BRC Global Standard Food Safety Issue 8

Draft for Industry Consultation

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How this publication is organised?

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

The document consists of the following sections:

Part I Introduction

Provides an introduction to 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 to this document and the consultation process

The information included in this consultation document has been developed and reviewed by working groups 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 for Food Safety Issue 8 is an extensive consultation to understand stakeholders' views on the draft proposals.

This document therefore contains the proposals for Issue 8 and is structured as follows:

- Section II – full details of the proposed requirements for Issue 8
- 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 audit protocol, by email, to enquiries@brcglobalstandards.com using the feedback form provided.

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 on both parts 1 and 2		

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.

Where a site's products require high risk, high care or ambient high care production facilities, 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 goods (i.e. products not manufactured or processed on the site but bought in and sold by the site) the site can opt for an additional, voluntary audit on these activities at the same time as their main BRC Global Standard audit. For Issue 7 these requirements formed a separate voluntary module but these requirements have now been incorporated into the Standard and are detailed in section 9.

1 1.1	**Senior management commitment** Senior management commitment and continual improvement
	☆ **FUNDAMENTAL**
SOI	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.
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe, ~~and~~ 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.
1.1.2	The site's senior management shall have a documented strategic plan for the development and continuing improvement of food safety culture. This shall include: • defined activities involving all sections of the company • an action plan indicating how the activities will be undertaken and intended timescales • review of the effectiveness of completed activities
1.1.3	The site's senior management shall ensure that clear objectives are defined to maintain and improve the safety, 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.
1.1.4	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually as a minimum, to review the site performance against the Standard and objectives set in clause 1.1.3~~2~~. The review process shall include the evaluation of:

	• previous management review action plans and timeframes • results of internal, second-party and/or third-party audits • review of any objectives that have not been met, to understand the underlying reasons for the failure. This information shall be used when setting future objectives and to facilitate continual improvement. • customer complaints and results of any customer feedback • incidents (including both recalls and withdrawals), corrective actions, out-of-specification results and non-conforming materials • review of the management of the systems for HACCP, food defence and authenticity • resource requirements. Records of the meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.
1.1.5	The site shall have a demonstrable meeting programme which enables food safety, legality, integrity and quality issues to be brought to the attention of senior management. These meetings shall occur at least monthly. ~~and allows for the resolution of issues requiring immediate action.~~ 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 system (eg a whistleblower system) that enables staff to confidentially report concerns relating to product safety, integrity, quality and legality to senior management. The mechanism (eg the relevant telephone number) for reporting concerns must 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 safely and in compliance with the requirements of this Standard.
1.1.8	The company's senior management shall have a system 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 applicable in the country of raw material supply, production and, where known, the country where the product will be sold.
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 BRC 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 Global Standard for Food Safety certification. Relevant departmental managers or their deputies shall be available as required during the audit.
1.1.12	The site's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.
1.1.13	The company shall comply with the relevant sections of the Standard protocol where this is the responsibility of the company. Where there are valid, justified circumstances preventing compliance with the protocol these shall be documented.
1.1.14	The BRC logo shall only be used in accordance with the conditions of use detailed in protocol section 4.6 of the Standard protocol.
1.2	Organisational structure, responsibilities and management authority
	The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality and quality.
1.2.1	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.

1.2.2	The site's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instructions.

2	**The food safety plan – HACCP**
	☆**FUNDAMENTAL**
SOI	The company shall have a fully implemented and effective food safety plan ~~based~~incorporating ~~on~~the Codex Alimentarius HACCP principles.
2.1	The HACCP food safety team ~~— Codex Alimentarius Step 1~~
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/technical, production operations, engineering and other relevant functions. The team leader shall have an in-depth knowledge of HACCP or food safety plan and be able to demonstrate competence, ~~and~~ experience and training. Where there is a legal requirement for specific training, this shall be in place (eg requirements for a PCQI in the USA). The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated hazards. In the event of the site not having appropriate in-house knowledge, external expertise may be used, but day-to-day management of the food safety system shall remain the responsibility of the company.
2.1.2	The scope of each HACCP or food safety plan, including the products and processes covered, shall be defined.
2.2	Prerequisite programmes
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 • pest control • maintenance programmes for equipment and buildings

		• personal hygiene requirements • staff training • purchasing • transportation arrangements • processes to prevent cross-contamination • allergen controls. The control measures and monitoring procedures for the prerequisite programmes must be clearly documented and shall be included within the development and reviews of the HACCP or food safety plan.
2.3		Describe the product ~~– Codex Alimentarius Step 2~~
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) • target 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.
2.4		Identify intended use ~~– Codex Alimentarius Step 3~~
2.4.1		The intended use of the product by the customer, and any known alternative use, 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).
2.5		Construct a process flow diagram ~~— Codex Alimentarius Step 4~~
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.
2.6		Verify flow diagram ~~— Codex Alimentarius Step 5~~
2.6.1		The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge at least annually. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.
2.7		List all potential hazards associated with each process step, conduct a hazard analysis and consider any measures to control identified hazards ~~— Codex Alimentarius Step 6, Principle 1~~
2.7.1		The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and allergen risks (refer to clause 5.3). 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 hazards 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.
2.8	Determine the critical control points (CCPs) ~~– Codex Alimentarius Step 7, Principle 2~~
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.
2.9	Establish critical limits for each CCP ~~– Codex Alimentarius Step 8, Principle 3~~
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.

2.10	Establish a monitoring system for each CCP ~~– Codex Alimentarius Step 9, Principle 4~~
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: • on-line measurement • off-line 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 an authorised person. Where records are in electronic form there shall be evidence that records have been checked and verified.
2.11	Establish a corrective action plan ~~– Codex Alimentarius Step 10, Principle 5~~
2.11.1	The HACCP food safety team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel with regard to any products that have been manufactured during the period when the process was out of control.
2.12	Establish verification procedures ~~– Codex Alimentarius Step 11, Principle 6~~
2.12.1	Procedures of verification shall be established to confirm that the HACCP 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.

2.13	HACCP documentation and record keeping ~~– Codex Alimentarius Step 12, Principle 7~~
2.13.1	Documentation and record keeping shall be sufficient to enable the site to verify that the HACCP and food safety controls, including controls managed by prerequisite programmes, are in place and maintained.
2.14	Review the HACCP plan
2.14.1	The HACCP food safety team shall review the HACCP plan and prerequisite programmes at least annually and prior to any changes which may affect food~~product~~ safety. As a guide, these may include the following, although this is not an exhaustive list: • change in raw materials or supplier of raw materials • change in ingredients/recipe • change in processing conditions, 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, for example, a recall of a similar product) • 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 validation recorded. Where appropriate, the changes shall also be reflected in the company's product safety policy and food safety objectives.

3	**Food safety and quality management system**
3.1	Food safety and quality manual
SOI	The company's processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe product.

3.1.1	The site's documented procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual.
3.1.2	The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to 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 include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language).
3.2	Document~~ation~~ control
SOI	The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use.
3.2.1	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 (eg auhorised access, control of amendments, password protected) • backed up to prevent loss
3.3	Record completion and maintenance
SOI	The site shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.
3.3.1	Records shall be legible, maintained in good condition and retrievable. Any alterations to records shall be authorised and justification for alteration shall be recorded. Where records are in electronic form these shall ~~be~~also be: • ~~-~~suitably backed up to prevent loss. • stored securely (eg authorised access, control of amendments, password protected)

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). As a minimum, records shall be retained for the shelf life of the product plus 12 months.
3.4	~~Internal audits~~Food safety and quality management audits
	☆**FUNDAMENTAL**
SOI	The company shall be able to demonstrate it verifies the effective application of the food safety plan and the implementation of the requirements of the Global Standard for Food Safety.
3.4.1	There shall be a scheduled programme of internal audits ~~throughout the year~~. As a minimum this programme will include at least 4 different audit dates spread throughout the year. As a minimum the scope of the internal audit programme shall ~~with a scope which covers~~include: • ~~the implementation of~~ the food safety plan or the HACCP programme~~,~~ • activities which implement the food safety plan or HACCP programme (eg supplier approval, corrective actions and verification) • ~~-~~prerequisite programmes ~~and~~ (eg hygiene, pest control) • procedures implemented to achieve this Standard. Each internal audit within the programme shall have a defined ~~The~~ scope and consider a defined activity or section of the food safety plan or HACCP plan. The frequency that each activity is audited ~~of the audits~~ shall be established in relation to the risks associated with the activity and previous audit performance; all activities shall be covered at least once each year~~annually~~.
3.4.2	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be independent (~~i.~~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 actions and timescales for their implementation shall be agreed and completion of the actions verified.
3.4.4	In addition to the internal audit programme there shall be a separate programme of documented inspections to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production. As a minimum t~~T~~hese inspections shall include: • hygiene inspections to assess cleaning and housekeeping performance • fabrication inspections to identify risks to the product from the building or equipment. The frequency of these inspections shall be based on risk but will be no less than once per month in open product areas.
3.5	Supplier and raw material approval and performance monitoring
3.5.1	Management of suppliers of raw materials and packaging
SOI	☆**FUNDAMENTAL** The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including packaging) to the safety, authenticity, legality and quality of the final product are understood and managed.
3.5.1.1	The company shall undertake a documented risk assessment of each raw material or group of raw materials including packaging to identify potential risks to product safety, legality and quality. This shall take into account the potential for: • allergen contamination • foreign-body risks • microbiological contamination • chemical contamination • variety or species cross-contamination • substitution or fraud (see clause 5.4.2). Specific consideration shall be given to any risks associated with raw materials (such as animals, fish and seafood) which are subject to legislative control of prohibited substances (eg pharmaceuticals, veterinary medicines, heavy metals or pesticides). 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 assessments shall be reviewed: ~~at least annually.~~ • when there is a change in a raw material, raw material processing or the supplier of the raw material • if a new risk emerges • following a product recall or withdrawal, where a specific raw material is implicated. • at least every 3 years
3.5.1.2	The company shall have a documented supplier approval ~~and ongoing monitoring~~ procedure to ensure that all suppliers of raw materials, including packaging, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval ~~and monitoring~~ procedure shall be based on risk and include one or a combination of: • valid certification to the applicable BRC Global Standard or a standard benchmarked by the Global Food Safety Initiative (GFSI). The scope of the certification shall include the raw materials purchased. ~~(e.g. to BRC Global Standards or other GFSI-recognised scheme)~~ OR • 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 2nd or 3rd party then 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, for suppliers assessed as low risk only, and where a valid risk-based justification is provided, initial and ongoing approval may be based on a completed supplier questionnaire, with a scope that includes product safety, traceability, HACCP review and good manufacturing practices, that has been reviewed and verified by a demonstrably competent person. ~~Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers will be required to notify the site of any significant changes in the interim.~~ ~~The site shall have an up-to-date list of approved suppliers.~~
3.5.1.3	There shall be a documented process for the ongoing review and monitoring of suppliers, based on risk and using 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, this shall include 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 shall be readily available to relevant staff (eg at goods receipt).
3.5.1.5	Where raw materials (excluding packaging) are purchased from companies that are not the manufacturer, packer or consolidator (eg purchased from an agent~~,s or~~ broker or wholesaler)~~s~~, the site shall know the identity of the last manufacturer or packer, or for bulk commodity products the consolidation place of the raw material. AND 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 ~~the~~a BRC Standard (eg BRC Global Standard for Agents and Brokers) or a standard benchmarked by the Global Food Safety Initiative (GFSI).
3.5.1.6 WG recommended moving from 3.9.3	The company shall ensure that its suppliers of raw materials (including 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 relevant exceptions shall be identified to the customer.
3.5.2	Raw material and packaging acceptance, ~~and~~ monitoring and management procedures
SOI	Controls on the acceptance of raw materials (including packaging) shall ensure that these do not compromise the safety, legality or quality of products and where appropriate any claims of authenticity.

3.5.2.1		The company shall have a documented procedure for the acceptance of raw materials and packaging on receipt based upon the risk assessment (clause 3.5.1.1). Raw material (including packaging) acceptance and its release for use shall be based on 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 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 packaging) are communicated to goods receipt personnel and ensure 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).
3.5.2.3		Where the site is in receipt of live animals, there shall be an inspection by a suitably competent individual, at lairage and evisceration to ensure that animals are fit for human consumption.
3.5.3		Management of suppliers of services
SOI		The company shall be able to demonstrate that where services are outsourced the service is appropriate and any risks presented to food safety, legality and quality have been evaluated to ensure effective controls are in place.
3.5.3.1		There shall be a documented 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, packaging or products • off-site packing of products • laboratory testing • catering services • waste management.

	• food safety consultants This approval and monitoring process shall be risk-based and shall 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 (ie 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 potential food safety risks associated with the service have been addressed.
3.5.4	Management of subcontracted, outsourced processing ~~and packing~~
SOI	Where any process step in the manufacture ~~or packing~~ of a product ~~which is included within the scope of certification~~ is subcontracted or 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.
3.5.4.1	The company shall be able to demonstrate that where part of the production process ~~or final packing~~ is outsourced and undertaken off-site this has been declared to the brand owner and, where required, approval granted.
3.5.4.2	The company shall ensure that subcontractors are approved and monitored, to ensure 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 ~~by successful completion of either:~~ ~~certification to the applicable BRC Global Standard for Food Safety or other GFSI-recognised scheme~~ ~~a documented site audit with a scope to include product safety, traceability, HACCP review and good manufacturing practices by an experienced and demonstrably competent product safety auditor.~~valid certification to the applicable BRC Global Standard or a standard benchmarked by the Global Food Safety Initiative (GFSI).
3.5.4.3	Any outsourced processing ~~or packing~~ operations shall: • be undertaken in accordance with established contracts which clearly define any processing and/or packing requirements and product specification

	• maintain product traceability.
3.5.4.4	The company shall establish inspection and test procedures for products where part of the processing ~~or packing~~ has~~ve~~ been outsourced, including visual, chemical and/or microbiological testing.~~,~~ The frequency and methods of inspection or testing shall be dependent on risk assessment.
3.6	Specifications
SOI	Specifications shall exist for raw materials including packaging, finished products and any product or service which could affect the integrity of the finished product.
3.6.1	Specifications for raw materials and packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements. The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological or physical standards).
3.6.2	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. ~~-~~The~~yse~~ 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 t~~T~~he company is manufacturing customer branded products, they shall seek formal agreement of finished product specifications ~~with relevant parties~~. Where specifications are not formally agreed then the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place.
3.6.4	~~Specifications shall be reviewed whenever products change (e.g. ingredients, processing method) or at least every 3 years. The date of review and the approval of any changes shall be recorded.~~ Specification review shall be sufficiently frequent to ensure data is current, taking into account product changes, suppliers, regulations and other risks. Reviews and changes shall be documented.
3.7	Corrective and preventive actions
	☆**FUNDAMENTAL**

SOI	The site shall be able to demonstrate that it uses the information from identified failures in the food safety and quality management system to make necessary corrections and prevent recurrence.
3.7.1	The site shall have a documented procedure for handling and correcting failures identified in the food safety and quality system.
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 • an appropriate timescale for correction • the person responsible for correction • verification that the correction has been implemented and is effective • identification of the root cause of the non-conformity and implementation of any necessary actions to prevent recurrence.
3.8	Control of non-conforming product
SOI	The site shall ensure that any out-of-specification product is effectively managed to prevent unauthorised release.
3.8.1	There shall be documented 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) • 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.

		• root cause analysis and implementing ongoing improvements, to avoid recurrence.
3.9		Traceability
		☆**FUNDAMENTAL**
SOI		The site shall be able to trace all raw material product lots (including packaging) from its suppliers through all stages of processing and dispatch to its customers and vice versa.
3.9.1		The site shall have a documented traceability procedure designed to maintain traceability throughout the site's processes. As a minimum this shall include: • how the traceability system works • the labelling and records required
3.9.2~~1~~		Identification of raw materials, (including ~~primary and any other relevant~~ packaging), ~~processing aids,~~ intermediate/semi-processed products, part-used materials, finished products and materials pending investigation shall be adequate to ensure traceability.
3.9.3~~2~~		The site shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material supplier (including ~~primary~~ packaging) to finished product and vice versa, including quantity check/mass balance. The traceability test shall include a summary of the documents that should be referenced during the traceability test, and clearly show the links between these documents. This shall occur at a predetermined frequency, as a minimum annually, and results shall be retained for inspection. ~~Full~~ The traceability should be achievable within 4 hours.
~~3.9.3~~ WG requested clause moved to 3.5.1.4		~~The company shall ensure that its suppliers of raw materials 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.~~

3.9.4		Where rework or any reworking operation is performed, traceability shall be maintained.
3.10		Complaint handling
SOI		Customer complaints shall be handled effectively and information used to reduce recurring complaint levels.
3.10.1		All complaints shall be recorded, investigated and the results of the investigation 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.
3.11		Management of incidents, product withdrawal and product recall
SOI		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.
3.11.1		The company shall have documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality. This shall include consideration of contingency plans to maintain 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. • 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 as 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 • root cause analysis and implementing ongoing improvements, to avoid recurrence. The procedure shall be capable of being operated at any time.
3.11.3	The product recall and withdrawal procedures shall be tested, at least annually, in a way that ensures their effective operation. Results of the test shall be retained and shall include timings of key activities. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary.
3.11.4	In the event of a product recall, the certification body issuing the current certificate for the site against this Standard shall be informed within 3 working days of the decision to issue a recall.
~~3.12~~	~~Customer focus and communication~~
~~SOI~~	~~The company shall ensure that any customer-specific policies or requirements are understood, implemented and clearly communicated to relevant staff and, where appropriate, suppliers of raw materials, packaging and services.~~
~~3.12.1~~	~~Where a company is requested to follow specific customer requirements, codes of practice, methods of working etc., these shall be made known to relevant staff within the site and implemented.~~

~~3.12.2~~	~~Effective processes shall be in place for communicating customer-specific requirements to the suppliers of raw materials and services as applicable.~~

4	Site standards
4.1	External standards
SOI	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.
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site (from potential contaminants, flooding etc.), they shall be reviewed in response to any changes.
4.1.2	The external areas shall be maintained in good order. Where ~~buildings are surrounded by~~ grassed or planted areas 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 avoid contamination of the product.
4.1.3	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).
4.2	Site Security and food defence
SOI	~~Security s~~Systems shall ensure that products, premises and brands are protected from ~~theft or~~ malicious actions ~~contamination~~ while under the control of the site.
4.2.1	~~The company shall undertake a documented assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements to reduce risks shall be implemented and reviewed at least annually.~~ The company shall undertake a documented risk assessment of the potential risks to products from any deliberate attempt to inflict contamination or damage. This risk assessment shall include both internal and external threats.

	The assessment shall be reviewed at least annually.
4.2.2	Where raw materials or products are identified as being at particular risk, controls shall be introduced to manage these risks. Where prevention is not sufficient or possible, systems shall be in place to identify any tampering. These controls shall be monitored and results documented. The controls shall be reviewed at least annually.
4.2.3	Areas where a significant risk is identified shall be defined, monitored and controlled. This shall include external product and ingredient storage, and intake points. Policies and systems shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors is controlled. ~~Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled.~~ A visitor ~~reporting~~ monitoring system shall be in place. Staff shall be trained in site security procedures and ~~encouraged to report unidentified or unknown visitors~~ food defence.
4.2.4	External storage tanks, silos and any intake pipes with an external opening shall be secured to prevent unauthorised access (eg by using locks on intake pipes, tank farms with locked gates,~~ed~~ security controlled perimeters).
4.2.5	Where required by legislation, the site shall maintain appropriate registrations with relevant authorities. ~~be registered with, or be approved by, the appropriate authority.~~
4.3	Layout, product flow and segregation
SOI	☆**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.
~~4.3.1~~ Moved to 8.1	~~Where a site has high risk, high care or ambient high care areas, There shall be a map of the site which designates areas (zones) where product is at different levels of risk from contamination; that is:~~ ~~• 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.~~
4.3.1~~2~~	There shall be map of the site. ~~site map(s)~~ As a minimum, this map shall define: • 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 • 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 flow.
4.3.2~~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.
4.3.3~~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~~ WG: move to new section (8.1)	~~Where high-risk areas are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials (including packaging), equipment, personnel, waste, airflow, air quality and utilities provision (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 risk of product contamination (e.g. the disinfection of materials on entry).~~
~~4.3.6~~ WG: move to new section (8.1)	~~Where high-care areas are part of the manufacturing site there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials (including packaging), equipment, personnel, waste, airflow, air quality and utilities provision (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.~~
~~4.3.7~~ WG: move to new section (8.1)	~~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~~ ~~• flow of raw materials, packaging, products, equipment, personnel and waste~~ ~~• airflow and air quality~~ ~~• utilities (including drains).~~ ~~Effective processes shall be in place to protect the final product from this contamination. These processes may include segregation, management of process flow or other controls.~~
4.3.~~4~~8	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.
4.3.~~5~~9	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.
4.4	Building fabric, raw material handling, preparation, processing, packing and storage areas
SOI	The fabrication of the site, buildings and facilities shall be suitable for the intended purpose.
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~~ WG: move to new section (currently 8.2)	~~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 location of any equipment fitted to prevent the back-up of waste water. The flow of drains shall not present a risk of contamination of the high-risk/care area.~~
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 are adjacent to, or pass over production lines, 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 is designed to be opened for ventilation purposes, shall be adequately screened to prevent the ingress of pests.
~~4.4.8~~ Moved to 4.9.3	~~Where they pose a risk to product, glass windows shall be protected against breakage.~~
4.4.8	Doors (both internal and external) shall be maintained in good condition. As a minimum, this shall include:

	• 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.
~~4.4.11~~ WG: Move to 4.9.3	~~Where they constitute a risk to product, bulbs and strip lights – including those on electric fly-killer devices – shall be adequately protected. Where full protection cannot be provided, alternative management such as wire-mesh screens or monitoring procedures shall be in place.~~
4.4.10	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.
~~4.4.12~~ WG: move to new section (8.2)	~~High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.~~
4.5	Utilities – water, ice, air and other gases
SOI	Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination.
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 or pose no risk of contamination according to applicable legislation. The microbiological and chemical quality of water shall be analysed at least annually. The sampling points, 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 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	Where legislation specifically permits the use of water which may not be potable for initial product cleaning (e.g. for the storage/washing of fish), the water shall meet the designated legal requirements for this operation.
4.5.4	Air and, other gases and steam used as an ingredient or directly in contact with, or as an ingredient in, products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.
4.6	Equipment
SOI	All food-processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.
4.6.1	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.
4.6.2	Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.
4.7	Maintenance
SOI	An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns.
4.7.1	There shall be a documented planned maintenance schedule or condition monitoring system which includes all plant and processing equipment. The maintenance requirements shall be defined when commissioning new equipment.
4.7.2	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment damage, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.
4.7.3	Where temporary repairs are made, these shall be controlled to ensure the safety or legality of a product 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 product 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.~~, which records that product contamination hazards have been removed from machinery and equipment.~~
~~4.7.5~~ WG: move to new section (8.3)	~~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 the area and be retained in the area.~~
4.7.5~~6~~	Materials and parts used for equipment and plant maintenance, shall be of an appropriate grade or quality. Those~~and~~ materials that pose a risk by direct or indirect contact with raw materials, intermediate and finished products, such as lubricating oil, shall be food grade and of a known allergen status.
4.7.6~~7~~	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.
4.8	Staff facilities
SOI	Staff facilities shall be sufficient to accommodate the required number of personnel, and shall be designed and operated to minimise the risk of product contamination. The facilities shall be maintained in good and clean condition.
4.8.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear).
4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material handling, preparation, processing, packing and storage areas.
4.8.3	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~~ WG: move to new section (8.4)	~~Where an operation includes a high-risk area, personnel shall enter via a specially designated changing facility at the entrance to the high-risk area. The changing facilities shall meet the following requirements:~~ • ~~Clear instructions shall be provided for the order of changing into and out of dedicated protective clothes to prevent the contamination of clean clothing.~~ • ~~Protective clothing shall be visually distinctive from that worn in other areas and shall not be worn outside the high-risk area.~~ • ~~Hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing (i.e. hand-washing after hair covering and footwear has been put on, but before handling clean protective clothing).~~ • ~~Prior to entry to high-risk areas, hand-washing and disinfection shall be provided and used.~~ • ~~Dedicated footwear shall be provided to be worn in the high-risk area with an effective system to segregate areas for wearing high-risk and other footwear (i.e. a barrier or bench system). By exception the use of boot-wash facilities is accepted where these demonstrably provide an effective control of footwear to prevent the introduction of pathogenic material into high-risk areas.~~ ~~A programme of environmental monitoring shall be established to assess the effectiveness of footwear controls.~~
~~4.8.5~~ WG: move to new section (8.4)	~~Where an operation includes a high-care area, personnel shall enter via a specially designated changing facility with arrangements to ensure that protective clothing will not be contaminated before entry to the high-care area. This shall incorporate the following requirements:~~ • ~~Clear instructions for the order of changing into and out of dedicated protective clothes to prevent the contamination of clean clothing.~~ • ~~Site-provided footwear shall not be worn outside the factory.~~ • ~~Protective clothing shall be visually distinctive from that worn in lower risk areas and shall not be worn outside of the high-care area.~~ • ~~Hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing.~~ • ~~On entry to high-care areas, hand-washing and disinfection shall be provided and used.~~ ~~There shall be an effective control of footwear to prevent the introduction of pathogens into high-care areas. This may be by a controlled change of footwear before entering the area or by the use of controlled and managed boot-wash facilities.~~ ~~A programme of environmental monitoring shall be established to assess the effectiveness of footwear controls.~~

4.8.46	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 as 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.
4.8.57	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 4.8.6 shall apply and signs shall be in place to direct people to hand-washing facilities before entering production.
4.8.68	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.
4.8.79	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.
4.8.810	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 introduction of allergenic material to the site).
4.9	Chemical and physical product contamination control Raw material handling, preparation, processing, packing and storage areas

SOI	Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.
4.9.1	Chemical control
4.9.1.1	Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include as a minimum: • an approved list of chemicals for purchase • availability of material safety data sheets (SDS) 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 with restricted access to authorised personnel • use by trained personnel only.
4.9.1.2	Where strongly scented or taint-forming materials have to be used, for instance for building work, procedures shall be in place to prevent the risk of taint contamination of products.
4.9.2	Metal control
4.9.2.1	There shall be a documented policy for the control of the use of sharp metal implements including knives, cutting blades on equipment, needles and wires. This shall include a record of inspection for damage and the investigation of any lost items. Snap-off-blade knives shall not be used.
4.9.2.2	The purchase of ingredients and packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided. Staples, paper clips and drawing pins shall not be used in open product areas. Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.
4.9.3	Glass, brittle plastic, ceramics and similar materials
4.9.3.1	Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination.

4.9.3.2	Documented procedures for handling glass and other brittle materials (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 as a minimum: • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise potential for product contamination.
4.9.3.3	Documented procedures detailing the action to be taken in case of breakage of glass or other brittle items shall be implemented and include the following: • training of staff • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising to continue production • changing of workwear and inspection of footwear • specifying those staff authorised to carry out the above points • recording the breakage incident. • Mechanisms for the safe disposal of contaminated product
4.9.3.4 WG moved from 4.4.8	Where they pose a risk to product, glass windows shall be protected against breakage.
4.9.3.5 WG moved from 4.4.11	Where they constitute a risk to product, bulbs and strip lights (including those on electric fly-killer devices) shall be adequately protected. Where full protection cannot be provided, alternative management such as wire-mesh screens or monitoring procedures shall be in place.
4.9.4	Products packed into glass or other brittle containers
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, as 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.
4.9.5	Wood
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 to ensure it is in good condition and free from damage or splinters which could contaminate products.
4.9.6	Other physical contaminants
4.9.6.1	Documented procedures shall be in place for the removal of packaging from raw materials (eg debagging or deboxing procedures) to prevent contamination of the raw material during these processes.
4.9.6.2	Pens used in open product areas shall be controlled to minimise risk of physical contamination (eg designed without small parts and detectable by foreign body detection equipment).
4.10	Foreign-body detection and removal equipment
SOI	The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies.
4.10.1	Foreign-body detection and removal equipment

4.10.1.1		A documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination. Typical equipment to be considered may include: • filters • sieves • metal detection • magnets • optical sorting equipment • X-ray detection equipment • other physical separation equipment (e.g. gravity separation, fluid bed technology).
4.10.1.2		The type, location and sensitivity of the detection and/or removal method shall be specified as part of the 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 Additional text moved from 4.10.3.5 as some overlap and applicable to all FB methods not just metal detection.		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 the testing procedure identifying any failure of the foreign body detector and/or removal equipment. Action shall include a combination of isolation, quarantining and re-inspection of all product 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.
4.10.2		Filters and sieves
4.10.2.1 Duplication of 4.10.1.4		Filters and sieves used for foreign-body control shall be of a specified mesh size or gauge and designed to provide the maximum practical protection for the

	product. ~~Material retained or removed by the system shall be examined and recorded to identify contamination risks.~~
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage on a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified this shall be recorded and the potential for contamination of products investigated and appropriate action taken.
4.10.3	Metal detectors and X-ray equipment
4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve the protection of final products from metal contamination. Where metal detectors are not used justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective method of protection (e.g. use of X-ray, fine sieves or filtration of products).
4.10.3.2	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 documented procedures for the operation and testing of the metal detection or X-ray equipment. This shall include as 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 ~~checking~~ testing procedures shall ~~be based on good practice and shall~~ as a minimum include~~:~~ ~~the following:~~ • 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 ferrous only may be applicable. • A test that both the detection and rejection mechanisms are working effectively under normal working conditions. • Checks that test the memory/reset function of the metal detector by passing successive test packs through the unit 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 centre of the metal detector aperture and wherever possible be carried out by inserting the test piece within a clearly identified sample pack of the food being produced at the time of the test. 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 at least daily, during both line start up and at the end of the production period.
~~4.10.3.5~~ Moved to 4.10.1.3	~~The site shall establish and implement corrective action and reporting procedures in the event of the testing procedure identifying any failure of the foreign-body detector. Action shall include a combination of isolation, quarantining and re-inspection of all product produced since the last successful test.~~
4.10.4	Magnets
4.10.4.1	The type, location and strength of magnets shall be fully documented. Documented procedures shall be in place for the inspection, cleaning, strength testing and integrity checks. Records of all checks shall be maintained.
4.10.5	Optical sorting equipment
4.10.5.1	Each unit shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.
4.10.6	Container cleanliness – glass jars, cans and other rigid containers
4.10.6.1	Based on risk assessment, procedures shall be implemented to minimise foreign-body contamination originating with the packaging container (e.g. jars, cans and other 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.
4.11	Housekeeping and hygiene
SOI	☆**FUNDAMENTAL** 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.
4.11.1	The premises and equipment shall be maintained in a clean and hygienic condition.
4.11.2 High risk/care covered in 8.5	Documented cleaning procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures for processing equipment, food contact surfaces ~~and environmental cleaning in high-care/high-risk areas~~ shall as a minimum include the: • 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. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.
4.11.3 Reference to high risk/care moved to 8.5	~~As a minimum for food contact surfaces, processing equipment and for environmental cleaning in high-care/high-risk areas, l~~Limits of acceptable and unacceptable cleaning performance shall be defined for food contact surfaces and processing equipment. ~~This~~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). ~~A~~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 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 instigate improvements where required.
4.11.6 High risk/care moved to 8.5	Cleaning equipment and tools 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. ~~Equipment used for cleaning in high-care and high-risk areas shall be visually distinctive and dedicated for use in that area.~~
4.11.7	Cleaning in place (CIP)
~~4.11.7.1~~	~~Cleaning-in-place (CIP) facilities, where used, shall be monitored and maintained to ensure their effective operation.~~
~~4.11.7.2~~	~~A schematic diagram of the layout of the CIP system including process piping circuits shall be available. There shall be an inspection report or other validation that:~~ • ~~systems are hygienically designed with no dead areas, limited interruptions to flow streams and good system drain ability~~ • ~~scavenge/return pumps are operated to ensure that there is no build-up of CIP solutions in the vessels~~

	~~• spray balls and rotating spray devices effectively clean vessels by providing full surface coverage and are periodically inspected for blockages~~ ~~• CIP equipment has adequate separation from active product lines (e.g. through the use of double seat valves, manually controlled links, blanks in pipework or make-or-break connections with proxy switches as interlocks) to prevent or safeguard against cross-contamination.~~ ~~The system shall be revalidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.~~
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, the company shall assess the risk of cross-contamination (eg due to the re-introduction of allergens or different meat species used in previous production runs). 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.
~~4.11.7.3~~	~~The CIP equipment shall be operated to ensure effective cleaning is carried out:~~ ~~The process parameters, time, detergent concentrations, flow rate and temperatures shall be defined to ensure removal of the appropriate target hazard (e.g. soil, allergens, vegetative micro-organisms, spores). This shall be validated and records of the validation maintained.~~ ~~Detergent concentrations shall be checked routinely.~~ ~~CIP process verification shall be undertaken by analysis of rinse waters and/or first product through the line for the presence of cleaning fluids or by tests of ATP (bioluminescence techniques), allergens or micro-organisms as appropriate.~~ ~~Detergent tanks shall be kept stocked up and a log maintained of when these are drained, cleaned, filled and emptied. Recovered post-rinse solutions shall be monitored for a build-up of carry-over from the detergent tanks.~~ ~~Filters, where fitted, shall be cleaned and inspected at a defined frequency.~~

4.11.7.2	Critical limits shall be defined for key process parameters to ensure the removal of target hazards (eg soil, allergens, micro-organisms, spores). As a minimum this shall include: • times • detergent concentrations • flow rate or 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, including: • Detergent concentrations shall be checked routinely. • Recovered post-rinse solutions shall be monitored for a build-up of carry-over from the detergent tanks. • Filters, where fitted, shall be cleaned and inspected at a defined frequency. • Flexible hoses, where used, shall be stored hygienically when not in use, and inspected at a defined frequency to ensure they are in good condition.
4.11.7.4	Cleaning-in-place (CIP) facilities, where used, shall be monitored at a defined and documented frequency based on risk. This may include: • Process parameters defined in 4.11.7.2 • Correct connections, piping and settings in place • Correct process (eg valves opening/closing sequentially) • Effective completion of cleaning cycle • Effective results, including draining where required Procedures shall define the action to be taken if monitoring indicates that processing is outside defined limits.

4.11.8		Environmental monitoring
SOI		Risk based environmental monitoring programmes shall be in place for pathogens and spoilage organisms. As a minimum, this shall include all production areas with open, ready-to-eat products.
4.11.8.1		The design of the environmental monitoring programme shall be based on risk, and as a minimum include: • sampling protocol • identification of sample locations • frequency of tests

	• target organism(s) • test methods (eg settle plates, rapid testing, swabs) • recording and evaluation of results The programme and associated procedures shall be documented.
4.11.8.2	Appropriate control limits shall be defined. 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 a trend of increasing positive environmental results.
4.11.8.3	The company shall review the environmental monitoring programme at least annually and whenever: • changes in processing conditions, process flow or equipment • new developments in scientific information • failure of the programme to identify a significant issue (eg regulatory authority testing identifies positive results which the site programme has not) • product failure (products with positive tests) that are not identified in the environmental monitoring programme (ie if product tests give positive pathogen results then the programme should be reviewed to ensure that it remains effective) • extensive lack of positive results (ie a site with a long history of negative results should review the programme, for example to consider whether the correct parts of the factory are correctly tested, for the appropriate organisms,etc).

4.12	Waste/waste disposal
SOI	Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.
4.12.1	Where licensing is required 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 e~~E~~xternal waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: • clearly identified • designed for ease of use and effective cleaning

	• well maintained to allow cleaning and, where required, disinfection • emptied at appropriate frequencies • covered or doors kept closed as appropriate.
4.12.3	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.
4.13	Management of surplus food and products for animal feed
SOI	Effective processes shall be in place to ensure the safety and legality of by-products of the primary processing activity of the site.
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 authorised otherwise by the customer.
4.13.2	Where customer-branded products which do not meet specification are sold to staff or passed on to charities or other organisations this shall be with the prior consent of the brand owner. Processes shall be in place to ensure that all products are fit for consumption and meet legal requirements.
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 relevant legislative requirements.
4.14	Pest ~~control~~Management
SOI	The whole site shall have an effective preventive pest ~~control~~ management programme in place to minimise the risk of infestation and there shall be the resources available to respond rapidly to any issues which occur to prevent risk to products. Pest management programmes shall comply with applicable legislation.
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 ~~identifi~~documented in pest ~~control~~ management records and be part of an effective pest ~~management~~

	control programme to eliminate or manage the infestation such 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 ~~control~~ management organisation, or shall have appropriately trained staff, for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. This risk assessment shall be reviewed whenever there are changes to the building or production processes. Where the services of a pest management~~control~~ contractor are employed, the service scope shall be clearly defined and reflect the activities of the site.
4.14.3	Where a site undertakes its own pest ~~control~~management, it shall be able to effectively demonstrate that: • pest ~~control~~ 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 control 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 ~~control~~ management documentation and records shall be maintained. This shall include as a minimum: • an up-to-date plan of the full site, identifying ~~numbered~~ pest control devices and their locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and for the contractor • details of pest control products used, including instructions for their effective use and action to be taken in case of emergencies • any observed pest activity • details of pest control treatments undertaken.
4.14.5	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	Fly-killing devices, ~~and/or~~ pheromone traps and/or other insect monitoring devices shall be correctly sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used.
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~~7~~	In the event of infestation, or evidence of pest activity, immediate action shall be taken to identify at-risk product and to minimise the risk of product contamination. Any potentially affected products should be subject to the non-conforming product procedure.
4.14.9~~8~~	Records of pest ~~control~~ 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~~9~~	An in-depth, documented pest ~~control~~ management survey shall be undertaken at a frequency based on risk, but as a minimum annually, by a pest control expert to review the pest control measures in place. The survey shall: • provide an in-depth inspection of the facility for pest activity • review the existing pest ~~control~~ management measures in place and make any recommendations for change. The timing of the survey shall be such as to allow access to equipment for inspection where a risk of stored product insect infestation exists.
4.14.11~~10~~	Results of pest ~~control~~ management inspections shall be assessed and analysed for trends on a regular basis, but, as a minimum: • in the event of an infestation • annually. This shall include ~~a catch~~ analysis from trapping and monitoring devices to identify problem areas. The analysis shall be used as a basis for improving the pest ~~control~~ management procedures.
4.14.12~~1~~	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.

4.15	Storage facilities
SOI	All facilities used for the storage of raw materials, packaging, in-process products and finished products shall be suitable for its purpose.
4.15.1	Documented procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment, understood by relevant staff and implemented accordingly. These may include, as appropriate: • 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. Obsolete packaging shall be stored in a separate area and systems shall be in place to prevent accidental use.
4.15.3	Where temperature control is required (for example, 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 materials are used in the

	correct order in relation to their manufacturing date and within the prescribed shelf life.
4.16	Dispatch and transport
SOI	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.
4.16.1	Documented 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 dispatch of products shall be inspected prior to loading to ensure that they are 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 documented 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 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 & conditions and verified or the contracted company shall be certificated to the Global Standard for Storage and Distribution or similar GFSI-recognised scheme.

5	Product control
5.1	Product design/development
SOI	Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced.
5.1.1	The company shall provide clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards which would be unacceptable to the site or customers (e.g. the introduction of allergens, glass packaging or microbiological risks).
5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or authorised HACCP committee member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.
5.1.3	Trials using production equipment shall be carried out where it is necessary to validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.
5.1.4	Initial ~~S~~shelf-life trials shall be undertaken using documented protocols reflecting conditions experienced during storage, transport and handling to determine product shelf life. Reflecting conditions expected during manufacture, storage, distribution and use.

	Results shall be recorded and retained and shall confirm compliance with 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.
5.1.5	The site shall ensure pet food is formulated/designed for the intended use (eg where products are designed for complete diet or as a complementary product).
5.1.6	Where a site's product range includes pet food products for multiple, different animal species, the site shall have specific procedures for the management of any ingredient, raw material, product or rework that can be harmful to unintended recipients.
5.1.7	Where the site manufactures, processes or packs pet food products that contain medicinal substances, the site shall have specific procedures for the management of the medicated raw materials and finished products. As a minimum, this shall include: • identification of medication-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products, rework and any new product development ingredients or products. • mechanisms to ensure correct concentrations of medicinal substances in finished products • procedures (eg cleaning procedures) to prevent contamination of non-medicated pet food with materials containing medicinal substances • specific procedures to ensure the correct labelling of medicated pet food
5.2	Product labelling
SOI	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.
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.
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 a product is designed to enable a claim to be made to satisfy a consumer group (e.g. a nutritional claim, reduced sugar), the company shall ensure that the product formulation and production process is fully validated to meet the stated claim.
5.2.4	Where the label information is the responsibility of a customer or a nominated third party the company shall provide: • information to enable the label to be accurately created • information whenever a change occurs which may affect the label information.
5.2.5	Where cooking instructions are provided to ensure product safety, they shall be fully validated to ensure that, when cooked according to the instructions, they will consistently produce a safe, ready-to-eat product.
5.3	Management of allergens
SOI	☆**FUNDAMENTAL** The site shall have a system for the management of allergenic materials which minimises the risk of allergen contamination of products and meets legal requirements for labelling in the country of manufacture and country of sale.
5.3.1	The site shall carry out an assessment of raw materials to establish the presence and likelihood of contamination by allergens (refer to glossary). This shall include review of raw material specifications and, where required, obtain additional information from suppliers, for example through questionnaires to understand the allergen status of the raw material, its ingredients and the factory in which it is produced.
5.3.2	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 and establish documented policies and procedures for handling

	raw materials, intermediate and finished products to ensure cross-contamination is avoided. This 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	Documented procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination (cross-contact) into products not containing the allergen. This 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, 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 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. National 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 allergy or food 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 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.
5.4	Product authenticity, claims and chain of custody
SOI	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.
5.4.1	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. Such information may, for example, come from: • trade associations • government sources • private resource centres.
5.4.2	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 • nature of the raw material. The vulnerability assessment shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risk. It shall be formally reviewed annually.
5.4.3	Where raw materials are identified as being at particular risk of adulteration or substitution appropriate assurance and/or testing processes shall be in place to reduce the risk.
5.4.4	Where products are labelled or claims are made on finished packs which are dependent on a status of a raw material including: • specific provenance or origin

		• breed/varietal claims • assured status (e.g. GlobalGAP) • genetically modified organism (GMO) status • identity preserved • named specific trademarked ingredients the status of each batch of the raw material shall be verified. 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 or at least every 6 months in the absence of a scheme-specific requirement.
5.4.5		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.
5.4.6		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.
5.5		Product packaging
SOI		Product packaging shall be appropriate for the intended use and shall be stored under conditions to prevent contamination and minimise deterioration.
5.5.1		When purchasing or specifying ~~food contact~~ packaging the supplier of packaging materials shall be made aware of any particular characteristics of the food (e.g. high fat content, pH, ~~or~~ usage conditions such as microwaving, other packaging used on the product) which may affect packaging suitability. Certificates of conformity or other evidence shall be available for product packaging to confirm it complies with relevant 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 (eg 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

	• timely disposal of obsolete packaging • appropriate procedures for the disposal of obsolete printed materials (eg rendering trademarked materials unusable)
5.6	Product inspection and laboratory testing
SOI	The company shall undertake or subcontract inspection and analyses which are critical to confirm product safety, legality, integrity and quality, using appropriate procedures, facilities and standards.
5.6.1	Product inspection and testing
5.6.1.1	There shall be a scheduled programme of ~~testing covering~~ product testing~~s and the processing environment,~~ which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, frequency and specified limits shall be documented.
5.6.1.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. The significance of external laboratory results shall be understood and acted upon accordingly. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.
5.6.1.3	The site shall ensure that a system of ongoing validation of the shelf-life ~~assessment~~ 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.
5.6.2	Laboratory testing
5.6.2.1	Pathogen testing (including environmental testing) 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.
5.6.2.2	Where routine testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented, implemented and shall include consideration of: • design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • protective clothing arrangements

	• processes for obtaining product samples • disposal of laboratory waste.
5.6.2.3	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025. Documented justification shall be available where accredited methods are not undertaken.
5.6.2.4	Procedures shall be in place to ensure reliability of laboratory results, other than those critical to safety and legality specified in clause 5.6.2.3. 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) • use of appropriately calibrated and maintained equipment.
5.6.2.5	The significance of 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 implemented promptly to address any exceedance of these limits.
5.7	Product release
SOI	The site shall ensure that finished product is not released unless all agreed procedures have been followed.
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 release authorised.

6	**Process control**
6.1	Control of operations

	☆**FUNDAMENTAL**
SOI	The site shall operate to documented procedures and/or work instructions that ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.
6.1.1	Documented process specifications and work instructions shall be available for the key processes in the production of products to ensure product safety, legality and quality. The procedures/specifications 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 • any additional critical control points identified in the HACCP plan. Process specifications shall be in accordance with the agreed finished product specification.
6.1.2	Process monitoring, such as of temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification.
6.1.3	In circumstances where process parameters or product quality are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.
6.1.4	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).
6.1.5	In the case of equipment failure or deviation of the process from specification, procedures shall be in place to establish the safety status and quality of the product to determine the action to be taken.
6.2	Labelling and pack control

	☆**FUNDAMENTAL**
SOI	The management controls of product labelling activities shall ensure that products will be correctly labelled and coded.
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 pack~~ag~~ing machines. Where off-line coding or printing of packaging materials occurs: • setting and amendments to the printer parameters (eg the input of, or changes to, date codes) shall only be completed by an authorised member of staff • ~~,~~ controls~~hecks~~ shall be in place to ensure that only correctly printed material is available at the pack~~ag~~ing machines.
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 all products and packaging from the previous production have been removed from the line before changing to the next production.
6.2.3	Documented 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 • 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 on-line verificationvision equipment (eg bar code scanners) is used to check product labels and printing, the site shall establish and implement documented procedures for the operation and testing of the equipment procedures shall be in place to ensure that the system is correctly set up and capable of alerting or rejecting product when packaging information is out of specification. Testing of the equipment shall be completed at least: • at the start of the packing run • during the packing run • when changing batches of packaging materials • at the end of each production run.
6.3	Quantity – weight, volume and number control
SOI	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.
6.3.1	The frequency and methodology of quantity checking shall meet the requirements of 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 documented procedures for the operation and testing of online check weighers. As a minimum this shall include: • consideration of any legal requirements • responsibilities for testing the equipment • operating effectiveness and any variation to this for particular products • the methods and frequency of testing the check weigher • recording of the results of tests
6.4	Calibration and control of measuring and monitoring devices
SOI	The site shall be able to demonstrate that measuring equipment is sufficiently accurate and reliable to provide confidence in measurement results.

6.4.1	The site shall identify and control measuring equipment used to monitor critical control points, product safety and legality. This shall include as 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.

7	**Personnel**
7.1	Training: raw material handling, preparation, processing, packing and storage areas
	☆**FUNDAMENTAL**
SOI	The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.

7.1.1	All relevant personnel, including 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 as 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 • the delivery of training in the appropriate language of trainees.
7.1.4	All relevant personnel, including engineers, agency-supplied staff and temporary staff and contractors, shall have received general allergen awareness training and be trained in the site's allergen-handling procedures.
7.1.5	Records of all training shall be available. This shall include as 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 copy of 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.
7.1.6	The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.
7.2	Personal hygiene: raw material handling, preparation, processing, packing and storage areas
SOI	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.

7.2.1		The requirements for personal hygiene shall be documented and communicated to all personnel. This shall include as a minimum the following requirements: • watches shall not be worn • jewellery shall not be worn, with the exception of a plain wedding ring, ~~or~~ wedding wristband or medical alert jewellery • rings and studs in exposed parts of the body, such as ears, noses, tongues and eyebrows, shall not be worn • fingernails shall be kept short, clean and unvarnished • false fingernails 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.
7.3		Medical screening
SOI		The company shall have procedures in place to ensure that employees, agency staff, contractors or visitors are not a source of transmission of food-borne diseases to products.
7.3.1		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, 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 documented procedures for employees, contractors and visitors relating to action to be taken where they may be suffering from or have been in contact with an infectious disease. Expert medical advice shall be sought where required.
7.4	Protective clothing: employees or visitors to production areas
SOI	Suitable site-issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.
7.4.1	The company shall document and communicate to all employees (including agency and temporary personnel), contractors or visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. in production areas, storage areas, etc~~high-care or high-risk areas~~). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, use of canteen and smoking areas).
7.4.2	Protective clothing shall be available that: • is provided in sufficient numbers for each employee • is of suitable design to prevent contamination of the product (as a minimum containing no external pockets above the waist or sewn-on buttons) • fully contains all scalp hair to prevent product contamination • includes snoods for beards and moustaches, where required, to prevent product contamination.
7.4.3 High risk/care moved to 8.7	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 • ~~protective clothing for high-risk or high-care areas is commercially sterile following the washing and drying process~~

	• 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 to protect the employee from the products handled and the clothing is worn in enclosed product or low-risk areas only.
~~7.4.4~~ move to new section (8.7)	~~Where protective clothing for high-care or high-risk areas is cleaned by a contracted or in-house laundry, this shall be audited either directly or by a third party. The frequency of these audits should be based on risk.~~
7.4.4~~5~~ High risk/care moved to 8.7	Protective clothing shall be changed at an appropriate frequency, based on risk. ~~For high-risk and high-care areas the protective clothing shall be changed at least daily.~~
7.4.5~~6~~	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~~7~~	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.

8 High Risk, High Care and Ambient High Care Production Risk Zones

Where a site produces products that require handling in high risk, high care and/or ambient high care production facilities (refer to appendix 2 for the definition of products that require these facilities), all the relevant requirements from sections 1 – 7 of the Standard must be fulfilled in addition to the requirements in this section.

8	High Risk, High Care and Ambient High Care Requirements
SOI	The site shall be able to demonstrate that production facilities and controls are suitable to prevent pathogen contamination of products.

8.1 Layout, Product Flow and Segregation in High Risk, High Care & Ambient High Care

8.1.1 (formerly 4.3.1)	The map of the site (refer to clause 4.3.1) shall include areas (zones) where the product is at different levels of risk from contamination; that is: • 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.
8.1.2 (formerly 4.3.5)	Where high-risk areas are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials (including packaging), equipment, personnel, waste, airflow, air quality and utilities provision (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 risk of product contamination (e.g. the disinfection of materials on entry).
8.1.3 (formerly 4.3.6)	Where high-care areas are part of the manufacturing site there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials (including packaging), equipment, personnel, waste, airflow, air quality and utilities provision (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.
8.1.4 (formerly 4.3.7)	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 • flow of raw materials, packaging, products, equipment, personnel and waste • airflow and air quality • utilities (including drains).

		Effective processes shall be in place to protect the final product from this contamination. These processes may include segregation, management of process flow or other controls.

8.2 Building Fabric in High Risk, High Care & Ambient High Care	
8.2.1 (formerly 4.4.4)	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 location of any equipment fitted to prevent the back-up of waste water. The flow of drains shall not present a risk of contamination of the high-risk/care area.
8.2.2 (formerly 4.4.13)	High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.

8.3 Maintenance in High Risk, High Care & Ambient High Care	
8.3.1 (formerly 4.7.5)	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 the area and be retained in the area.
8.3.2	Where equipment is removed from the area, the site shall have a documented procedure to ensure the cleanliness and removal of contamination hazards, before being accepted back into the area.
8.3.3	Where portable equipment (eg handheld devices) is used in high risk or high care areas these items: • shall be visually distinctive and dedicated for use in that area OR • there shall be specific procedures (eg a full clean) to ensure this does not result in contamination.

8.4 Staff Facilities for High Rick, High Care & Ambient High Care

8.4.1
(formerly 4.8.4 and 4.8.5)
	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 shall be visually distinct from that worn in other areas and shall not be worn outside the area.
	• Hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean of the clean clothing (ie hand-washing after hair covering and footwear has been put on, but before handling clean protective clothing)
	• Hand-washing and disinfection shall be provided and used. As a minimum these shall be:
	  ○ prior to entry for high risk areas
	  ○ on entry for high care areas
	• Dedicated site footwear shall be provided by the site which shall not be worn outside the factory.
	• There shall be an effective control of footwear to prevent the introduction of pathogens into the area. This may be by segregation and controlled change of footwear before entering the area (ie 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 pathogenic material into the area.
	A programme of environmental monitoring shall be used to assess the effectiveness of footwear controls.

8.5 Housekeeping and hygiene in high risk, high care & ambient high care

8.5.1 (formerly 4.11.2)	Documented cleaning procedures shall be in place and maintained for the building, plant and all equipment. Environmental cleaning procedures in high-care/high-risk areas shall as a minimum include the: • 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. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.
8.5.2 (formerly 4.11.3)	Limits of acceptable and unacceptable cleaning performance shall be defined for high risk/care production risk zones. 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 frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.
8.5.3 (formerly 4.11.6)	Equipment used for cleaning in high-care and high-risk areas shall be visually distinctive and dedicated for use in that area.
8.5.4	CIP systems used for cleaning high risk or high care areas shall be dedicated for use in that area and separate from those used in low risk areas.

8.6 Waste/Waste Disposal in High Risk, High Care & Ambient High Care	
8.6.1	Waste disposal systems shall ensure that the risk of contamination to 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 and shall not be moved between different production risk zones.

8.7 Protective Clothing in High Risk, High Care & Ambient High Care	
8.7.1	Laundering of protective clothing for high risk and high care areas shall take place by an approved contracted or in-house laundry using defined criteria to

(formerly 7.4.3)	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, low risk, etc. • effective cleaning of the protective clothing • protective clothing is commercially sterile following the washing and drying process • cleaned clothes are supplied protected from contamination until use (e.g. by the use of covers or bags).
8.7.2 (formerly 7.4.4)	Where protective clothing for high-care or high-risk areas is cleaned by a contracted or in-house laundry, this shall be audited either directly or by a third party. The frequency of these audits should be based on risk.
8.7.3 (formerly 7.4.5)	Protective clothing shall be changed at an appropriate frequency, based on risk, and as a minimum daily.

9 Requirements of the traded goods

Where a site purchases and sells food products, that are stored in the site's facilities, that would normally fall within the scope of the Standard, but which are not manufactured, further processed or repacked at the site being audited, the site's management of these products may be incorporated into the audit scope using the section 9 (Traded Goods).

Where the company applies for certification of the management of traded goods, all relevant requirements from the core Standard (sections 1 to 8) must also be fulfilled in addition to the requirements outlined in this section.

9.1	**Approval and performance monitoring of manufacturers/packers of traded food products**
SOI	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.

9.1.1	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).
9.1.2	The company shall have a documented supplier approval procedure to ensure that all suppliers of raw materials, including 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 one or a combination of: • valid certification to the applicable BRC Global Standard or a standard benchmarked by the Global Food Safety Initiative (GFSI). The scope of the certification shall include the products purchased. OR • 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 2nd or 3rd party then 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, for suppliers assessed as low risk only, and where a valid risk-based justification is provided, initial and ongoing approval may be based on a completed supplier questionnaire, with a scope that includes product safety, traceability, HACCP review and good manufacturing practices, that has been reviewed and verified by a demonstrably competent person.
9.1.3	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.
9.1.4	There shall be a documented 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.

9.2 Specifications	
SOI	Specifications or information to meet legal requirements and assist customers in the safe usage of the product shall be maintained and available to customers.
9.2.1	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. These may be the form of a printed or electronic document, or part of an online specification system.
9.2.2	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.
9.2.3	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).
9.2.4	Specification review shall be sufficiently frequent to ensure data is current, taking into account product changes, suppliers, regulations and other risks. Reviews and changes shall be documented.

9.3 Product inspection and laboratory testing

SOI	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.
9.3.1	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.
9.3.2	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.
9.3.3	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.
9.3.4	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.
9.3.5	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.

9.4 Product legality	
SOI	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.
9.4.1	The company shall have documented processes to verify the legality of products which are traded. This shall include as applicable: • 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.

9.5 Traceability	
SOI	The company shall be able to trace all product lots back to the last manufacturer and forward to the customer of the company.
9.5.1	The site shall maintain a traceability system for all batches of product which 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.
9.5.2	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).
9.5.3	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

Unannounced Audits

The unannounced audit programme remains voluntary and sites can continue to opt for an announced or an unannounced audit. However, previous versions of the Standard provided two options for unannounced audits:

- Option 1 - A single unannounced audit
- Option 2 - A split audit with an unannounced audit of good manufacturing practices and a later, announced audit primarily to review records and procedures.

The option 2 unannounced audit has consistently proven to be unpopular, with very few sites selecting to be audited in this way. It has therefore been removed from Issue 8.

Global Markets Programme

The Global Markets 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 8 of the Standard and the revised scheme will be published in due course, as a separate document.

Interim Reporting

One of the consistent concerns raised by key stakeholders (e.g. customers, certificated sites, regulators) is the time gap between audit and confirmation of audit result (e.g. availability of certificate & audit report).

Following each audit an 'interim' report shall be made available on the BRC Directory within 10 calendar days of the audit. This will be a simple summary of information with the contents strictly limited to date of audit, basic site information, details of the audit scope and the non- conformities found.

No grade will be included in the interim report since the certification details (including details of the site's corrective actions) are still under independent technical review when this report is completed.

Audit Report

The audit report is one of the vital outputs from the audit. It is important that completion of the report:

- Facilitates robust auditing, focusing on product safety
- Provides sufficient details for stakeholders

The Working Group is currently reviewing options and ideas for the Issue 8 audit report and further information will be published when it is available.

Product labelling

An analysis of product recall and withdrawal data shows that the underlying cause of the greatest number of problems is still associated with labelling and packing of products. Problems occur either because the label information is incorrect, as a result of changes to ingredients or suppliers, or because of errors made during the packing process.

To attempt to focus on the issue, the vertical audit (which already forms part of the audit) will include a comparison of an example of the product's packaging/labels with the relevant product specification(s) and recipe.

Non-Conformities, Grading and Corrective Actions

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. Therefore, these will remain unchanged from Issue 7.

Audit Frequency

No changes have been proposed to audit frequency. Therefore, these will remain unchanged from Issue 7.

Voluntary Modules

Issue 7 of the Standard was designed to enable the addition of voluntary modules to the routine audit, to enable sites to demonstrate compliance to specific sets of requirements to meet specific market or customer requirements. This process will continue for Issue 8.

Traded Goods

The Traded Goods voluntary module has been incorporated into the main text of the Standard (section 9 of the requirements) and the requirements updated to reflect the equivalent requirements in the core Standard. This has the advantage of locating the text within the main document, thus allowing the module to be accredited.

The Traded Goods module will remain voluntary and any site with applicable products may opt into these additional requirements to demonstrate to customers that good management practices are in place, relating to the traded goods.

As this now forms a section of the Standard, non-conformities against requirements of the Traded Goods module will be included in the assessment of the site's grade.

Communication with Certification Bodies

In addition to the reasons listed in Issue 7, sites must inform their certification body of:

- legal proceedings with respect to product safety, legality or issues which significantly affect the operation of the site
- enforcement by authorities related to product safety or legality (e.g. enforcement notices)
- any recalls or withdrawals since the last BRC audit that involved local or national authorities (EHO, FSA etc).

Auditor training

There is no change to auditor competence requirements.

All auditors will have to complete the mandatory training to Issue 8.