This shall ensure that they are: • in a clean condition • free from strong odours which may cause taint to products • in a suitable condition to prevent damage to products during transit • equipped to ensure any temperature requirements can be maintained throughout transportation. Records of inspections shall be maintained.
4.16.3	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 monitor and record at predetermined frequencies the correct operation of refrigeration equipment shall be used and records maintained.
4.16.4	Maintenance systems and documented cleaning procedures shall be available for all vehicles and equipment used for loading/unloading. There shall be records of the measures taken.
4.16.5	The company shall have procedures for the transport of products, which shall include: • 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 that the safety of the products is assessed and records maintained.
4.16.6	~~Where the company employs third-party contractors, all the requirements specified in this section shall be clearly defined in the contract or terms and conditions and verified, or the contracted company shall be certificated to the Global Standard for Storage and Distribution or similar GFSI-recognised scheme.~~

	Where the company uses contractors, the company shall have a documented supplier approval procedure to ensure risks to food quality and safety are effectively managed during dispatch and transport operations. The approval procedure shall be based on risk and include either one or a combination of: • a valid certification to the applicable BRCGS Standard (e.g. Global Standard for Storage and Distribution) or GFSI-benchmarked standard. **Or** • a completed contract or terms and conditions. As a minimum, this will include all the requirements of clauses 4.16.1 to 4.16.5. This shall have been reviewed and verified by a demonstrably competent person.

5Product control

5.1Product design/development

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.

Clause		Requirements
5.1.1		The company shall have a procedure for new product development and changes to existing product, packaging and manufacturing processes. This procedure shall include ~~provide clear guidelines on~~ any restrictions to the scope of new product development~~s~~ to control the introduction of hazards which would be unacceptable to the site or customers (e.g. the introduction of allergens, glass packaging, ~~or~~ microbiological risks or the introduction of ingredients that may affect product claims).
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		Initial shelf-life trials shall be undertaken using documented protocols that reflect conditions expected during manufacture, storage, transport/distribution, use and handling to determine product shelf life. Results shall be recorded and retained and shall confirm compliance with the relevant microbiological, chemical and organoleptic criteria/sensory analysis. 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.

5.2Product labelling

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.

Clause	Requirements
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 and ingredient specifications. The company shall have a procedure for artwork approval and sign-off.

5.2.2	There shall be effective processes in place to ensure that labelling information is reviewed whenever changes occur to: • the product recipe • raw materials • the supplier of raw materials • the country of origin of raw materials • legislation.
5.2.3	Where the label information is the responsibility of a customer or a nominated second- or third- party, the company shall provide information: • to enable the label to be accurately created • whenever a change occurs which may affect the label information.
5.2.4	Where cooking instructions are provided to ensure product safety, they shall be fully validated to ensure that, when the product is cooked according to the instructions, a safe, ready-to-eat product is consistently produced.

5.3Management of allergens

Pet food and animal feed manufacturers certificated to the Standard are required to meet the appropriate allergen management legislation in the country of intended sale of the products. Therefore, if there is no legislation relating to allergens in pet food/animal feed, this section of the Standard may be considered as 'not applicable' for pet food or animal feed destined for those countries.

In some parts of the world, allergen claims (e g. gluten- or dairy-free) are made on pet food or animal feed products. Therefore, where a site makes an allergen claim on a pet food or animal feed, it is required to meet all of the requirements within section 5.3.

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The site shall have a system for the management of allergenic materials which minimises the risk of allergen contamination (cross-contact) of products and meets legal requirements for labelling in the country of sale.

Clause	**Requirements**
5.3.1	The site shall carry out an assessment of raw materials to establish the presence and likelihood of contamination (cross-contact) by allergens (see glossary). This shall include a review of the raw material specifications and, where required, the acquisition of additional information from suppliers (e.g. through questionnaires to understand the allergen ~~status~~profile of the raw material, its ingredients and the factory in which it is produced).
5.3.2	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.
5.3.3	A documented risk assessment shall be carried out to identify routes of contamination (cross-contact) and establish documented policies and procedures for handling raw materials and intermediate and finished products to ensure cross-contamination (cross-contact) is avoided. This assessment shall include: • consideration of the physical state of the allergenic material (i.e. powder, liquid, particulate)

		• identification of potential points of cross-contamination (cross-contact) through the process flow • assessment of the risk of allergen cross-contamination (cross-contact) at each process step • identification of suitable controls to reduce or eliminate the risk of cross-contamination (cross-contact).
5.3.4		Procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination (cross-contact) of products not containing the allergen. These shall include, as appropriate: • physical or time segregation while allergen-containing materials are being stored, processed or packed • the use of separate or additional protective overclothing 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 • 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 and contractors and for catering purposes.
5.3.5		Where rework is used, or reworking operations are carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.
5.3.6		Where a justified, risk-based assessment demonstrates that the nature of the production process is such that cross-contamination (cross-contact) from an allergen cannot be prevented, a warning should be included on the label. Legislation, n~~N~~ational guidelines or codes of practice shall be used when making such a warning statement.
5.3.7		Where a claim is made regarding the suitability of a food for individuals with a food allergy or food sensitivity (sometimes referred to as a food hyper-sensitivity)~~sufferers~~, the site shall ensure that the production process is fully validated to meet the stated claim and the effectiveness of the process is routinely verified. This shall be documented.
5.3.8		Equipment or area-cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination (cross-contact) by allergens. The cleaning methods shall be validated to ensure that 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.

5.4Product authenticity, claims and chain of custody

Systems shall be in place to minimise the risk of purchasing fraudulent or adulterated food raw materials and to ensure that all product descriptions and claims are legal, accurate and verified.

Clause	Requirements
5.4.1	Where personnel are engaged in vulnerability assessments, the individual or team responsible shall understand potential food fraud risks. This shall include knowledge of raw materials used by the site and the principles of vulnerability assessment.

5.4.2		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 (i.e. fraudulent raw materials). Such information may come from, for example: • trade associations • government sources • private resource centres • activities completed for clause 1.1.8.
5.4.3		A documented vulnerability assessment shall be carried out on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution. This shall take into account: • historical evidence of substitution or adulteration • economic factors which may make adulteration or substitution more attractive • ease of access to raw materials through the supply chain • sophistication of routine testing to identify adulterants • the nature of the raw material. The output from this assessment shall be a documented vulnerability assessment plan. This plan shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risks. It shall be ~~formally~~ reviewed annually and whenever there is: • a change in raw material or a supplier of raw materials • emergence of a new risk (e.g. known adulteration of an ingredient or developments in scientific information associated with authenticity of the site's products or raw materials, for example, information obtained as part of clause 1.1.8) • following a significant product safety incident (e.g. a product recall) where the authenticity of the site's products or raw materials is implicated.
5.4.4		Where raw materials are identified as being at particular risk of adulteration or substitution, the vulnerability assessment plan shall include appropriate assurance and/or testing processes to mitigate the identified risks.
5.4.5		Where products are labelled or claims are made on finished packs which are dependent on the status of a raw material, the status of each batch of the raw material shall be verified. These claims include: • specific provenance or origin • breed/varietal claims • assured status (e.g. GlobalG.A.P.) • genetically modified organism (GMO) status • identity preserved • named specific trademarked ingredients. The facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The site shall undertake documented mass balance tests at a frequency to meet the particular scheme requirements of any scheme they are certificated to, or ~~at least every 6 months~~ in the absence of a scheme-specific requirement, at least one mass balance test every 6 months.
5.4.6		Where claims are made about the methods of production (e.g. organic, halal, kosher) the site shall maintain the necessary certification status in order to make such a claim.

5.4.7		Where a product is designed to enable a claim to be made, the company shall ensure that the product formulation and the production process are fully validated to meet the stated claim and any legal requirements (in the country of intended sale) relating to the claim. 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.

5.5Product packaging

Product packaging and processes for the purchase of product packaging shall be appropriate for the intended use. ~~and~~Packaging shall be stored under conditions to prevent contamination and minimise deterioration.

Clause		Requirements
5.5.1		When purchasing or specifying primary packaging, the supplier of packaging materials shall be made aware of any particular characteristics of the food or existing packaging (e.g. high fat content, pH, usage conditions such as microwaving, other packaging used on the product, use of recyclable or reusable packaging materials) which may affect packaging suitability. Certificates of conformity or other evidence shall be available for primary packaging to confirm it complies with applicable food safety legislation and is suitable for its intended use.
5.5.2		Product liners and bags purchased by the company for use in direct contact with ingredients, or work in process, shall be appropriately coloured (e.g. contrasting colour to the product) and resistant to tearing to prevent accidental contamination.
5.5.3		The company shall have a procedure to manage obsolete packaging (including labels). This shall include: • mechanisms to prevent accidental use of obsolete packaging • control and disposal of obsolete packaging • appropriate procedures for the disposal of obsolete printed materials (e.g. rendering trademarked materials unusable).

5.6Product inspection, product testing and laboratory analysis

The company shall undertake or subcontract inspection and analyses which are critical to confirm product safety, authenticity, legality, ~~integrity~~ and quality, using appropriate procedures, facilities and standards.

~~5.6.1Product inspection and testing~~

Clause	Requirements
5.6.1	There shall be a scheduled programme of product testing which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, processes for obtaining product samples (including where appropriate, their delivery to a laboratory), frequency and specified limits shall be documented.

5.6.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. The significance of ~~external~~onsite and laboratory results shall be understood and acted upon accordingly. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends. Where legal limits apply, these shall be understood and appropriate action taken promptly to address any exceedance of these limits. Where applicable, the measurement uncertainty associated with laboratory test results shall be considered.
5.6.3	The site shall ensure that a system of validation and ongoing verification of the shelf life is in place. This shall be based on risk and shall include sensory analysis and, as applicable, microbiological testing and relevant chemical factors such as pH and a_w. Records and results from shelf-life tests shall verify the shelf-life period indicated on the product.

~~5.6.2Laboratory testing~~

~~Clause~~	~~Requirements~~
5.6.4	Pathogen testing (including pathogens tested as part of the site environmental monitoring~~testing~~ programme) shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be fully segregated from the production and storage areas and have operating procedures to prevent any risk of ~~product~~ contamination of products or production areas.
5.6.5	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 include consideration of: • operating procedures to contain laboratory activities, including the design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • hygiene and protective clothing arrangements • ~~processes for obtaining product samples~~ • movement of materials that may pose a risk to products, raw materials or the production area, into and out of the laboratory, including the disposal of laboratory waste. • the management and monitoring of laboratory equipment Where testing activities are performed in production or storage areas (e.g. at the line tests or rapid tests) these shall be located, designed or operated to prevent product contamination.
5.6.6	Where the company undertakes or subcontracts analyses which are critical to product safety, authenticity or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025, including proficiency testing where applicable. Documented justification shall be available where accredited methods are not undertaken.
5.6.7	Procedures shall be in place to ensure reliability of laboratory results, other than those critical to safety and legality specified in clause 5.6.6~~2.3~~. These shall include:

	• use of recognised test methods, where available • documented testing procedures • ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required • use of a system to verify the accuracy of test results (e.g. ~~ring or~~ proficiency testing where applicable) • use of appropriately calibrated and maintained equipment.
~~5.6.2.5~~	~~The significance of laboratory results shall be understood and acted upon accordingly.~~ ~~Appropriate action shall be taken promptly to address any unsatisfactory results or trends.~~ ~~Where legal limits apply, these shall be understood and appropriate action taken promptly to address any exceedance of these limits.~~

5.7Product release

The site shall ensure that finished product is not released unless all agreed procedures have been followed.

Clause	Requirements
5.7.1	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 the release has been authorised.

5.8Pet food and animal feed

Where a site produces pet food or animal feed, all the relevant requirements from sections 1–7 of the Standard must be fulfilled in addition to the requirements in this section.

The site shall ensure that pet food and animal feed products are safe and fit for intended use.

Clause	Requirements
5.8.1	The site shall ensure pet food and animal feed is formulated/designed for the intended use (e.g. where products are designed for complete diet or as a complementary product).
5.8.2	Where a site's product range includes pet food or animal feed products for different animal species, the site shall have specific procedures for the management of any ingredients, raw materials, products or rework that could be harmful to unintended recipients.
5.8.3	Where the site manufactures, processes or packs pet food or animal feed products that contain medicinal substances, the site shall have specific procedures for the management of the medicated raw materials and finished products. At a minimum, these procedures shall include: • identification of medication-containing materials handled on site. These can be raw materials, processing aids, intermediate and finished products, rework or any new product or product development ingredients • supplier approval equivalent to section 3.5.1 for all medicated raw materials

	• specific staff training on the correct handling of medicated materials • mechanisms to ensure the correct concentrations of medicinal substances in finished products • procedures (e.g. cleaning procedures) to prevent contamination of non-medicated pet food or animal feed with materials containing medicinal substances • specific procedures to ensure the correct labelling of medicated pet food and animal feed. • waste disposal mechanisms (see section 4.12) include the safe and legal disposal of medicated raw materials and products
5.8.4	Site procedures shall be designed and implemented to meet the relevant pet food and animal feed product safety legislation (both in the country of production and in the country of sale).

5.9Animal Primary Conversion

Where a site completes animal primary conversion (e.g. for red meat, poultry or fish) the following requirements apply, in addition to those within the rest of the Standard.

For animal primary conversion, the site shall operate controlled processes that ensure products are safe and fit for intended use.

Clause	Requirements
5.9.1	The company shall undertake a risk assessment, for potential prohibited substances (i.e. those prohibited by legislation in the country of operation or intended country of sale). Example substances include pharmaceuticals, veterinary medicines (e.g. growth hormones), heavy metals and pesticides. The risk assessment may be completed as part of clause 3.5.1.1 or as a separate activity. The results of the risk assessment shall be included in raw material acceptance and testing procedures and for the processes adopted for supplier approval and monitoring (i.e. sections 3.5.1.2 – 3.5.2.3 of this Standard).
5.9.2	Where the site is in receipt of live animals, there shall be an inspection by a suitably competent individual at lairage and post mortem to ensure that the animals are fit for human consumption.
5.9.3	The site shall operate procedures to ensure the traceability of all edible parts of the carcass (i.e. all parts that are intended for the human food supply chain) is maintained~~, until the carcass is deemed fit for human consumption~~.
5.9.4	The site shall establish defined time and temperature requirements for all post-slaughter processes (for example, post-slaughter cooling, processing, storage and distribution). These requirements shall be defined for all chilled or frozen, edible parts of the carcass.

6Process control

6.1Control of operations

☆ FUNDAMENTAL

The site shall operate to 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 or food safety plan.

Clause		Requirements
6.1.1		Documented process specifications and work instructions/procedures shall be available for the key processes in the production of products to ensure product safety, legality and quality. The specifications/procedures as appropriate shall include: • 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 • storage conditions (e.g. storage temperatures) • any additional critical control points identified in the HACCP or food safety plan. Process specifications shall be in accordance with the agreed finished product specification. The site shall review the process specifications and work instructions/procedures prior to any changes which may affect food safety.
6.1.2		Where equipment settings are critical to the safety or legality of the product, changes to the equipment settings shall only be completed by trained and authorised staff. Where applicable, controls shall be password-protected or otherwise restricted.
6.1.3		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.
6.1.4		In circumstances where process parameters or product quality are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.
6.1.5		Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated and verified 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).
6.1.6		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.

6.1.7		Where a site handles products or materials (e.g. by-products from production processes) that are outside the scope of the audit, these shall be controlled to ensure that they do not create a product safety, authenticity or legality risk to products within the scope.

6.2Labelling and pack control

☆ **FUNDAMENTAL**

The management controls of product labelling activities shall ensure that products will be correctly labelled and coded.

Clause		Requirements
6.2.1		There shall be a formal process for the allocation of packaging materials to packing lines and control in the packing area which ensures that only the packaging for immediate use is available to the packing machines. Where offline coding or printing of packaging materials occurs: • setting and amendments to the printer parameters (e.g. the input of, or changes to, date codes) shall only be completed by an authorised member of staff • controls shall be in place to ensure that only correctly printed material is available at the packing machines. Processes shall be in place to check label use is reconciled with expected use and the cause of any inconsistencies investigated.
6.2.2		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 cleared and are ready for production. Documented checks shall be carried out at product changes to ensure that all products and printed packaging and labels from the previous production have been removed from the line before changing to the next production.
6.2.3		Procedures shall be in place to ensure that all products are packed into the correct packaging and correctly labelled. These shall include checks: • at the start of packing • during the packing run (e.g. at predefined intervals and when printed packaging or labels are brought to the line during the production run) • when changing batches of packaging materials • at the end of each production run. The checks shall also include verification of any printing carried out at the packing stage including, as appropriate: • date coding • batch coding • quantity indication • pricing information • bar coding • country of origin • allergen information.

6.2.4	Where online verification equipment (e.g. bar code scanners) is used to check product labels and printing, the site shall establish and implement procedures for the operation and testing of the equipment to ensure that the system is correctly set up and capable of alerting or rejecting product when packaging information is out of specification. At a minimum, testing of the equipment shall be completed at: • the start of the packing run • the end of the packing run • a frequency based on the site's ability to identify, hold and prevent the release of any implicated materials should the equipment fail (e.g. during the packing run or when changing batches of packaging materials). The site shall establish and implement procedures in the event of a failure in the online verification equipment (e.g. a documented and trained manual checking procedure).

6.3Quantity – weight, volume and number control

The site 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 requirements.

Clause	Requirements
6.3.1	The frequency and methodology of quantity checking shall meet the requirements of the appropriate legislation governing quantity verification, and records of checks shall be retained.
6.3.2	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.
6.3.3	Where used, the site shall establish procedures for the operation and testing of online check weighers. At a minimum, this shall include: • consideration of any legal requirements • responsibilities for testing the equipment • operating effectiveness and any variations for particular products • methods and frequency of testing the check weighers • processes for handling rejected packs • records of the test results.

6.4Calibration and control of measuring and monitoring devices

The site shall be able to demonstrate that measuring equipment is sufficiently accurate and reliable to provide confidence in measurement results.

Clause	Requirements
6.4.1	The site shall identify and control measuring equipment used to monitor critical control points and product safety, legality and quality. This shall include, at a minimum: • 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.
6.4.2	All identified measuring devices, including new equipment, shall be checked and, where necessary, adjusted: • at a predetermined frequency, based on risk assessment • to a defined method traceable to a recognised national or international standard where possible. Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform.
6.4.3	Reference measuring equipment shall be calibrated and traceable to a recognised national or international standard and records maintained. The uncertainty of calibration shall be considered when equipment is used to assess critical limits.
6.4.4	Procedures shall be in place to record actions to be taken when the prescribed measuring 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 be taken to ensure at-risk product is not offered for sale.

7Personnel

7.1Training: raw material handling, preparation, processing, packing and storage areas

☆ FUNDAMENTAL

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.

Clause	Requirements
7.1.1	All ~~relevant~~ personnel, including agency-supplied staff, 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 site shall put in place documented programmes covering the training needs of ~~relevant~~ personnel. These shall include, at a minimum: • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training • delivery of training in the appropriate language of trainees.
7.1.4	All relevant personnel, including engineers, agency-supplied staff, temporary staff and contractors, shall have received general allergen awareness training and be trained in the site's allergen-handling procedures.
7.1.5	All relevant personnel (including relevant agency-supplied staff, temporary staff and contractors) shall have received training on the site's labelling and packing processes which are designed to ensure the correct labelling and packing of products.
7.1.6	Records of all training shall be available. These shall include, at a minimum: • 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 • for internal courses, a reference to the material, work instruction or procedure that is used in the training. Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
7.1.7	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.

7.2Personal hygiene: raw material handling, preparation, processing, packing and storage areas

The site's personal hygiene standards shall be developed to minimise the risk of product contamination from personnel, be appropriate to the products produced and be adopted by all personnel, including agency-supplied staff, contractors and visitors to the production facility.

Clause	Requirements
7.2.1	The requirements for personal hygiene shall be documented and communicated to all personnel. These shall include, at a minimum, the following: • watches and similar wearable devices shall not be worn • jewellery shall not be worn, with the exception of a plain ~~wedding~~ ring, wedding wristband or medical alert jewellery • rings and studs in exposed parts of the body, such as ears, noses and eyebrows, shall not be worn • fingernails shall be kept short, clean and unvarnished • false fingernails and nail art shall not be permitted • excessive perfume or aftershave shall not be worn. Compliance with the requirements shall be checked routinely.
7.2.2	Hand-washing 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 contains a metal detectable strip. These shall be site-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.

7.3Medical screening

The company shall have procedures in place to ensure that employees, agency staff, contractors or visitors are not a source of transmission of infections, diseases, conditions or food-borne diseases to products.

Clause	Requirements
7.3.1	The site shall make employees aware of the symptoms of infection, disease or condition which would prevent a person working with open food. The site shall have a procedure which enables notification by employees, including temporary employees, and visitors to the site, of any relevant symptoms, 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 made aware of the types of symptoms, infection, disease or condition which would prevent a person visiting areas with open food. Where permitted by law, visitors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from

	any symptoms 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 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.

7.4Protective clothing: employees or visitors to production areas

Suitable site-issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.

Clause	Requirements
7.4.1	The company shall document and communicate to all employees (including agency and temporary personnel), contractors or visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. production areas, storage areas etc.). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, and use of canteen and smoking areas).
7.4.2	Protective clothing shall be available that: • is provided in sufficient numbers for each employee • is of suitable design to prevent contamination of the product (at 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	Laundering of protective clothing shall take place by an approved contracted or in-house laundry using defined criteria to validate the effectiveness of the laundering process. The laundry must operate procedures which ensure: • adequate segregation between dirty and cleaned clothes • effective cleaning of the protective clothing • cleaned clothes are supplied protected from contamination until use (e.g. by the use of covers or bags). Washing of protective clothing by the employee is exceptional but shall be acceptable where: • -the protective clothing is not used for product safety purposes, for example, it is used to protect the employee from the products handled and • and the protective clothing is worn in enclosed product or low-risk areas only.
7.4.4	Protective clothing shall be changed at an appropriate frequency, based on risk.
7.4.5	If gloves are used, they shall be replaced regularly. Where appropriate, gloves shall be suitable for food use, of a disposable type, of a distinctive colour (blue where possible), be intact and not shed loose fibres.

7.4.6	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.

8Production risk zones - hHigh-risk, high-care and ambient high-care production risk zones

Where a site produces products where the production process, or part of it, that requires handling in high-risk, high-care and/or ambient high-care production facilitiesproduction zones (see clause 4.3.1 for this assessment and Aappendix 2 for the definition of products that require these facilitiesthese production zones), all the relevant requirements from sections 1–7 of the Standard must be fulfilled in addition to the requirements in this section.

The site shall be able to demonstrate that production facilities and controls are suitable to prevent pathogen contamination of products.

8.1Layout, product flow and segregation in high-risk, high-care and ambient high-care zones

~~The site shall be able to demonstrate that production facilities and controls are suitable to prevent pathogen contamination of products.~~

Clause	Requirements
8.1.1	~~The map of the site (see clause 4.3.1) shall include areas (zones) where the product is at different levels of risk from contamination. The map shall show:~~ ~~• high-risk areas~~ ~~• high-care areas~~ ~~• ambient high-care areas~~ ~~• low-risk areas~~ ~~• enclosed product areas~~ ~~• non-product areas.~~ ~~See Appendix 2 for guidelines on defining the production risk zones.~~ ~~This zoning shall be taken into account when determining the prerequisite programmes for the particular areas of the site.~~ The map of the site (see clause 4.3.2) shall include the location of the pathogen control step(s).
8.1.2	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, the nature of the materials (including packaging), the equipment, the personnel, the disposal of waste, the flow of air, the air quality, and the provision of utilities (including drains). 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 the risk of product contamination (e.g. the disinfection of materials on entry).
8.1.3	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, the nature of materials (including packaging), the equipment, the personnel, the disposal of waste, the flow of air, the air quality, and the provision of utilities (including drains).

		Where physical barriers are not in place, the site shall have undertaken a documented risk assessment of the potential for cross-contamination, and effective, validated processes shall be in place to protect products from contamination, including the procedures for changeover from low risk to high-care.
8.1.4		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: • the raw materials and products • the flow of raw materials, packaging, products, equipment, personnel and waste • air flow and quality • the provision and location of utilities (including drains). Effective processes shall be in place to protect the final product from microbiological contamination. These processes may include segregation, management of process flow or other controls.

8.2Building fabric in high-risk and high-care zones

Clause		Requirements
8.2.1		Where sites include high-risk or high-care facilities, there shall be a map of the drains for these areas which shows the direction of flow and the location of any equipment fitted to prevent the back-up of waste water. The flow from drains shall not present a risk of contamination to the high-risk/care area.
8.2.2		High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented, based on a risk assessment that takes into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.
8.2.3		Where sites include removeable walls as part of the design of the high risk or high care area (e.g. to allow occasional movement of large items or specialist maintenance equipment) procedures shall be in place to ensure: • removeable walls are tight fitting • use is controlled, movement of the wall is only completed by trained and authorised staff • cleaning and reconditioning procedures are in place and completed prior to production

8.3Equipment and Maintenance in high-risk and high-care zones

Clause	Requirements
8.3.1	Maintenance activities undertaken in high-risk and high-care areas shall respect the segregation requirements of the area. Wherever possible, tools and equipment shall be dedicated for use in that area and retained in the same.

8.3.2	Where equipment is removed from the high-risk or high-care area, the site shall have a procedure to ensure the cleanliness and removal of contamination hazards before being accepted back into the area. Records of acceptance back into the area shall be maintained.
8.3.3	Where portable equipment (e.g. handheld devices) and battery charging equipment is used in high-risk or high-care areas, these items shall either be: • visually distinctive and dedicated for use in that area **or** • have specific procedures (e.g. a full clean) to ensure that their use does not result in contamination.

8.4Staff facilities for high-risk and high-care zones

Clause	Requirements

8.4.1	Where an operation includes a high-risk or high-care area, personnel shall enter via a specially designated changing facility at the entrance to the area. The changing facilities shall incorporate the following:
	
	• clear instructions for the order of changing into and out of dedicated protective clothes to prevent the contamination of clean clothing
	• protective clothing that is visually distinct from that worn in other areas and which shall not be worn outside the area
	• a hand-washing routine during the changing procedure to prevent contamination of the clean clothing (i.e. hand-washing after hair covering and footwear have been put on, but before handling clean protective clothing)
	• provision and use of hand-washing and disinfection facilities. At a minimum these shall be:
	
	  • prior to entry for high-risk areas
	  • on entry for high-care areas
	
	• dedicated site footwear that is provided by the site and which shall not be worn outside the factory
	• an effective control of footwear to prevent the introduction of pathogens into the area. Control may be by segregation and a controlled change of footwear before entering the area (such as a barrier or bench system) or by the use of controlled and managed boot-wash facilities where these demonstrably provide an effective control of footwear to prevent the introduction of pathogens into the area.
	
	A programme of environmental monitoring shall be used to assess the effectiveness of footwear controls.

8.5Housekeeping and hygiene in high-risk and high-care zones

Clause		Requirements
8.5.1		Environmental cleaning procedures in high-care/high-risk areas shall consider the different microbiological risks associated with each production risk zone. ~~, a~~At a minimum cleaning procedures in high-risk and high-care areas shall include all of the requirements in clause 4.11.2.~~, include:~~ ~~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.~~ The frequency and methods of cleaning shall be based on risk, and the procedures shall be implemented to ensure that appropriate standards of cleaning are achieved.
8.5.2		Microbiological limits for acceptable and unacceptable cleaning performance shall be defined for high-risk/high-care production risk zones. These limits shall be based on the potential hazards relevant to the product or processing area. Therefore, acceptable levels of cleaning ~~may~~shall be defined, for example, by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing or chemical testing as appropriate. The site shall define the corrective action to be taken when monitored results are outside of the acceptable limits. Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard, the cleaning and disinfection procedures and frequencies shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.
8.5.3		Equipment used for cleaning in high-care and high-risk areas shall be: • -visually distinctive and dedicated for use in that area. • hygienically designed and fit for purpose • cleaned and stored in a hygienic manner to prevent contamination (for example storing equipment in designated locations, off the floor, when not in use).
8.5.4		Where the site uses CIP equipment, this will either be dedicated to the area (i.e. separate equipment for high-risk, high-care and other production areas) or the CIP system shall be designed and controlled so that it does not present a risk of contamination to the high-risk/high-care area (i.e. controlling direction of flow from high-risk/high-care to low-risk areas, preventing the recycling or reuse of rinse solutions from one area to another).

8.6Waste/waste disposal in high-risk, high-care zones

Clause		Requirements
8.6.1		Waste disposal systems shall ensure that the risk of contamination of products is minimised through the control of potential cross-contamination. Risk assessment shall consider the movement and flow of waste and waste containers. For example, waste bins should be dedicated to either high-risk or high-care areas and not be moved between different production risk zones.

8.7Protective clothing in high-risk and high-care zones

Clause	Requirements
8.7.1	Laundering of protective clothing for high-risk and high-care areas shall be by an approved contracted or in-house laundry using defined criteria to validate the effectiveness of the laundering process. The laundry must operate procedures which ensure: • adequate segregation between dirty and cleaned clothes • adequate segregation between clothes for high-risk, high-care and low-risk areas etc. • effective cleaning of the protective clothing • commercial sterilisation of the protective clothing following the washing and drying process • protection of the cleaned clothes from contamination until use ~~(e.g. by the use of covers or bags).~~
8.7.2	Where protective clothing for high-care or high-risk areas is cleaned by a contracted or in-house laundry, the laundry shall be audited either directly or by a third party. The frequency of these audits shall be based on risk.
8.7.3	Protective clothing for use in high-risk and high-care areas shall be changed at an appropriate frequency based on risk, and at a minimum daily.

9Requirements for traded products

Traded products are defined as food products, that would normally fall within the scope of the Standard and are stored at the site's facilities, but that are not manufactured, processed, reworked packed or labelled at the site being audited, the site's management of these products is covered by the requirements in this section.

~~Where a site purchases and sells food products that would normally fall within the scope of the Standard and are stored at the site's facilities, but which are not manufactured, further processed or packed at the site being audited, the site's management of these products is covered by the requirements in this section.~~

All the relevant requirements from sections 1 to 8 must also be fulfilled in addition to the requirements outlined in this section.

Where a site wishes to be audited against section 9 of the Standard, all of the food products and food raw materials traded must be included within the audit scope. It is not permitted to include some traded food products or food raw materials and exclude others.

Non-conformities against clauses within section 9 of the Standard will be recorded on the audit report and included in the calculation of the site's grade.

Where a site has traded food products or food raw materials onsite but wishes them to be excluded from the scope of the audit, this will be recorded as an exclusion from scope on the audit report.

9.1The Food Safety Plan - HACCP

The site shall operate a HACCP or product safety plan for the processes for which it is responsible.

Clause	Requirements
9.1.1	The company shall either • have a HACCP or food safety plan specifically for the traded products handled onsite or • incorporate the traded products into its existing HACCP or food safety plans (see section 2). The scope of traded products HACCP or food safety plan shall include the products and the processes for which the site is responsible, as a minimum this will include goods receipt, storage and dispatch.

9.2 Approval and performance monitoring of manufacturers/packers of traded food products

The company shall operate procedures for approval of the last manufacturer or packer of food products which are traded to ensure that traded food products are safe, legal and manufactured in accordance with any defined product specifications.

Clause	Requirements
9.2.1	The company shall have a documented supplier approval procedure which identifies the process for initial and ongoing approval of suppliers and the manufacturer/processor of each product traded. The requirements shall be based on the results of a risk assessment which shall include consideration of: • the nature of the product and associated risks • customer-specific requirements • legislative requirements in the country of sale or importation of the product • source or country of origin • potential for adulteration or fraud • potential risks in the supply chain to the point of receipt of the goods by the company • the brand identity of products (i.e. customer own brand or branded product).

9.2.2	The company shall have a procedure for the initial and ongoing approval of manufacturers of products. This approval procedure shall be based on risk and include either one or a combination of:
	• a valid certification to the applicable BRCGS ~~Global~~ Standard or GFSI-benchmarked standard. The scope of the certification shall include the products purchased
	• supplier audits, with a scope to include product safety, traceability, HACCP review and good manufacturing practices, undertaken by an experienced and demonstrably competent product safety auditor. Where this supplier audit is completed by a second or third party, the company shall be able to:
	  • demonstrate the competency of the auditor
	  • confirm that the scope of the audit includes product safety, traceability, HACCP review and good manufacturing practices
	  • obtain and review a copy of the full audit report
	or
	• where a valid risk-based justification is provided and the supplier is assessed as low risk only, a completed supplier questionnaire may be used for initial approval. The questionnaire shall have a scope that includes product safety, traceability, HACCP review and good manufacturing practices, and it shall have been reviewed and verified by a demonstrably competent person.

9.2.3	Records shall be maintained of the manufacturer's/packer's approval process, including audit reports or verified certificates confirming the product safety status of the manufacturing/packing sites supplying the products traded. There shall be a process of review and records of follow-up of any issues identified at the manufacturing/packing sites with the potential to affect food products traded by the company.
9.2.4	There shall be a process for the ongoing review of manufacturers/packers, based on risk and using defined performance criteria, which may include complaints, results of any

	product tests, regulatory warnings/alerts, customer rejections or feedback. The process shall be fully implemented. Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status. Records of the review shall be kept.

9.3Specifications

Specifications or information to meet legal requirements and assist customers in the safe usage of the product shall be maintained and available to customers.

Clause	Requirements
9.3.1	Specifications shall be available for all products. These shall either be in the agreed format as supplied by the customer or, where this is not specified, include key data to meet legal requirements and assist the customer in the safe usage of the product. Specifications may be in the form of a printed or electronic document, or part of an online specification system.
9.3.2	The company shall seek formal agreement of the specifications with relevant parties. Where specifications are not formally agreed, the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place.
9.3.3	Companies shall operate demonstrable processes to ensure that any customer-specified requirements are met. This may be by inclusion of customer requirements within buying specifications or by undertaking further work on the purchased product to meet the customer's specification (e.g. sorting or grading of product).
9.3.4	Specification review shall be sufficiently frequent to ensure that data is current or at a minimum every 3 years, taking into account product changes, suppliers, regulations and other risks. Reviews and changes shall be documented.

9.4Product inspection and laboratory testing

The site shall operate processes to ensure that the products received comply with buying specifications and that the supplied product is in accordance with any customer specification.

Clause	Requirements
9.4.1	The site shall have a product sampling or assurance programme to verify that the products are in accordance with buying specifications and meet legal and safety requirements. Where verification is based on sampling, the sample rate and assessment process shall be risk-based. Records of the results of assessments or analysis shall be maintained.

9.4.2	Where verification of conformity is provided by the supplier (e.g. certificates of conformity or analysis), the level of confidence in the information provided shall be supported by commissioning periodic independent product analysis.
9.4.3	Where claims are made about the products being handled, including the provenance, chain of custody and assured or 'identity preserved' status of a product or raw materials used, supporting information shall be available from the supplier or independently to verify the claim.
9.4.4	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 non-accredited test methods are used.
9.4.5	Test and inspection results shall be retained and reviewed to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.

9.5Product legality

The company shall have processes in place to ensure that the food products traded comply with the legal requirements in the country of sale where known.

Clause	Requirements
9.5.1	The company shall have documented processes to verify the legality of products which are traded. These processes shall include as appropriate: • labelling information • compliance with relevant legal compositional requirements • compliance with quantity or volume requirements. Where such responsibilities are undertaken by the customer, this shall be clearly stated in contracts.

9.6Traceability

The company shall be able to trace all product lots back to the last manufacturer and forward to the customer of the company.

Clause		Requirements
9.6.1		The site's traceability procedure (see clause 3.9.1) shall include details of the system used for the traceability of traded products. The ~~site shall maintain a~~ traceability system ~~for~~ shall ensure that for all batches of product ~~which~~ the site can identify the last manufacturer or, in the case of primary agricultural products, the packer or place of last significant change to the product. Records shall also be maintained to identify the recipient of each batch of product from the company.
9.6.2		The company shall test the traceability system at least annually to ensure that traceability can be determined back to the last manufacturer and forward to the recipient of the product

	from the company. This shall include identification of the movement of the product through the chain from the manufacturer to receipt by the company (e.g. each movement and intermediate place of storage).
9.6.3	The traceability test shall include the reconciliation of quantities of product received by the company for the chosen batch or product lot. Traceability should be achievable within 4 hours (1 day when information is required from external parties).

Part III - Summary of the Audit Protocol

Audit Options

For Issue 9 there are 3 different audit options:

- Option 1 – an announced onsite audit
- Option 2 – a blended, announced audit
- Option 3 – an unannounced onsite audit

Announced audit programme (with mandatory unannounced audit every 3 years)

For announced audits, the audit date is agreed between the site and the certification body in advance of the audit and all requirements of the Standard are audited within the onsite audit visit.

There is one significant change in the announced audit programme from Issue 8 to Issue 9 - due to the added confidence provided by unannounced audits, the GFSI Benchmark introduced a requirement for all certificated sites to have at least 1 unannounced audit within every 3-year period, even where they have opted to be part of the announced audit programme. Therefore, every 3 years, the audit will be unannounced; the certification body will notify the site and agree which year this will be, to ensure that the site is aware that an unannounced audit will take place in the coming year. However, the actual date of the unannounced audit will not be communicated to the site in advance.

All other aspects of the announced audit protocol remain unchanged.

Blended announced audit programme (with mandatory unannounced audit every 3 years)

The blended announced audit programme utilises the evolving role of ICT (information and communication technology) to incorporate remote assessment into the audit process.

The audit is split into two separate parts, a remote audit, followed by an on-site audit. The first part looks predominantly at the documented systems and records using ICT, while the second part is an announced on-site audit, and predominantly focuses on production, storage, and other onsite areas.

The blended announced audit is only offered by a certification body following a risk assessment which:

- confirms a robust audit is possible (e.g. availability of remote technology at the site)
- assesses the percentage of the audit that can be completed remotely, up to a maximum of 50% of the audit duration
- at the time of publication this option is only available for re-certification audits and not for initial audits (i.e it is not available for the first BRCGS audit at a site).

Sites opting for announced audits, including the blended announced audit, are required to have at least 1 unannounced audit within every 3-year period (further details are included in the section above on announced audits).

The advantage of this audit option resides in its ability to offer flexibility in the audit schedule.

Unannounced audit programme

The unannounced audit is mainly unchanged from Issue 8. It remains voluntary, but provides added confidence in certification to customers and creates marketing benefits where sites achieve the top BRCGS grade of AA+.

The audit will be unannounced and may occur at any stage within the last 4 months of the audit cycle, including the 28 days before the audit due date (this is a change from Issue 8, where the audit could take place in the last 9 months of the audit cycle).

The site may identify a maximum of 10 'non-audit' days where the site is not available for the unannounced audit to take place.

The date of the audit shall not be notified to the site in advance.

Audit Report

The audit report is one of the vital outputs from the audit. It is important that completion of the report, provides a complete and accurate summary of the audit, with sufficient details for all the stakeholders using it.

The Working Group is currently reviewing options and ideas for the Issue 9 audit report and further information will be published when it is available.

Non-conformities, Grading, Corrective Action, Root Cause Analysis and Preventive Action

No changes have been proposed to the levels of non-conformity, the grading process or requirements for the site to complete corrective and preventive actions.

Preventive action remains an important element of continual improvement; the implementation of effective permanent improvements to the product safety, authenticity, legality and quality processes and systems. Root cause analysis remains a vital tool to achieve this. Therefore, these will remain unchanged from Issue 8.

Audit Frequency

No changes have been proposed to audit frequency. Therefore, these will remain unchanged from Issue 8.

Additional Voluntary Modules

The Standard has been designed to enable additional voluntary modules to be added to the routine audit. The additional voluntary modules enable sites to demonstrate compliance to specific sets of requirements in order to meet specific market or customer requirements.

It is expected that new modules will be developed and become available for use throughout the life of this issue of Issue 9.

START!

The START! Programme will undergo a full review to ensure that it remains applicable and relevant for smaller sites and those who are developing their product safety and quality systems.

This review will take place after publication of Issue 9 of the Standard and the revised scheme will be published in due course, as a separate document.