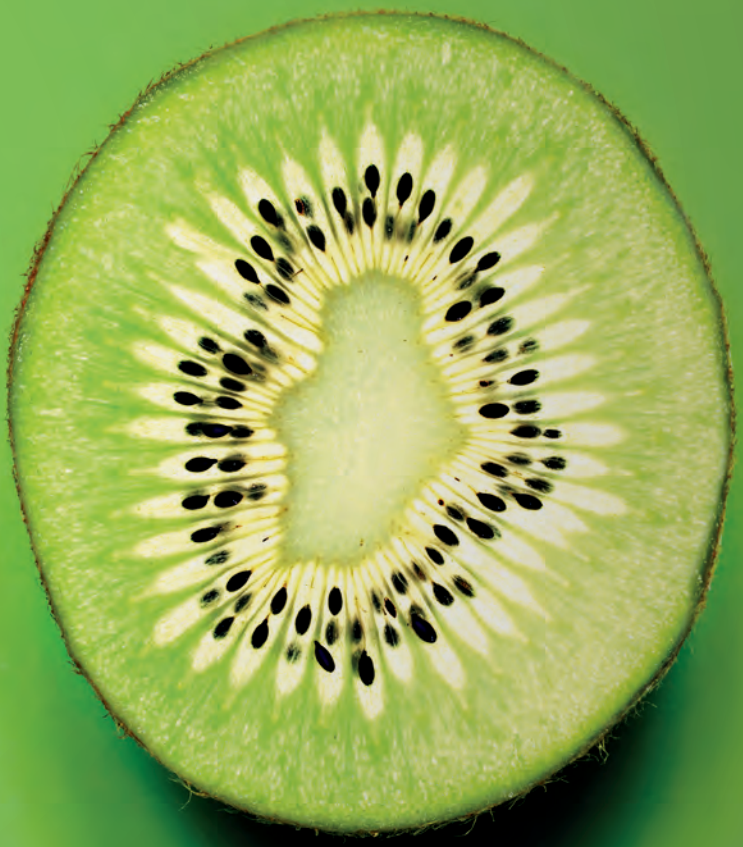
BRC GLOBAL STANDARDS

GLOBAL STANDARD

FOOD SAFETY



ISSUE 7

GLOBAL STANDARD

FOOD SAFETY

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ISSUE 7

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For more information about BRC, contact:

British Retail Consortium
Second Floor
21 Dartmouth Street
London
SW1H 9BP

Tel: +44 (0) 20 7854 8900
Fax: +44 (0) 20 7854 8901

Email: enquiries@brcglobalstandards.com
Website: www.brcglobalstandards.com

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HOW THIS PUBLICATION IS ORGANISED

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

The document consists of the following parts:

PART I
THE FOOD SAFETY MANAGEMENT SYSTEM

Provides an introduction and background to the development and benefits of the Standard.

PART II
REQUIREMENTS

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

PART III
AUDIT PROTOCOL

Provides information on the audit process and rules for the awarding of certificates. It details the different certification programmes available within the Standard as well as information on logos and the BRC Global Standards Directory.

PART IV
MANAGEMENT AND GOVERNANCE OF THE SCHEME

Describes the management and governance systems in place for the Standard and for the management of certification bodies registered to operate the scheme.

APPENDICES

The appendices provide other useful information including auditor competency requirements, product categories and a glossary of terms.

PART I
THE FOOD SAFETY MANAGEMENT SYSTEM

INTRODUCTION

THE FOOD SAFETY MANAGEMENT SYSTEM

PART I
THE FOOD SAFETY MANAGEMENT SYSTEM

INTRODUCTION

Welcome to the seventh issue of the Global Standard for Food Safety. Originally developed and published in 1998, the Standard has been updated at regular intervals since to reflect the latest thinking in food safety, and has now attained usage worldwide. The Standard provides a framework for food manufacturers to assist them in the production of safe food and to manage product quality to meet customers' requirements. Certification against the Standard is recognised by many retailers, food service companies and manufacturers around the world when assessing the capabilities of their suppliers. In response to demand, the Global Standard for Food Safety has been translated into many languages to facilitate implementation by food businesses across the world.

The Global Standard for Food Safety has been developed to specify the food safety, quality and operational criteria required to be in place within a food manufacturing organisation to fulfil obligations with regard to legal compliance and protection of the consumer. The format and content of the Standard is designed to allow an assessment of a company's premises, operational systems and procedures by a competent third party – the certification body – against the requirements of the Standard.

WHAT'S NEW FOR ISSUE 7?

The development of Issue 7 followed a wide consultation to understand stakeholders' requirements and a review of emerging issues in the food industry. The information 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.

The focus of attention for this issue has been on:

- continuing to ensure consistency of the audit process
- providing a Standard with the flexibility to include additional voluntary modules to reduce the audit burden
- encouraging sites to put systems in place to reduce their exposure to fraud
- encouraging greater transparency and traceability in the supply chain
- encouraging adoption of the Standard as a means of improving food safety in small sites and facilities where processes are still in development.

The requirements of the Issue 7 Standard are an evolution from previous issues with a continued emphasis on management commitment, a Hazard Analysis and Critical Control Point (HACCP)-based food safety programme and supporting quality management system. The objective has been to direct the focus of the audit towards the implementation of good manufacturing practices within the production areas with increased emphasis on areas which have traditionally resulted in recalls and withdrawals (e.g. label and packing management).

Voluntary unannounced programmes

There has been an increasing growth in unannounced audits among specifiers and this has been seen to provide a greater confidence in the implementation of a food safety culture. The two alternative options for unannounced audits developed in Issue 6 have been retained, although the restriction to Grade A and B sites has been lifted to enable the unannounced option to be available to all sites. The unannounced programmes remain voluntary but provide added confidence in certification to customers and create marketing benefits where sites achieve the top BRC grade of AA+.

BRC Global Markets programme

As the BRC certification Standard continues to develop it is important to provide opportunities to recognise and encourage the development of food safety systems in small sites where the full requirements of the Standard may add less value and in sites that are still developing food safety management systems. We have taken the opportunity to revise the former Enrolment Programme

and align this more closely with the Global Food Safety Initiative (GFSI) Global Markets programme. The new scheme will now enable audits and recognition against a set of requirements of the Standard identified as basic level and a further set of requirements at intermediate level.

Details of the new programmes can be found in the audit protocol of the Standard (see Part III).

Additional voluntary modules

Issue 7 has been developed to enable the incorporation of additional voluntary modules which sites can elect to include with the audit to meet particular customer or scheme needs. The BRC will continue to develop such modules and make these available on the website in response to market needs. It is expected that this flexibility will enable sites to meet regional or specific customer expectations and reduce the number of site audits.

THE SCOPE OF THE GLOBAL STANDARD FOR FOOD SAFETY

The Global Standard for Food Safety sets out the requirements for the manufacture of processed foods and the preparation of primary products supplied as retailer-branded products, branded food products and food or ingredients for use by food service companies, catering companies and food manufacturers. Certification will only apply to products that have been manufactured or prepared at the site where the audit has taken place and will include storage facilities that are under the direct control of the production-site management.

The Standard shall not apply to food products which do not undergo any process at the site audited or to activities relating to wholesale, importation, distribution or storage outside the direct control of the company. The BRC has developed a range of Global Standards setting out the requirements for the wide range of activities undertaken in the production, packaging, storage and distribution of food. Appendix 1 provides further details of the scopes of, and relationship between, the current Global Standards.

FOOD SAFETY LEGISLATION

The Standard has always been intended to assist sites and their customers to comply with legislative requirements for food safety. Legislation covering food safety differs in detail worldwide but generally requires food businesses to:

- undertake a HACCP or risk-based approach to the management of food safety
- provide a processing environment which ensures that the risks of product contamination are minimised
- ensure the presence of a detailed specification which is lawful and consistent with compositional and safety standards and good manufacturing practice
- ensure they satisfy themselves that their suppliers are competent to produce the specified product, comply with legal requirements and operate appropriate systems of process control
- make visits, from time to time and where practical, to verify the competence of their suppliers or receive the result of any other audit of the supplier's system for that purpose
- establish and maintain a risk-assessed programme for product examination, testing or analysis
- monitor and act upon customer complaints.

The Global Standard for Food Safety has been developed to assist businesses to meet these requirements.

BENEFITS OF THE GLOBAL STANDARD FOR FOOD SAFETY

Adoption of the Standard leads to a number of benefits to food businesses. The Standard:

- is internationally recognised and GFSI compliant and provides a report and certification that can be accepted by customers in place of their own audits, thus reducing time and cost
- provides a single standard and protocol that governs an accredited audit by third-party certification bodies, allowing a credible independent assessment of a company's food safety and quality systems
- enables certificated companies to appear in the publicly available part of the BRC Global Standards Directory, allowing recognition of their achievements and use of a logo for marketing purposes
- is comprehensive in scope, covering areas of quality, legality and product safety
- addresses part of the legislative requirements of the food manufacturer and their customers
- enables companies to ensure their suppliers are following good food safety management practices
- provides a range of audit options, including announced and unannounced audit programmes, to satisfy customer demands and enable companies to demonstrate compliance through a process which best suits their operation and the maturity of their food safety systems

- requires completion of corrective actions on non-conformity to the Standard and a root cause analysis to identify preventive controls before certification, thus reducing the need for customers to follow up audit reports.

THE CERTIFICATION PROCESS

The Global Standard for Food Safety is a process and product certification scheme. In this scheme, food businesses are certificated upon completion of a satisfactory audit by an auditor employed by an independent third party – the certification body. The certification body in turn shall have been assessed and judged as competent by a national accreditation body.

In order for a food business to receive a valid certificate on completion of a satisfactory audit, the organisation must select a certification body approved by the BRC. The BRC lays down detailed requirements that a certification body must satisfy in order to gain approval and operates a comprehensive compliance programme to ensure high standards are maintained.

EFFECTIVE DATE OF ISSUE 7

As with all revisions of the Global Standards, there must be recognition that a transition period is in place between publication and full implementation. This allows time for the retraining of all auditors and allows manufacturers to prepare for the new issue of the Standard. Therefore, certification against Issue 7 will commence from 1 July 2015. All certificates issued against audits carried out prior to 1 July 2015 will be against Issue 6 and be valid for the period specified on the certificate.

ACKNOWLEDGEMENTS: A 'THANK YOU' FROM THE BRC

The BRC wishes to acknowledge all those food industry experts who have contributed to the preparation of the Global Standard for Food Safety Issue 7 or provided invaluable feedback through the consultation process. All those who participated in the working groups are listed in Appendix 10.

THE FOOD SAFETY MANAGEMENT SYSTEM

PRINCIPLES OF THE GLOBAL STANDARD FOR FOOD SAFETY

A food business must have a full understanding of the products produced, manufactured and distributed, and have systems in place to identify and control hazards significant to the safety of food. The Global Standard for Food Safety is based on two key components: senior management commitment and a HACCP-based system (which provides a step-by-step approach to managing food safety risks).

Senior management commitment

Within a food business, food safety must be seen as a cross-functional responsibility that includes activities that draw on many departments, using different skills and levels of management expertise across the organisation. Effective food safety management extends beyond technical departments and must involve commitment from production operations, engineering, distribution management, procurement of raw materials, customer feedback and human resource activity such as training.

The starting point for an effective food safety plan is the commitment of senior management to the development of an all-encompassing policy as a means to guide the activities that collectively assure food safety. The Global Standard for Food Safety places a high priority on clear evidence of senior management commitment.

A HACCP-based system

The Global Standard for Food Safety requires the development of a food safety plan based on HACCP. The development of the plan requires the input of all relevant departments and must be supported by senior management.

THE EXPECTATION OF THE GLOBAL STANDARD FOR FOOD SAFETY

The Global Standard for Food Safety requires the development of and compliance with the following:

- **Senior management commitment** The resources required for demonstration of commitment to achieving the requirements of the Standard are detailed in Part II, section 1.
- **A HACCP plan** This provides a focus on the significant product and process food safety hazards that require specific control to assure the safety of individual food products or lines as detailed in Part II, section 2.
- **A quality management system** Details of the organisational and management policies and procedures that provide a framework by which the organisation will achieve the requirements in this Standard as given in Part II, section 3.
- **Prerequisite programmes** The basic environmental and operational conditions in a food business that are necessary for the production of safe food. These control generic hazards covering good manufacturing and good hygienic practice as detailed in Part II, sections 4–7.

PART II
REQUIREMENTS

HOW THE REQUIREMENTS ARE SET OUT

1 SENIOR MANAGEMENT COMMITMENT

2 THE FOOD SAFETY PLAN – HACCP

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 and must be complied with in order for a certificate to be issued.

COLOUR CODING OF REQUIREMENTS

There is a choice of audit protocols available for undertaking audits and certification against this Standard. Audits may be undertaken in a single visit (as either an unannounced or announced audit), or sites may opt for the split audit option, where the first part of the audit (part 1) is unannounced and concentrates on good manufacturing practices and there is a later, scheduled, announced audit (part 2) that reviews primarily records and procedures.

The audit requirements within the Standard have been colour coded to provide a guide as to which requirements would be expected to be covered on part 1 and part 2 audits where this audit option is selected. The colour coding also helps to identify the requirements that would usually be expected to be audited as part of the assessment of the production areas and facilities or would form part of such an audit trail initiated in the factory.

Key to colour coding of requirements

Requirements assessed on part 1 – audit of good manufacturing practice	
Requirements assessed on part 2 – 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.

1 SENIOR MANAGEMENT COMMITMENT

1.1 SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT

FUNDAMENTAL

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

CLAUSE	REQUIREMENTS
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe and legal 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 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.
1.1.3	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 1.1.2. 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 • customer complaints and results of any customer feedback • incidents, 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.
1.1.4	The site shall have a demonstrable meeting programme which enables food safety, legality and quality issues to be brought to the attention of senior management at least monthly and allows for the resolution of issues requiring immediate action.
1.1.5	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.
1.1.6	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.
1.1.7	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.
1.1.8	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.
1.1.9	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.

CLAUSE	REQUIREMENTS
1.1.10	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.

1.2 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.

CLAUSE	REQUIREMENTS
1.2.1	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, 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
The company shall have a fully implemented and effective food safety plan based on Codex Alimentarius HACCP principles.

2.1 THE HACCP FOOD SAFETY TEAM – CODEX ALIMENTARIUS STEP 1

CLAUSE	REQUIREMENTS
2.1.1	The HACCP plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for quality/technical, production operations, engineering and other relevant functions. The team leader shall have an in-depth knowledge of HACCP and be able to demonstrate competence and experience. The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated 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 plan, including the products and processes covered, shall be defined.

2.2 PREREQUISITE PROGRAMMES

CLAUSE	REQUIREMENTS
2.2.1	The site shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list: • cleaning and sanitising • 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.

2.3 DESCRIBE THE PRODUCT – CODEX ALIMENTARIUS STEP 2

CLAUSE	REQUIREMENTS
2.3.1	A full description for each product or group of products shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list: • composition (e.g. raw materials, ingredients, allergens, recipe) • origin of ingredients • physical or chemical properties that impact food safety (e.g. pH, a_w) • treatment and processing (e.g. cooking, cooling) • packaging system (e.g. modified atmosphere, vacuum) • storage and distribution conditions (e.g. chilled, ambient) • target safe shelf life under prescribed storage and usage conditions.

CLAUSE	REQUIREMENTS
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 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

CLAUSE	REQUIREMENTS
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

CLAUSE	REQUIREMENTS
2.5.1	A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP 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

CLAUSE	REQUIREMENTS
2.6.1	The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge at least annually. 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

CLAUSE	REQUIREMENTS
2.7.1	The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and allergen risks (refer to clause 5.3). It shall also take account of the preceding and following steps in the process chain.

CLAUSE	REQUIREMENTS
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

CLAUSE	REQUIREMENTS
2.8.1	For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. Critical control points (CCPs) shall be those control points which are required in order to prevent or eliminate a food safety hazard or reduce it to an acceptable level. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be modified at that step, or at an earlier step, to provide a control measure.

2.9 ESTABLISH CRITICAL LIMITS FOR EACH CCP – CODEX ALIMENTARIUS STEP 8, PRINCIPLE 3

CLAUSE	REQUIREMENTS
2.9.1	For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be: • measurable wherever possible (e.g. time, temperature, pH) • supported by clear guidance or examples where measures are subjective (e.g. photographs).
2.9.2	The HACCP food safety team shall validate each CCP. Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.

2.10 ESTABLISH A MONITORING SYSTEM FOR EACH CCP – CODEX ALIMENTARIUS STEP 9, PRINCIPLE 4

CLAUSE	REQUIREMENTS
2.10.1	A monitoring procedure shall be established for each CCP to ensure compliance with critical limits. The monitoring system shall be able to detect loss of control of CCPs and wherever possible provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list: • 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

CLAUSE	REQUIREMENTS
2.11.1	The HACCP food safety team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel with regard to any products that have been manufactured during the period when the process was out of control.

2.12 ESTABLISH VERIFICATION PROCEDURES – CODEX ALIMENTARIUS STEP 11, PRINCIPLE 6

CLAUSE	REQUIREMENTS
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 – CODEXALIMENTARIUS STEP 12, PRINCIPLE 7

CLAUSE	REQUIREMENTS
2.13.1	Documentation and record keeping shall be sufficient to enable the site to verify that the HACCP controls, including controls managed by prerequisite programmes, are in place and maintained.

2.14 REVIEW THE HACCP PLAN

CLAUSE	REQUIREMENTS
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 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) • 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 plan and/or prerequisite programmes, fully documented and validation recorded.

3 FOOD SAFETY AND QUALITY MANAGEMENT SYSTEM

3.1 FOOD SAFETY AND QUALITY MANUAL

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.

CLAUSE	REQUIREMENTS
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 DOCUMENTATION CONTROL

The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use.

CLAUSE	REQUIREMENTS
3.2.1	The company shall have a procedure to manage documents which form part of the food safety and quality system. This shall include: • a list of all controlled documents indicating the latest version number • the method for the identification and authorisation of controlled documents • a record of the reason for any changes or amendments to documents • the system for the replacement of existing documents when these are updated.

3.3 RECORD COMPLETION AND MAINTENANCE

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

CLAUSE	REQUIREMENTS
3.3.1	Records shall be legible, maintained in good condition and retrievable. Any alterations to records shall be authorised and justification for alteration shall be recorded. Where records are in electronic form these shall be suitably backed up to prevent loss.
3.3.2	Records shall be retained for a defined period with consideration given to: • any legal or customer requirements • the shelf life of the product. This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing). As a minimum, records shall be retained for the shelf life of the product plus 12 months.

3.4 INTERNAL AUDITS

FUNDAMENTAL
The company shall be able to demonstrate it verifies the effective application of the food safety plan and the implementation of the requirements of the Global Standard for Food Safety.

CLAUSE	REQUIREMENTS
3.4.1	There shall be a scheduled programme of internal audits throughout the year with a scope which covers the implementation of the HACCP programme, prerequisite programmes and procedures implemented to achieve this Standard. The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance; all activities shall be covered at least annually.
3.4.2	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be independent (i.e. 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 the results shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.
3.4.4	In addition to the internal audit programme there shall be a programme of documented inspections to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production. These inspections shall include: • 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

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.

CLAUSE	REQUIREMENTS
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 • substitution or fraud (see clause 5.4.2). 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.

CLAUSE	REQUIREMENTS
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: • certification (e.g. to BRC Global Standards or other GFSI-recognised scheme) • 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 or, for suppliers assessed as low risk only, supplier questionnaires. 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	Where raw materials are purchased from agents or brokers, the site shall know the identity of the last manufacturer or packer, or for bulk commodity products the consolidation place of the raw material. Information to enable the approval of the manufacturer, packer or consolidator, as in clause 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 BRC Global Standard for Agents and Brokers.
3.5.1.4	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 PROCEDURES

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.

CLAUSE	REQUIREMENTS
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.

3.5.3 MANAGEMENT OF SUPPLIERS OF SERVICES

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

CLAUSE	REQUIREMENTS
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 • laboratory testing • catering services • waste management.
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 OUTSOURCED PROCESSING AND PACKING

Where any process step in the manufacture or packing of a product which is included within the scope of certification is subcontracted 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.

CLAUSE	REQUIREMENTS
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 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.
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 have been outsourced, including visual, chemical and/or microbiological testing, dependent on risk assessment.

3.6 SPECIFICATIONS

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

CLAUSE	REQUIREMENTS
3.6.1	Specifications for raw materials and 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 shall include key data to meet customer and legal requirements and assist the user in the safe usage of the product.
3.6.3	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that 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.

3.7 CORRECTIVE AND PREVENTIVE ACTIONS

FUNDAMENTAL

The site shall be able to demonstrate that it uses the information from identified failures in the food safety and quality management system to make necessary corrections and prevent recurrence.

CLAUSE	REQUIREMENTS
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

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

CLAUSE	REQUIREMENTS
3.8.1	There shall be 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.

3.9 TRACEABILITY

FUNDAMENTAL

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.

CLAUSE	REQUIREMENTS
3.9.1	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.
3.9.2	The site shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material including primary packaging to finished product and vice versa, including quantity check/mass balance. This shall occur at a predetermined frequency, as a minimum annually, and results shall be retained for inspection. Full traceability should be achievable within 4 hours.
3.9.3	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

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

CLAUSE	REQUIREMENTS
3.10.1	All complaints shall be recorded, investigated and the results of the investigation of the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.
3.10.2	Complaint data shall be analysed for significant trends. Where there has been a significant increase in a complaint or a serious complaint, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.

3.11 MANAGEMENT OF INCIDENTS, PRODUCT WITHDRAWAL AND PRODUCT RECALL

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

CLAUSE	REQUIREMENTS
3.11.1	The company shall have 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. 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. 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

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.

CLAUSE	REQUIREMENTS
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

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

CLAUSE	REQUIREMENTS
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site (from potential contaminants, flooding etc.), they shall be reviewed in response to any changes.
4.1.2	The external areas shall be maintained in good order. Where buildings are surrounded by grassed or planted areas, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to avoid contamination of the product.
4.1.3	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).

4.2 SECURITY

Security systems shall ensure that products are protected from theft or malicious contamination while under the control of the site.

CLAUSE	REQUIREMENTS
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.
4.2.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.
4.2.3	External storage tanks, silos and any intake pipes with an external opening shall be locked.
4.2.4	Where required by legislation, the site shall be registered with, or be approved by, the appropriate authority.

4.3 LAYOUT, PRODUCT FLOW AND SEGREGATION

FUNDAMENTAL

The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with relevant legislation.

CLAUSE	REQUIREMENTS
4.3.1	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.
4.3.2	The site map(s) shall define: • access points for personnel • access points for raw materials (including packaging) • 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.
4.3.3	Contractors and visitors, including drivers, shall be made aware of all procedures for access to premises and the requirements of the areas they are visiting, with special reference to hazards and potential product contamination. Contractors working in product processing or storage areas shall be the responsibility of a nominated person.
4.3.4	The movement of personnel, raw materials, packaging, rework and/or waste shall not compromise the safety of products. The process flow, together with the use of demonstrably effective procedures, shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products.
4.3.5	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	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.

CLAUSE	REQUIREMENTS
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.
4.3.8	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.
4.3.9	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

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

CLAUSE	REQUIREMENTS
4.4.1	Walls shall be finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.
4.4.2	Floors shall be suitably hard wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious, be maintained in good repair and facilitate cleaning.
4.4.3	Drainage, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety. Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain. Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage.
4.4.4	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.
4.4.5	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.
4.4.6	Where suspended ceilings or roof voids are present, adequate access to the void shall be provided to facilitate inspection for pest activity, unless the void is fully sealed.
4.4.7	Where there is a risk to product, windows, and roof glazing which is designed to be opened for ventilation purposes, shall be adequately screened to prevent the ingress of pests.
4.4.8	Where they pose a risk to product, glass windows shall be protected against breakage.
4.4.9	Doors shall be maintained in good condition: • External doors and dock levellers shall be close fitting or adequately proofed. • External doors to open product areas shall not be opened during production periods except in emergencies. Where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.
4.4.10	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.

CLAUSE	REQUIREMENTS
4.4.11	Where they constitute a risk to product, bulbs and strip lights – including those on electric fly-killer devices – shall be adequately protected. Where full protection cannot be provided, alternative management such as wire-mesh screens or monitoring procedures shall be in place.
4.4.12	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.
4.4.13	High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.

4.5 UTILITIES – WATER, ICE, AIR AND OTHER GASES

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

CLAUSE	REQUIREMENTS
4.5.1	All water 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, other gases and steam used directly in contact with, or as an ingredient in, products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.

4.6 EQUIPMENT

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

CLAUSE	REQUIREMENTS
4.6.1	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.
4.6.2	Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.

4.7 MAINTENANCE

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

CLAUSE	REQUIREMENTS
4.7.1	There shall be a 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, which records that product contamination hazards have been removed from machinery and equipment.
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.
4.7.6	Materials used for equipment and plant maintenance and that pose a risk by direct or indirect contact with raw materials, intermediate and finished products, such as lubricating oil, shall be food grade and of a known allergen status.
4.7.7	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

Staff facilities shall be sufficient to accommodate the required number of personnel, and shall be designed and operated to minimise the risk of product contamination. The facilities shall be maintained in good and clean condition.

CLAUSE	REQUIREMENTS
4.8.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear).
4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material handling, preparation, processing, packing and storage areas.
4.8.3	Outdoor clothing and other personal items shall be stored separately from production clothing within the changing facilities. Facilities shall be available to separate clean and dirty production clothing.

CLAUSE	REQUIREMENTS
4.8.4	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	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.
4.8.6	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.
4.8.7	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.

CLAUSE	REQUIREMENTS
4.8.8	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations. Electronic cigarettes shall not be permitted to be used or brought into production or storage areas.
4.8.9	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.
4.8.10	Where catering facilities are provided on the premises, they shall be suitably controlled to prevent contamination of 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

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

4.9.1 CHEMICAL CONTROL

CLAUSE	REQUIREMENTS
4.9.1.1	Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include as a minimum: • an approved list of chemicals for purchase • availability of material safety data sheets and specifications • confirmation of suitability for use in a food-processing environment • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • a designated storage area 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

CLAUSE	REQUIREMENTS
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

CLAUSE	REQUIREMENTS
4.9.3.1	Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination.
4.9.3.2	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: • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising to continue production • changing of workwear and inspection of footwear • specifying those staff authorised to carry out the above points • recording the breakage incident.

4.9.4 PRODUCTS PACKED INTO GLASS OR OTHER BRITTLE CONTAINERS

CLAUSE	REQUIREMENTS
4.9.4.1	The storage of the containers shall be segregated from the storage of raw materials, product or other packaging.
4.9.4.2	Systems shall be in place to manage container breakages between the container cleaning/inspection point and container closure. This shall include, 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

CLAUSE	REQUIREMENTS
4.9.5.1	Wood should not be used in open product areas except where this is a process requirement (e.g. maturation of products in wood). Where the use of wood cannot be avoided, the condition of wood shall be continually monitored to ensure it is in good condition and free from damage or splinters which could contaminate products.

4.10 FOREIGN-BODY DETECTION AND REMOVAL EQUIPMENT

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

CLAUSE	REQUIREMENTS
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	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.
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

CLAUSE	REQUIREMENTS
4.10.2.1	Filters and sieves used for foreign-body control shall be of a specified mesh size or gauge and designed to provide the maximum practical protection for the product. 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

CLAUSE	REQUIREMENTS
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).

CLAUSE	REQUIREMENTS
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 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.
4.10.3.5	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

CLAUSE	REQUIREMENTS
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

CLAUSE	REQUIREMENTS
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

CLAUSE	REQUIREMENTS
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

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.

CLAUSE	REQUIREMENTS
4.11.1	The premises and equipment shall be maintained in a clean and hygienic condition.
4.11.2	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	As a minimum for food contact surfaces, processing equipment and for environmental cleaning in high-care/high-risk areas, limits of acceptable and unacceptable cleaning performance shall be defined. This shall be based on the potential hazards (e.g. microbiological, allergen, foreign-body contamination or product-to-product contamination). Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing or chemical testing as appropriate. 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.

CLAUSE	REQUIREMENTS
4.11.6	Cleaning equipment shall be: • hygienically designed and fit for purpose • suitably identified for intended use (e.g. colour coded or labelled) • cleaned and stored in a hygienic manner to prevent contamination. 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)

CLAUSE	REQUIREMENTS
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.
4.11.7.3	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.

4.12 WASTE/WASTE DISPOSAL

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

CLAUSE	REQUIREMENTS
4.12.1	Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and records of removal shall be maintained and available for audit.

CLAUSE	REQUIREMENTS
4.12.2	External waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: • clearly identified • designed for ease of use and effective cleaning • well maintained to allow cleaning and, where required, disinfection • emptied at appropriate frequencies • covered or doors kept closed as appropriate.
4.12.3	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

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

CLAUSE	REQUIREMENTS
4.13.1	Surplus customer-branded products shall be disposed of in accordance with customer-specific requirements. Customer brand names shall be removed from packed surplus products under the control of the factory before the product enters the supply chain unless 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

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

CLAUSE	REQUIREMENTS
4.14.1	If pest activity is identified it shall not present a risk of contamination to products, raw materials or packaging. The presence of any infestation on site shall be identified in pest control records and be part of an effective pest management 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 organisation, or shall have appropriately trained staff, for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. Where the services of a pest control contractor are employed, the service scope shall be clearly defined and reflect the activities of the site.

CLAUSE	REQUIREMENTS
4.14.3	Where a site undertakes its own pest control, it shall be able to effectively demonstrate that: • pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • 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 • dedicated locked facilities are used for the storage of pesticides.
4.14.4	Pest control 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 device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and for the contractor • details of pest control products used, including instructions for their effective use and action to be taken in case of emergencies • any observed pest activity • details of pest control treatments undertaken.
4.14.5	Bait stations or other rodent 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 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	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.
4.14.8	Records of pest control 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.
4.14.9	An in-depth, documented pest control 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 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.
4.14.10	Results of pest control 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 devices to identify problem areas. The analysis shall be used as a basis for improving the pest control procedures.
4.14.11	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

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

CLAUSE	REQUIREMENTS
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, 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

Procedures shall be in place to ensure that the management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety, security or quality of the products.

CLAUSE	REQUIREMENTS
4.16.1	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 • 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.

CLAUSE	REQUIREMENTS
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. 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 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

Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced.

CLAUSE	REQUIREMENTS
5.1.1	The company shall 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	Shelf-life trials shall be undertaken using documented protocols reflecting conditions experienced during storage, transport and handling. Results shall be recorded and retained and shall confirm compliance with relevant microbiological, chemical and organoleptic criteria. Where shelf-life trials prior to production are impractical, for instance for some long-life products, a documented science-based justification for the assigned shelf life shall be produced.

5.2 PRODUCT LABELLING

Product labelling shall comply with the appropriate legal requirements and contain information to enable the safe handling, display, storage and preparation of the product within the food supply chain or by the customer.

CLAUSE	REQUIREMENTS
5.2.1	All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer. There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe and ingredient specifications.
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.

5.3 MANAGEMENT OF ALLERGENS

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 sale.

CLAUSE	REQUIREMENTS
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 through the process flow • assessment of the risk of allergen cross-contamination at each process step • identification of suitable controls to reduce or eliminate the risk of cross-contamination.
5.3.4	Documented procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination into products not containing the allergen. This shall include as appropriate: • 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 the nature of the production process is such that cross-contamination 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 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

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

CLAUSE	REQUIREMENTS
5.4.1	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 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

Product packaging shall be appropriate for the intended use and shall be stored under conditions to prevent contamination and minimise deterioration.

CLAUSE	REQUIREMENTS
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) 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 and resistant to tearing to prevent accidental contamination.

5.6 PRODUCT INSPECTION AND LABORATORY TESTING

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

5.6.1 PRODUCT INSPECTION AND TESTING

CLAUSE	REQUIREMENTS
5.6.1.1	There shall be a scheduled programme of testing covering products and the processing environment, which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, frequency and specified limits shall be documented.
5.6.1.2	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 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

CLAUSE	REQUIREMENTS
5.6.2.1	Pathogen 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.

CLAUSE	REQUIREMENTS
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.

5.7 PRODUCT RELEASE

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

CLAUSE	REQUIREMENTS
5.7.1	Where products require positive release, procedures shall be in place to ensure that release does not occur until all release criteria have been completed and release authorised.

6 PROCESS CONTROL

6.1 CONTROL OF OPERATIONS

FUNDAMENTAL
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.

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

CLAUSE	REQUIREMENTS
6.2.1	There shall be a formal process for the allocation of packaging materials to packing lines and control in the packing area which ensures that only the packaging for immediate use is available to the packaging machines. Where off-line coding or printing of packaging materials occurs, checks shall be in place that only correctly printed material is available at the packaging machines.

CLAUSE	REQUIREMENTS
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 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.
6.2.4	Where on-line vision equipment is used to check product labels and printing, procedures shall be in place to ensure that the system is correctly set up and capable of alerting or rejecting product when packaging information is out of specification.

6.3 QUANTITY – WEIGHT, VOLUME AND NUMBER CONTROL

The site shall operate a quantity control system which conforms to legal requirements in the country where the product is sold and any additional industry sector codes or specified customer requirements.

CLAUSE	REQUIREMENTS
6.3.1	The frequency and methodology of quantity checking shall meet the requirements of 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.

6.4 CALIBRATION AND CONTROL OF MEASURING AND MONITORING DEVICES

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

CLAUSE	REQUIREMENTS
6.4.1	The site shall identify and control measuring equipment used to monitor critical control points, 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
The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.

CLAUSE	REQUIREMENTS
7.1.1	All relevant personnel, including agency-supplied staff, temporary staff and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.
7.1.2	Where personnel are engaged in activities relating to critical control points, relevant training and competency assessment shall be in place.
7.1.3	The site shall put in place documented programmes covering the training needs of relevant personnel. These shall include 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. 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

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

CLAUSE	REQUIREMENTS
7.2.1	The requirements for personal hygiene shall be documented and communicated to all personnel. 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 • 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

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.

CLAUSE	REQUIREMENTS
7.3.1	The site shall make employees aware of the symptoms of infection, disease or condition which would prevent a person working with open food. The site shall have a procedure which enables notification by employees, including temporary employees, 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

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

CLAUSE	REQUIREMENTS
7.4.1	The company shall document and communicate to all employees (including agency and temporary personnel), contractors or visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. 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	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	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.
7.4.5	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.
7.4.6	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.
7.4.7	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.

PART III
AUDIT PROTOCOL

INTRODUCTION

1 GENERAL PROTOCOL – AUDIT PREPARATION

2 ANNOUNCED AUDIT PROTOCOL

PART III
AUDIT PROTOCOL

INTRODUCTION

The Global Standard for Food Safety provides companies with a series of options with which to be audited and certificated. This flexible approach is in response to market demand and allows companies to choose an audit option which best suits their customers' requirements, factory operations and the maturity of their food safety systems.

The general audit protocol describes the requirements for auditing and certification which are applicable to all of the audit programmes. This should be read and fully understood. The process is summarised in Figure 1.

Each of the audit options has its own particular characteristics and these are described in detail in sections 2–6 of this part (Part III). Section 7 sets out the process and marketing opportunities for all sites after certification.

Every effort has been made to ensure that the content of this audit protocol is accurate at the time of publication. However, it may be subject to minor change, and reference should be made to the BRC Global Standards website (**www.brcglobalstandards.com**), where changes will be published.

Conformance by the company to the requirements of the Global Standard for Food Safety and its suitability for the awarding and continuing retention of certification will be assessed by an independent audit company – the certification body. Certification will be graded according to the audit option selected and the number and type of non-conformities, which shall also influence the frequency of ongoing audits. This part describes the process to be followed by a company seeking certification.

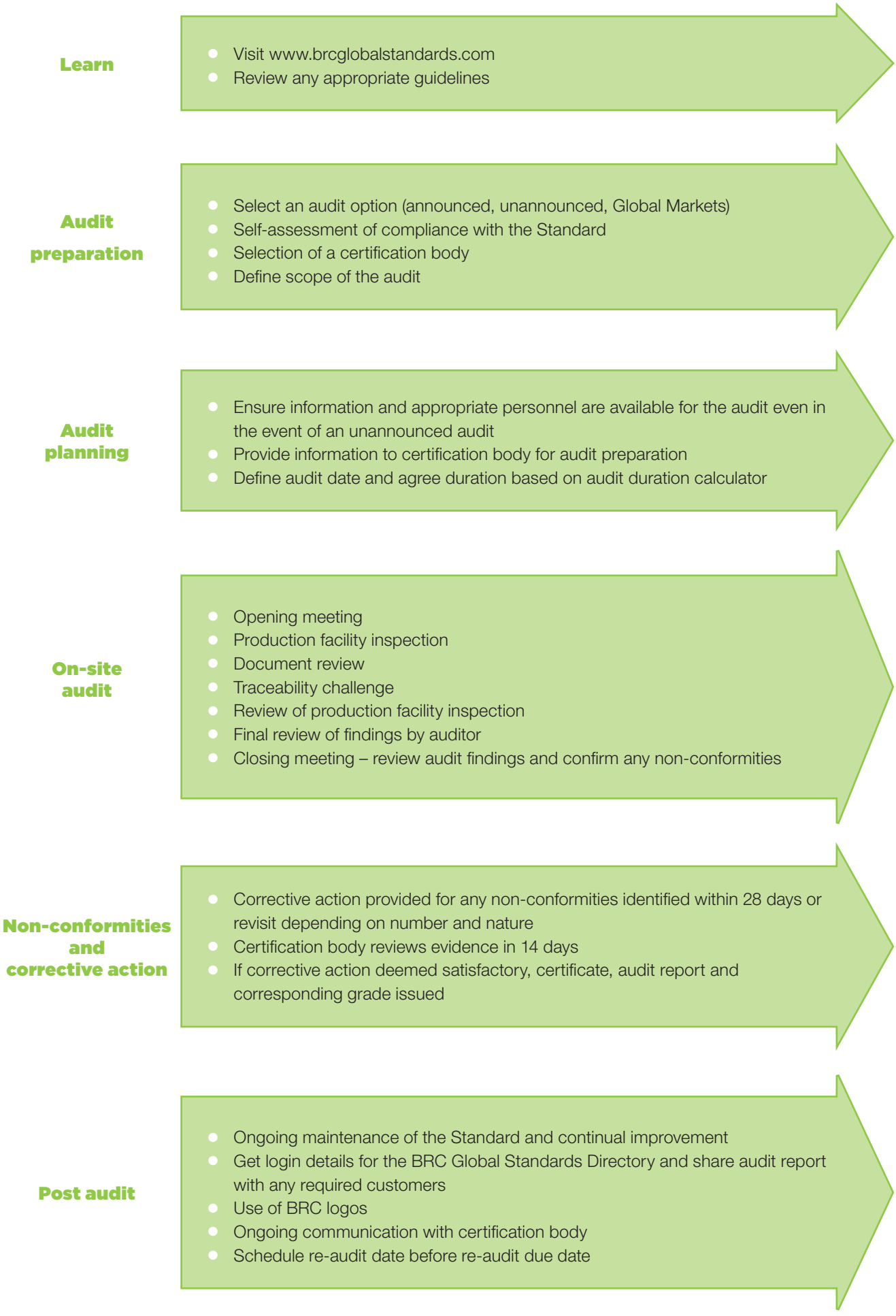


FIGURE 1 AUDIT PROTOCOL – HOW TO GAIN CERTIFICATION

1 GENERAL PROTOCOL – AUDIT PREPARATION

1.1 SELECTION OF AN AUDIT OPTION

There are a number of options and processes available for sites to demonstrate their commitment to the Global Standard for Food Safety.

1.1.1 Announced audit programme

This is available for existing certificated sites and those new to certification. The audit date is agreed with the certification body in advance of the audit and all requirements of the Standard are audited within the audit visit.

Successful sites are awarded a certificate with the grade of AA, A, B, C or D depending on the number and type of non-conformities identified.

More details on the announced audit programme can be found in Part III, section 2.

1.1.2 Unannounced audit programme

The unannounced audit options are available to all sites although sites which are not currently certificated need to recognise that the audit may not take place for up to 1 year from the date of application. The unannounced audit options provide sites with the opportunity to demonstrate the maturity of their quality systems and successful sites are awarded grades of AA+, A+, B+, C+ or D+ depending upon the type and number of non-conformities identified at the audit.

The conducting of an independent, unannounced review of the production facilities, systems and procedures under this scheme provides a site's customers with added confidence in the site's ability to consistently maintain standards. This may influence the frequency of customer audits, where conducted, and other performance measures applied by the customer.

There are two options for unannounced audits, which allow companies to decide the one best suited to their business requirements; the grading and reporting for each is the same. For option 1, the whole Standard is audited on a single unannounced audit visit, typically lasting 2–3 days.

For option 2, the audit visit is split into two separate visits, each typically lasting 1–2 days. The first visit, which is unannounced, audits predominantly factory good manufacturing practices, as highlighted by the colour-coding system in the Standard requirements. The second part of the audit, which is planned, looks predominantly at the documented systems and records. This approach allows companies to ensure that appropriate managers are available to assist with the audit of documentation.

The unannounced audit process for options 1 and 2 is summarised in Figure 2. More details on the unannounced audit programme can be found in Part III, sections 3 and 4.

1.1.3 BRC Global Markets programme

This three-step programme is modelled on the GFSI Global Markets programme and is most suitable for companies that are new to the Standard and are in the process of developing their food safety systems. It is recognised that many sites need a little time to develop their food safety systems and culture to meet the full BRC certification requirements.

The programme is also applicable to some very small sites, particularly where the full requirements for certification may not always be practical or add value to the business.

The programme allows sites to be audited against specific requirements of the BRC Global Standard identified as basic-level or intermediate-level food safety requirements and attain recognition at basic or intermediate levels before progressing eventually to full certification. This allows sites to develop their food safety management processes in a progressive way and demonstrate their commitment to their customers.

Registration for the programme is carried out by the certification body with the BRC on behalf of the site and enables access to information provided by the BRC on the standards. The audit at the appropriate level is undertaken at a date agreed with the certification body and the attainment of a particular level recognised in the BRC Global Standards Directory.

More details on the BRC Global Markets programme can be found in Part III, section 5.

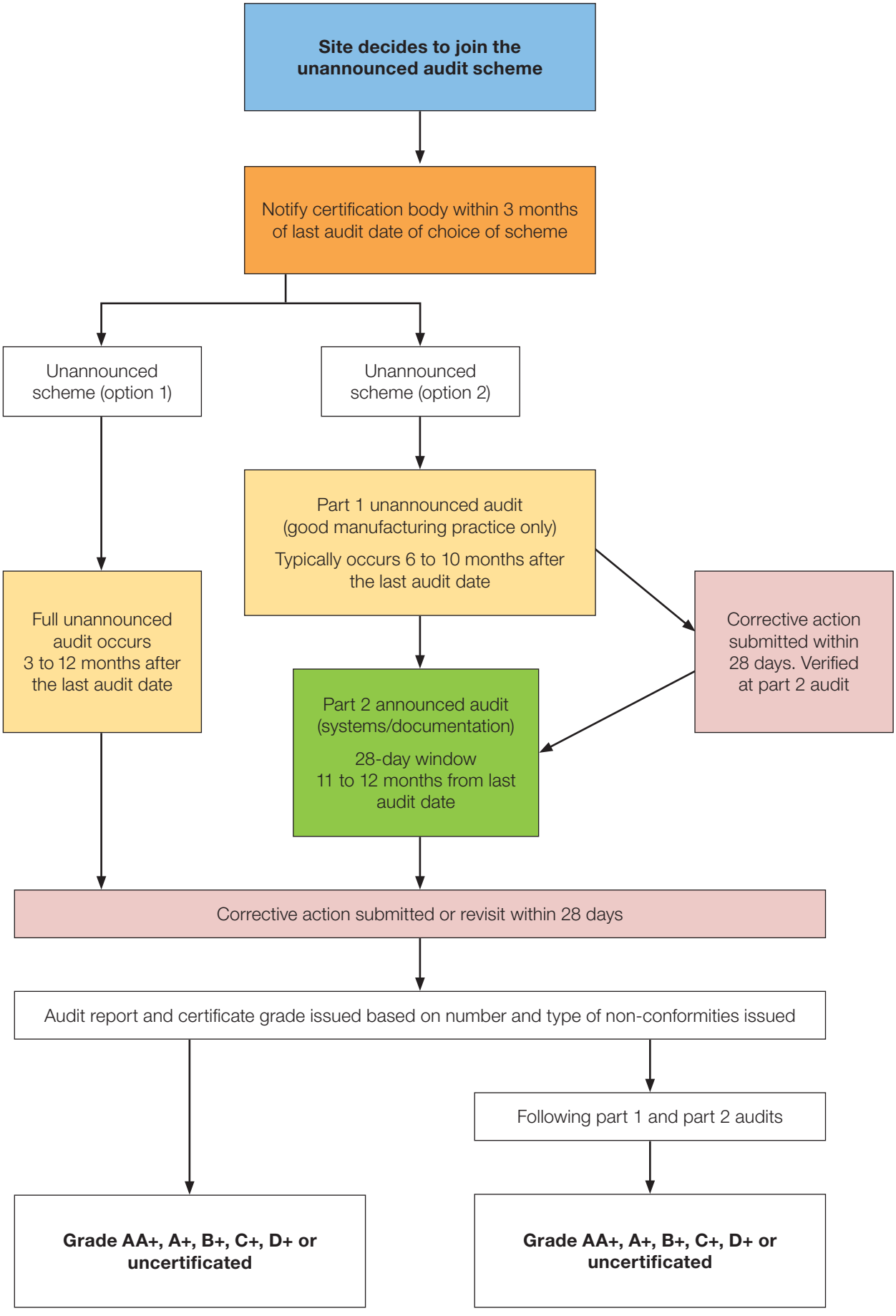


FIGURE 2 THE UNANNOUNCED AUDIT PROCESS

1.2 SELF-ASSESSMENT OF COMPLIANCE WITH THE STANDARD

It is essential that the site is assessed against the current issue of the Standard; this can be checked on the BRC Global Standards website (**www.brcglobalstandards.com**).

The Standard should be read and understood and a preliminary self-assessment should be conducted by the company against the Standard to prepare for the audit. Any areas of non-conformity should be addressed by the site.

Further information, guidance and training to ensure compliance with the Standard, including a downloadable self-assessment tool, is available at **www.brcglobalstandards.com**. The BRC also has a full range of further guidelines and supporting materials available through the BRC website and via the BRC Participate subscription service.

An optional on-site pre-assessment may be carried out by the selected certification body in preparation for the audit to provide guidance to the site on the process of certification. It should be noted, however, that under the rules for accredited certification, consultancy cannot be provided during any pre-assessment offered by the certification body that will later undertake the certification audit.

Manufacturing units that are newly built or 'commissioned' must ensure that systems and procedures in place are compliant before an initial BRC audit is undertaken. It is at the discretion of the company when they wish to invite a certification body to carry out an audit; however, it is unlikely that full compliance can be satisfactorily demonstrated at an audit undertaken less than 3 months from commencement of operation. This is likely to be the situation even where the site for certification uses quality systems developed by other certificated companies in the group.

1.3 SELECTION OF A CERTIFICATION BODY

Audits against the BRC Global Standards are only recognised if these are undertaken by certification bodies that are recognised and approved by the BRC. The BRC cannot advise on the selection of a specific certification body; however, the BRC has a comprehensive programme of measurement of certification body performance around specified key performance indicators (KPIs), the results of which are converted to a 5-star rating and published with the listing of all BRC-approved certification bodies on **www.brcdirectory.com**.

1.4 COMPANY/CERTIFICATION BODY CONTRACTUAL ARRANGEMENTS

A contract shall exist between the company and the certification body in accordance with the requirements of ISO/IEC 17065, detailing the scope of the audit and the reporting requirements. The contract shall also contain clauses which allow the effective management of the scheme by the BRC and accreditation of the certification body by their accreditation body. These are essential to ensure confidence in the way in which the scheme is managed and consistency achieved, which benefits all certificated sites. In particular it is a condition of certification to the scheme that:

- A copy of the audit report and any subsequent certificate or audit result shall be supplied to the BRC and may be supplied to the accreditation body in the agreed format for the BRC Global Standard used. Other documents in relation to the audit shall be made available to the BRC upon request. All documents submitted to the BRC shall be copies of original documents. Documents provided to the BRC will be treated as confidential.
- The auditor(s) may be accompanied by other personnel for training, assessment or calibration purposes. This activity may include:
  - training of new auditors by the certification body
  - routine certification body shadow audit programmes
  - witness audits by accreditation bodies
  - witness audits by the BRC.

The BRC reserves the right to conduct its own audit or visit to a site once certificated in response to complaints or as part of the routine BRC compliance activity to ensure the integrity of the scheme. Such visits may be announced or unannounced.

The BRC may contact the site directly in relation to its certification status or for feedback on certification body performance, or investigation into reported issues.

This publication sets out the requirements for sites that want to apply to be audited against the Standard and for sites issued with a certificate. Contracts between the certification body and the site shall include a clause acknowledging these obligations. This contract will be formulated by the certification body.

Non-compliance with any of these contractual obligations may affect the status of certification of the site.

1.5 REGISTRATION FEE

The BRC will require a registration fee to be collected by the certification body from the company for every audit undertaken. The certificate and audit report shall not be valid until the registration fee and the certification body's audit fees have been received, irrespective of the outcome of the certification process.

1.6 SCOPE OF AUDIT

1.6.1 Defining the audit scope

The scope of the audit – products produced and manufacturing processes – shall be agreed between the site and the certification body in advance of the audit to ensure the allocation of auditor(s) with the correct category and product knowledge.

The audit shall include all applicable requirements within the Standard and all production processes undertaken for the products included within the scope at the site seeking certification.

The audit scope and any permitted exclusions shall be clearly defined both on the audit report and on any certificate issued. The wording of the scope will be verified by the auditor during the site audit. The wording of the scope, of the product groups and, where applicable, the packaging format, shall enable a recipient of the report or certificate to clearly identify whether the products supplied have been included within the scope. This shall include a description of processing activities undertaken at the site that fall within the scope of this Standard, where this adds clarity for the user of the report or certificate (e.g. the slicing and packing of cooked meats).

1.6.2 Exclusions from scope

The fulfilment of the certification criteria relies on clear commitment from the site management to adopt the best practice principles outlined within the Standard and to the development of a food safety culture within the business. It follows therefore that the exclusion of products from the scope of certification shall only be permitted by exception.

The BRC logo can only be used by sites that have no exclusions.

The exclusion of products produced at a site will only be acceptable where:

- the excluded products can be clearly differentiated from products within scope

AND

- the products are produced in a physically segregated area of the factory.

Where exclusions are requested these shall be agreed with the certification body in advance of the audit. Exclusions shall be clearly stated on the audit report and certificate and the justification recorded on the audit report.

The certification of products must include audit of the entire process from raw material to end-product dispatch. It is not possible to exclude either parts of the process undertaken at the site or parts of the Standard. Where exclusions are accepted, the auditor(s) shall assess any hazards presented by excluded areas or products (e.g. the introduction of allergens or foreign-body risks) and non-conformities may be raised relating to the excluded area where this poses a risk to the products within the audit scope.

1.6.3 Additional manufacturing locations and head office assessments

The audit scope is expected to be site specific. There are, however, exceptional circumstances where the activities are undertaken at more than one location and where these can be included within a single report and certificate. This includes:

- the audit of a head office to review procedures controlled from head office
- the audit of more than one location where a single production process is carried out across two sites.

The detailed requirements for acceptance and management of such circumstances within the audit protocol are provided in Appendix 4.

1.6.4 Storage facilities – off-site

While the storage facilities on the same site as the production facility shall always be included within the audit of the site, it is not uncommon for sites to also own additional off-site storage facilities. Where additional storage facilities are owned and managed by the company in the vicinity of the production site (i.e. within a radius of 50 km), these shall be identified on the audit report and either audited as part of the site audit or specifically excluded.

1.6.5 Additional voluntary modules

In addition to the core Standard the BRC will develop a range of additional voluntary modules which may apply only to particular types of operation (e.g. sites trading goods) or may look in greater depth at a particular market concern (e.g. food defence or chain of custody). Where such voluntary modules are undertaken these will be listed on the scope of the report and certificate. If a voluntary module that is applicable to a site is not selected (such as traded goods), this shall be identified as an exclusion to ensure this is clear to the reader of the report or certificate.

A list of voluntary modules is available on the BRC Global Standards website (**www.brcglobalstandards.com**).

1.7 AUDITOR(S) SELECTION

It is the responsibility of the site to ensure that adequate and accurate information is given to the certification body, detailing the products it manufactures and the process technologies it uses, to enable the certification body to select an appropriate audit team with the required skills to undertake the audit. Auditors must be skilled to audit in the relevant product category, as listed in Appendix 6.

The certification body, auditors and the site must be aware of the need to avoid conflict of interest when arranging for an auditor(s) to visit the site. The site may decline the services of a particular auditor offered by the certification body. The same auditor is not permitted to undertake audits on more than three consecutive occasions at the same site.

Where the audit is not being carried out by the auditor(s) in the native language of the site, an appropriate translator shall be provided having knowledge of the technical terms used during the audit.

2 ANNOUNCED AUDIT PROTOCOL

2.1 AUDIT PLANNING

2.1.1 Preparation by the company

For initial audits the site shall agree a mutually convenient date, with due consideration given to the amount of work required to meet the requirements of the Standard.

There is a requirement on the site to be prepared for the audit, to have appropriate documentation for the auditor(s) to assess and to have appropriate staff available at all times during the on-site audit.

The site shall ensure that the production programme at the time of the audit covers products for the intended scope of the certification. Where possible, the widest range of these products shall be in production for the auditor(s) to assess. Where the product range is large or diverse, the auditor(s) has the discretion to continue the audit until sufficiently satisfied that the intended scope of the certification has been assessed. Where a significant production process is undertaken only during a different period of the year from the audit, a separate audit will be required to assess that production method.

2.1.2 Information to be provided to the certification body for audit preparation

The site shall supply the certification body with background information prior to the audit day to ensure the auditor(s) is fully prepared and to provide the best opportunity for the audit to be completed efficiently. The information will be requested by the certification body and may include but is not limited to:

- a summary of critical control points (CCPs)
- the process flow diagram
- a simple site plan
- the management organisational chart
- the list of products or product groups included within the audit scope
- typical shift patterns
- production schedules, to allow audits to cover relevant processes (e.g. night-time manufacture or where production processes are not carried out each day)
- recent quality issues, withdrawals or customer complaints and other relevant performance data.

The site shall make the previous year's audit report and certificate available to the certification body, where this is a contract with a new certification body.

2.1.3 Duration of the audit

Before the audit takes place, the certification body shall indicate the approximate duration of the audit. The typical duration of an audit is 2 to 3 days (8 hours/day) at the site. A calculator has been developed to assess the expected time required to undertake the audit of any particular site to ensure consistency and this shall be used as the basis for calculating the total audit duration. Full details can be found on the BRC Global Standards website (**www.brcglobalstandards.com**).

The calculation for the audit duration is based on:

- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of HACCP studies included within scope – a HACCP study corresponds to a family of products with similar hazards and similar production technology for the purpose of the calculator.

It is recognised that other factors may also influence the calculation but are considered to be less significant and therefore shall not influence the audit duration by more than 30% from the total calculated audit time. These factors include:

- the complexity of the manufacturing process
- the number of product lines
- the age of site and impact on material flow
- the labour-intensity of processes
- communication difficulties (e.g. language)
- the number of non-conformities recorded in the previous audit
- difficulties experienced during the audit requiring further investigation
- the quality of site preparation (e.g. documentation, HACCP, quality management systems).

If additional storage facilities, locations or head office assessments are included within the audit process (see Appendix 4) then additional time shall be allocated for this over and above that indicated in the audit calculator.

In the event that the audit against this Standard includes voluntary BRC modules or is intended to be combined with other audit Standards, the total audit time will need to be appropriately extended. Details of combined audits shall be specified on the audit report.

The calculation for audit duration shall determine the amount of time to be expected to undertake the audit at the site. Additional time will be required for the review of any documentary evidence provided and completion of the final audit report.

Deviation from the calculated audit timeframe must be justified and specified on the audit report.

2.2 THE ON-SITE AUDIT

The on-site audit consists of the following seven stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, including observing product changeover procedures, and interview of personnel.
- Document review – a review of the documented HACCP and quality management systems.
- Traceability challenge – including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications). This is a vertical audit – as specified within the BRC guidance document on audit techniques.
- Review of production facility inspection – to verify and conduct further documentation checks.
- Final review of findings by the auditor(s) – preparation for the closing meeting.
- Closing meeting – to review audit findings with the site. (Note that non-conformities are subject to subsequent independent verification by the certification body management.)

The site shall fully assist the auditor(s) at all times. It is expected that at the opening and closing meetings those attending on behalf of the site will be senior managers who have the appropriate authority to ensure that corrective action can be progressed if non-conformities are found. The most senior operations manager on site at the time of the audit or their nominated deputy shall be available at the audit and attend the opening and closing meetings.

The audit process gives emphasis to the practical implementation of food safety procedures and general good manufacturing practices. It is expected that approximately 50% of the audit will be spent auditing production and site facilities, interviewing staff, observing processes and reviewing documentation in production areas with the relevant staff.

During the audit, detailed notes shall be made regarding the site's conformities and non-conformities against the Standard and these will be used as the basis for the audit report. The auditor(s) shall assess the nature and severity of any non-conformity and shall discuss this with the accompanying manager at the time.

At the closing meeting, the auditor(s) shall present their findings and reconfirm all non-conformities that have been identified during the audit, but shall not make comment on the likely outcome of the certification process. Information on the process and timescales for the site to provide evidence to the auditor(s) of the corrective action to close non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor(s) either at the closing meeting or within one working day after completion of the audit.

At the closing meeting the auditor(s) shall provide the site with an explanation of the BRC Global Standards Directory, which allows secure access to audit data to both the client and their nominated customers, together with the feedback systems available to communicate with the certification body and with the BRC.

The decision to award certification and the grade of the certificate will be determined independently by the certification body management, following a technical review of the audit report and the closing of non-conformities in the appropriate timeframe. The company will be informed of the certification decision following this review.

2.3 NON-CONFORMITIES AND CORRECTIVE ACTION

The level of non-conformity assigned by an auditor against a requirement of the Standard is an objective judgement with respect to severity and risk and is based on evidence collected and observations made during the audit. This is verified by the certification body management.

2.3.1 Non-conformities

There are three levels of non-conformity:

- **Critical** Where there is a critical failure to comply with a food safety or legal issue.
- **Major** Where there is a substantial failure to meet the requirements of a 'statement of intent' or any clause of the Standard or a situation is identified which would, on the basis of available objective evidence, raise significant doubt as to the conformity of the product being supplied.
- **Minor** Where a clause has not been fully met but, on the basis of objective evidence, the conformity of the product is not in doubt.

The objective of the audit is to provide a true reflection of the standard of the operation and level of conformity against the Global Standard for Food Safety. Consideration should therefore be given to awarding a single major non-conformity where minor non-conformities are repeatedly raised against a particular clause of the Standard. Clustering of a significant number of minor non-conformities against a clause and recording this as a single minor non-conformity is not permitted. The certification body shall justify a high number (more than 20) of minor non-conformities where no more than one major non-conformity is given. This shall be detailed on the audit report.

2.3.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities during the audit, the site must undertake corrective action to remedy the immediate issue (correction) and to undertake an analysis of the underlying cause of the non-conformity (root cause) and develop a preventive action plan to address the root cause and prevent recurrence.

The process for 'closing out' non-conformities depends upon the level of non-conformity and the numbers of non-conformities identified.

Critical non-conformities or a combination of non-conformities resulting in non-certification

In some circumstances the number or severity of non-conformities raised at the audit prevents the site from being certificated following that audit. This will be the case where:

- a critical non-conformity is raised and/or
- a major non-conformity against the statement of intent of a fundamental clause is raised and/or
- the number or type of non-conformities exceeds the limits for certification, as per Table 1.

The grading of non-conformities will be reviewed by the independent certification process of the certification body as soon as possible after the audit. Where the review confirms that a certificate cannot be awarded, the site will be required to undertake another full audit before assessment for certification.

Due to the nature and number of non-conformities, it is unlikely that these non-conformities can be addressed and fully effective improvements implemented and established within a 28 day period – although there may be some exceptions. Therefore, the re-audit shall not take place any earlier than 28 days from the audit date.

Where this occurs at a certificated site, certification must be immediately withdrawn.

It is a requirement of some customers that they shall be informed when their suppliers have a critical non-conformity identified or fail to gain certification. In such circumstances the company shall immediately inform its customers and make them fully aware of the circumstances. Information on the corrective actions to be taken in order to address the non-conformities will also be provided to customers where required.

Major and minor non-conformities
No certificate shall be issued until major and minor non-conformities have been demonstrated as having been corrected, either permanently or via a temporary solution that is acceptable to the certification body.

For each non-conformity raised, the site shall, in addition to undertaking the necessary immediate corrective action, undertake a review of the underlying cause (root cause) of the non-conformity. The root cause shall be identified and an action plan to correct this, including timescale, provided to the certification body. The proposed preventive action shall be included in the audit report.

Close-out of non-conformities can be achieved either by objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken, or by the certification body undertaking a further on-site visit. An example of evidence submitted for correction of non-conformity is given in Appendix 8.

Where the number and level of non-conformities identified at the audit would result in a grade of D or D+ being awarded, the closure of non-conformities shall be by means of a further site visit to review the action taken. This visit shall be within 28 calendar days of the audit if a certificate is to be issued.

If satisfactory evidence is not provided within the 28 calendar-day period allowed for submission following the audit, certification will not be granted. The site will then require a further full audit in order to be considered for certification.

Non-conformities from the audit shall also be checked during the next site audit to verify effective close-out of the non-conformities and their root cause. Where the correction has been ineffective then a non-conformity shall be raised against clause 1.1.10.

The certification body will review objective evidence of corrective action completed prior to awarding a certificate.

2.4 GRADING OF THE AUDIT

The purpose of the certification grading system is to indicate to the user of the report the commitment of the site to continual compliance and will dictate the future audit frequency. The grade is dependent on the number and severity of the non-conformities identified at the time of the audit. Non-conformities are verified by a technical review process by the certification body management. If the review results in a change in the number and/or severity of non-conformities, the site shall be notified.

TABLE 1 SUMMARY OF GRADING CRITERIA, ACTION REQUIRED AND AUDIT FREQUENCY

GRADE ANNOUNCED	GRADE UNANNOUNCED	CRITICAL	MAJOR	MINOR	CORRECTIVE ACTION	AUDIT FREQUENCY
AA	AA+			5 or fewer	Objective evidence within 28 calendar days	12 months
A	A+			6 to 10	Objective evidence within 28 calendar days	12 months
B	B+			11–16	Objective evidence within 28 calendar days	12 months
B	B+		1	10 or fewer	Objective evidence within 28 calendar days	12 months
C	C+			17 to 24	Objective evidence within 28 calendar days	6 months
C	C+		1	11 to 16	Objective evidence within 28 calendar days	6 months
C	C+		2	10 or fewer	Objective evidence within 28 calendar days	6 months
D	D+			25 to 30	Revisit required within 28 calendar days	6 months
D	D+		1	17 to 24	Revisit required within 28 calendar days	6 months
D	D+		2	11 to 16	Revisit required within 28 calendar days	6 months
Not certificated		1 or more			Certificate not granted. Re-audit required	
Not certificated				31 or more	Certificate not granted. Re-audit required	
Not certificated			1	25 or more	Certificate not granted. Re-audit required	
Not certificated			2	17 or more	Certificate not granted. Re-audit required	
Not certificated			3 or more		Certificate not granted. Re-audit required	

Note that shaded cells indicate zero non-conformities.

2.5 AUDIT REPORTING

Following each audit, a full written report shall be prepared in the agreed format. The report shall be produced in English or in another language, dependent upon user needs. Where the report is produced in a language other than English, the audit summary sections shall, in addition, always be reported in English.

The audit report shall provide the company and customers or prospective customers with a profile of the company and an accurate summary of the performance of the site against the requirements of the Standard.

The audit report must assist the reader to be informed of:

- the food safety controls in place and improvements since the last audit
- 'best practice' systems, procedures, equipment or fabrication in place
- non-conformities, the corrective action taken and plans to correct the root cause (preventive actions).

The report shall accurately reflect the findings of the auditor during the audit. Reports shall be prepared and dispatched to the company within 42 calendar days of the completion of the full audit.

The audit report shall be uploaded to the BRC Global Standards Directory in a timely manner irrespective of whether a certificate is issued. The owner of the audit report may allocate access to the audit report to customers or other parties in the directory.

The audit report and associated documentation including auditor's notes shall be stored safely and securely for a period of 5 years by the certification body.

2.6 CERTIFICATION

After a review of the audit report and documentary evidence provided in relation to the non-conformities identified, a certification decision shall be made by the designated independent certification manager. Where a certificate is granted this shall be issued by the certification body within 42 calendar days of the audit. The certificate shall conform to the format shown in Appendix 7. Logos used on certificates (e.g. BRC and accreditation body logos) shall comply with their respective usage rules.

The certificate will detail:

- the scope of the audit and any accepted exclusions from scope
- the audit option chosen (i.e. announced) or whether the certificate is a reissue for an extension to scope
- the six-digit auditor registration number of the lead auditor.

The date(s) of audit specified on the certificate shall be the date of the audit relating to the granting of that certificate irrespective of whether later visits were made to verify corrective action arising from the audit.

While the certificate is issued to the site, it remains the property of the certification body, and that body controls its ownership, use and display.

2.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

2.7.1 Scheduling re-audit dates

The ongoing audit schedule and choice of audit programme will be agreed between the site and the certification body. The frequency of announced audits will be 6 or 12 months and is dependent upon the performance of the site at an audit as reflected by the grade (see Table 1).

The due date of the subsequent audit shall be calculated from the date of the initial audit, irrespective of whether further site visits were made to verify corrective action arising from the initial audit, and not from the certificate issue date.

The subsequent announced audit shall be scheduled to occur within a 28-day time period up to the next audit due date. This allows sufficient time for corrective action to take place in the event of any non-conformities being raised, without jeopardising continued certification.

It is the responsibility of the site to maintain certification. Where an audit is delayed beyond the due date, except in justifiable circumstances, this shall result in a major non-conformity being awarded at the next audit. Justifiable circumstances shall be documented in the audit report.

2.7.2 Certificate expiry – justifiable circumstances

There will be some circumstances where the certificate cannot be renewed on the 6-month or 12-month basis due to the inability of the certification body to conduct an audit. These justifiable circumstances, which would not result in the assigning of a major non-conformity (clause 1.1.8), can include when the site is:

- situated in a specific country or an area within a specific country where there is government advice to not visit and there is no suitable local auditor
- within a statutory exclusion zone that could compromise food safety or animal welfare
- in an area that has suffered a natural or unnatural disaster, rendering the site unable to produce or the auditor unable to visit
- affected by conditions that do not allow access to the site or restrict travel (e.g. heavy snow)
- producing seasonal products where production is delayed by a late start to the seasons (e.g. due to weather or product availability).

Moving the audit date to a more 'acceptable' later date for reasons of combining audits, lack of personnel or undertaking building work is not an acceptable reason for missing the due date.

It is not a justifiable reason to delay audits where sites are not in full production; however, audits must be undertaken while there are products are being manufactured.

If the renewal of the certificate is prevented due to these exceptional circumstances, the customer may still decide to take products from that site for an agreed time, as customers may still demonstrate legal compliance by other means, such as risk assessment and complaints records, to show that the site is still competent to continue production until another audit can be arranged.

2.7.3 Audits undertaken prior to due dates

The due date of renewal audits occur within a 28-day window prior to the 6-month or 12-month anniversary of the initial audit.

In some circumstances it is possible to undertake the audit earlier than these due dates, for example to reset the audit dates to allow combined audits with another scheme, or to include a product produced at a different season. Where an audit date is brought forward the following rules shall apply:

- The audit report will detail the reasons why an audit has been brought forward.
- The audit due date will be 'reset' to be 12 months (or 6 months depending on grade) from this audit date.
- The certificate should be issued with an expiry date of 12 months (or 6 months, depending on grade) + 42 days from the 'new' audit date.

2.7.4 Seasonal production sites

Refer to the glossary for the definition of 'seasonal production sites'.

A site that is open for 12 months of the year may process products in different seasons, but would not be classed as a seasonal production site as it would operate all the year round. If specific seasonal products are in scope there may be a case to visit the site more than once a year.

For true seasonal production sites there may be circumstances where the frequency of audits could be more than 12 months. The on-site audit date will be dictated by product harvest, which may be affected by the weather. The certificate expiry dates in these circumstances will be controlled by the actual audit date rather than the anniversary of the initial audit date. Justification needs to be included on the audit report.

3 UNANNOUNCED AUDIT PROTOCOL: OPTION 1 – FULL UNANNOUNCED AUDIT

This option involves a single unannounced audit against all of the requirements of the Standard. The date of the audit shall not be notified to the site in advance of the audit. The audit will be unannounced and replace the normal scheduled audit. Although the audit may occur at any stage between months 3 and 12 of the audit due date, this shall typically be within the last 4 months of the certification cycle.

3.1 AUDIT PLANNING

3.1.1 Selection of the unannounced audit option 1 programme

The site shall notify its certification body within 3 months of the last audit date of its intention to join or remain within the unannounced audit programme. This allows the opportunity for the site to select an alternative certification body if required while allowing the audit to be undertaken at a time of the certification body's choosing.

3.1.2 Preparation by the company

The actual audit date will not be provided by the certification body and it is therefore important that the site has arrangements in place to receive an audit and facilitate the audit process.

Success at an unannounced audit relies upon the ability of the site to share information and knowledge within the site, to have effective deputies to cover in the absence of a particular manager, and a shared responsibility within the management team for food safety and compliance with the Standard.

3.1.3 Information to be provided to the certification body for audit preparation

The site shall supply the certification body with background information prior to the audit day to ensure the auditor(s) is fully prepared and to provide the best opportunity for the audit to be completed efficiently. The information will be requested by the certification body and may include but is not limited to:

- a summary of critical control points (CCPs)
- the process flow diagram
- a simple site plan
- the management organisational chart
- the list of products or product groups included within the audit scope
- typical shift patterns
- production schedules, to allow audits to cover relevant processes (e.g. night-time manufacture or where production processes are not carried out each day)
- recent quality issues, withdrawals or customer complaints and other relevant performance data.

The company shall make the previous year's audit report and certificate available to the certification body, where this is a contract with a new certification body.

As the audit will be unannounced it is likely that the certification body will also require additional information to plan for the logistics of the audit process. This may include:

- recommended local hotels
- specific site directions, site entrance requirements, car parking
- a list of contacts when first arriving on site
- specific protective clothing arrangements
- any specific security arrangements to follow to gain access to the site.

3.1.4 Nominating non-audit days

The unannounced option 1 programme allows sites the opportunity to nominate 15 days when the site is not available for an audit. The dates must be provided at least 4 weeks in advance and the reason must be provided (e.g. a planned customer visit). The certification body may challenge the reason where this does not appear appropriate.

Days when the factory is not operating (e.g. weekends, public holidays, planned shutdowns for site holidays or maintenance) are not included within the 15 days. Any such non-production days shall be notified to the certification body when opting into the unannounced scheme.

Certification bodies are expected to operate discretion in the case of emergencies.

It is a condition of electing to join the unannounced scheme that the auditor shall be granted access to the site for the audit on arrival. If access is denied the site will be liable for the auditor's costs and will revert to the announced audit scheme. At the discretion of the certification body, the existing certificate may also be suspended or withdrawn.

3.1.5 Audit duration

Sufficient information shall have been provided to the certification body when selecting this option to allow for the selection of an auditor with the correct category qualifications and to allow sufficient time for the audit. The audit duration shall be calculated using the BRC audit calculator and the same time shall be allowed for the unannounced audit as would be expected for the usual announced audit.

The typical duration of an audit is 2 to 3 days (8 hours/day) at the site. A calculator has been developed to assess the expected time required to undertake the audit of any particular site to ensure consistency and this shall be used as the basis for calculating the total audit duration. Full details can be found on the BRC Global Standards website (**www.brcglobalstandards.com**).

The calculation for the audit duration is based on:

- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of HACCP studies included within scope – a HACCP study corresponds to a family of products with similar hazards and similar production technology for the purpose of the calculator.

It is recognised that other factors may also influence the calculation but are considered to be less significant and therefore shall not influence the audit duration by more than 30% from the total calculated audit time. These factors include:

- the complexity of the manufacturing process
- the number of product lines
- the age of the site and impact on material flow
- the labour-intensity of processes
- communication difficulties (e.g. language)
- the number of non-conformities recorded in the previous audit
- difficulties experienced during the audit requiring further investigation
- the quality of site preparation (e.g. documentation, HACCP, quality management systems).

If additional storage facilities, locations or head office assessments are included within the audit process (see Appendix 4) then additional time shall be allocated for this over and above that indicated in the audit calculator.

In the event that the audit against this Standard includes voluntary BRC modules or is intended to be combined with other audit Standards, the total audit time will need to be appropriately extended. Details of combined audits shall be specified on the audit report.

The calculation for audit duration shall determine the amount of time to be expected to undertake the audit at the site. Additional time will be required for the review of any documentary evidence provided and completion of the final audit report.

Deviation from the calculated audit timeframe must be justified and specified on the audit report.

The expected audit duration shall be notified to the site by the certification body in advance of the audit.

3.2 THE ON-SITE AUDIT

Sites opting for the unannounced scheme shall be obliged to accommodate the auditor and allow the audit to start immediately on arrival at the site. The audit process will follow the same procedures as outlined for an announced audit. There will be a short opening meeting after which the site production facility inspection will be expected to commence within 30 minutes of the auditor arriving on site.

The on-site audit consists of the following seven stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, including observing product changeover procedures, and interview of personnel.
- Document review – a review of the documented HACCP and quality management systems.
- Traceability challenge – including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications). This is a vertical audit – as specified within the BRC guidance document on audit techniques.
- Review of production facility inspection – to verify and conduct further documentation checks.
- Final review of findings by the auditor(s) – preparation for the closing meeting.
- Closing meeting – to review audit findings with the site. (Note that non-conformities are subject to subsequent independent verification by the certification body management.)

The site shall fully assist the auditor(s) at all times. It is expected that at the opening and closing meetings those attending on behalf of the site will be senior managers who have the appropriate authority to ensure that corrective action can be progressed if non-conformities are found. The most senior operations manager on site or their nominated deputy shall be available at the audit and attend the opening and closing meetings.

The audit process gives emphasis to the practical implementation of food safety procedures and general good manufacturing practices. It is expected that approximately 50% of the audit will be spent auditing production and site facilities, interviewing staff, observing processes and reviewing documentation in production areas with the relevant staff.

During the audit, detailed notes shall be made regarding the site's conformities and non-conformities against the Standard and these will be used as the basis for the audit report. The auditor(s) shall assess the nature and severity of any non-conformity and shall discuss this with the accompanying manager at the time.

At the closing meeting, the auditor(s) shall present their findings and reconfirm all non-conformities that have been identified during the audit, but shall not make comment on the likely outcome of the certification process. Information on the process and

timescales for the site to provide evidence to the auditor(s) of the corrective action to close non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor(s) either at the closing meeting or within one working day after completion of the audit.

At the closing meeting the auditor(s) shall provide the site with an explanation of the BRC Global Standards Directory, which allows secure access to audit data to both the client and their nominated customers, together with the feedback systems available to communicate with the certification body and with the BRC.

The decision to award certification and the grade of the certificate will be determined independently by the certification body management, following a technical review of the audit report and the closing of non-conformities in the appropriate timeframe. The company will be informed of the certification decision following this review.

3.3 NON-CONFORMITIES AND CORRECTIVE ACTION

Non-conformities and corrective actions are the same as for the announced audit scheme (see section 2.3).

3.4 GRADING OF THE AUDIT

The process for grading is the same as for the announced audit scheme (see section 2.4). The grade awarded following certification shall be based on the number and level of non-conformities, as outlined in Table 1. Note that the grade will have the addition of a plus symbol after the grade (i.e. AA+, A+, B+, C+ or D+).

3.5 AUDIT REPORTING

The audit reporting requirements are the same as for the announced audit scheme (see section 2.5). However, the report shall state 'Unannounced option 1'.

3.6 CERTIFICATION

The certification requirements are the same as for the announced audit scheme (see section 2.6). However, the certificate shall state 'Unannounced option 1'.

This certificate will supersede the existing certificate. The certificate shall be issued within 42 days of the audit and will have an expiry date based on the expiry date of the previous certificate plus 12 months, providing the site remains within the unannounced audit scheme. If the site decides to return to the announced audit programme, the certificate expiry date will be based 6 or 12 months from the date of the unannounced audit.

This ensures that where the audit occurs before the expiry of the current certificate and the site remains within the unannounced scheme it is not disadvantaged by a shorter certificate life and increased frequency of audits.

3.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

3.7.1 Scheduling re-audit dates

The site can choose whether to:

- remain within the unannounced option 1 programme
- transfer to the unannounced option 2 programme
- revert to the announced audit programme.

If the site wishes to remain in the option 1 programme the next audit will be unannounced. The audit may occur at any stage from 3 months after the last audit date through to 42 days prior to the certificate expiry date; however, this shall typically be within the last 4 months of the certification cycle. This allows sufficient time for corrective action to take place in the event of any non-conformities being raised without jeopardising continued certification.

It is the responsibility of the certification body to ensure that the audit is undertaken within the certification window and the late audit non-conformity clause (1.1.8) shall not apply.

If the site opts to move to the unannounced option 2 programme the rules for that programme will apply and the announced systems audit will occur within the 28-day window based on the initial audit date.

If the site wishes to withdraw from the unannounced audit programme, the next audit will be scheduled to occur within the 28 days up to and including the anniversary of the last audit date; this ensures that the maximum time between audits is not more than a year.

3.7.2 Seasonal production sites

The option 1 unannounced programme may be applied to seasonal production sites (see the glossary for the definition of 'seasonal production sites'). The following rules will, however, apply:

- The expected seasonal production dates shall be notified to the certification body at the time of choosing the unannounced scheme.
- No dates may be excluded within the production season.

The audit due dates for some sites producing seasonal products may occur towards the beginning of the product's season and this could limit the dates available to carry out unannounced audits before the end of the re-audit window. Therefore, in the first year that the site is within the unannounced option 1 scheme the audit window is extended to allow the unannounced audit to be carried out up to 6 weeks after the audit due date. There will be no penalty for late audits.

The subsequent next audit due date and the certificate expiry date (42 days later) shall be based on the typical season end date agreed between the site and the certification body. In practice this will mean the issue of a certificate with duration of more than 1 year on occasions.

Unannounced audits in year 2 may then occur at any date during the season and meet normal certification rules.

4 UNANNOUNCED AUDIT PROTOCOL: OPTION 2 – TWO-PART UNANNOUNCED AUDIT

The option 2 unannounced audit scheme divides the audit requirements into two separate audits. The first audit looks predominantly at the issues considered to be factory-based good manufacturing practices and is carried out as an unannounced audit. The second audit is predominantly based on reviewing documentation and records and can be planned to ensure the appropriate management staff are available to retrieve and discuss the records.

The requirements of the Standard are colour coded to identify the requirements which would be audited during different audit visits.

The planned part 2 audit allows this part of the audit to be combined with other planned certification audits where these are used to reduce audit costs.

4.1 AUDIT PLANNING

4.1.1 Selection of the unannounced audit option 2 programme

The site shall notify its certification body within 3 months of the last audit date of its intention to join or remain within the unannounced audit programme. This allows the opportunity for the site to select an alternative certification body if required while allowing the audit to be undertaken at a time of the certification body's choosing.

The unannounced part 1 audit shall occur at any stage between months 6 and 10 of the audit cycle (i.e. 2 to 6 months before the audit due date). This allows sites to correct any non-conformities identified at the audit to enable these to be reviewed at the part 2 audit.

The part 2 audit of documentation and records shall be planned to occur in the 28 days up to and including the anniversary of the last audit date (i.e. in the same time window as an announced audit). The date for this audit is agreed with the site in advance of the audit.

4.1.2 Preparation by the company

The audit process for the option 2 scheme involves two separate audit visits and preparation for each may be slightly different.

Part 1 Unannounced audit

The actual audit date for the unannounced good manufacturing practices audit will not be provided by the certification body and it is therefore important that the site has arrangements in place to receive an audit and facilitate the audit process.

Success at an unannounced audit relies upon the ability of the site to share information and knowledge within the site, to have effective deputies to cover in the absence of a particular manager, and a shared responsibility within the management team for food safety and compliance with the Standard.

Part 2 Announced audit
The second half of the audit is a planned audit primarily auditing the documented systems and records. It is important that the relevant managers or deputies are available to assist in providing information required for the success of the audit. The part 2 audit will also include a visit to the factory and review of actions taken following the previous part 1 unannounced audit.

The site shall ensure that the production programme at the time of the audit covers products for the intended scope of the certification. Where possible, the widest range of these products shall be in production for the auditor(s) to assess. Where a product type or processing method was not in production at the time of the part 1 unannounced audit then every effort should be made to ensure this is in production for the part 2 audit.

Where a significant production process is undertaken only during a different period of the year from either audit, a further separate audit will be required to assess that production method.

4.1.3 Information to be provided to the certification body for audit preparation
This is as per unannounced audit option 1 (see section 3.1.3).

4.1.4 Nominating non-audit days
The unannounced option 2 programme allows sites the opportunity to nominate 10 days when the site is not available for an audit. The dates must be provided at least 4 weeks in advance and the reason must be provided (e.g. a planned customer visit). The certification body may challenge the reason where this does not appear appropriate.

Days when the factory is not operating (e.g. weekends, public holidays, planned shutdowns for site holidays or maintenance) are not included within the 10 days. Any such non-production days shall be notified to the certification body when opting into the unannounced scheme.

Certification bodies are expected to operate discretion in the case of emergencies.

It is a condition of electing to join the unannounced scheme that the auditor shall be granted access to the site for the audit on arrival. If access is denied the site will be liable for the auditor's costs and will revert to the announced audit scheme. At the discretion of the certification body, the existing certificate may also be suspended or withdrawn.

4.1.5 Audit duration
Sufficient information shall have been provided to the certification body when selecting this option to allow for the selection of an auditor(s) with the correct category qualifications and to allow sufficient time for the audit. The total audit duration (i.e. parts 1 and 2) shall be calculated using the BRC audit calculator and the same total time shall be allowed for the unannounced audit option 2 as would be expected for the usual announced audit. The time for the part 2 audit may be adjusted based on the findings from the unannounced part 1 audit; for instance, more time may be required if there are a large number of non-conformities with corrective actions to review following the part 1 audit.

The typical total audit duration is 2 to 3 days (8 hours/day) at the site with the time divided evenly between the part 1 and part 2 audits. A calculator has been developed to assess the expected total time required to undertake the audit of any particular site to ensure consistency and this shall be used as the basis for calculating the total audit duration. Full details can be found on the BRC Global Standards website (**www.brcglobalstandards.com**).

The calculation for the audit duration is based on:

- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of HACCP studies included within scope – a HACCP study corresponds to a family of products with similar hazards and similar production technology for the purpose of the calculator.

It is recognised that other factors may also influence the calculation but are considered to be less significant and therefore shall not influence the audit duration by more than 30% from the total calculated audit time. These factors include:

- the complexity of the manufacturing process
- the number of product lines
- the age of the site and impact on material flow
- the labour-intensity of processes
- communication difficulties (e.g. language)
- the number of non-conformities recorded in the previous audit or part 1 audit
- difficulties experienced during the part 1 audit requiring further investigation
- the quality of site preparation (e.g. documentation, HACCP, quality management systems).

If additional storage facilities, locations or head office assessments are included within the audit process (see Appendix 4) then additional time shall be allocated for this over and above that indicated in the audit calculator.

In the event that the audit includes voluntary BRC modules or is intended to be combined with other audit Standards, the total audit time will need to be appropriately extended. Voluntary modules shall be audited as part of the part 2 audit and additional time shall be added to this part of the audit. Details of combined audits shall be specified on the audit report.

The calculation for audit duration shall determine the amount of time to be expected to undertake the audit at the site. Additional time will be required for the review of any documentary evidence provided and completion of the final audit report.

Deviation from the calculated audit timeframe must be justified and specified on the audit report.

The expected audit duration shall be notified to the site by the certification body in advance of the audit.

4.2 THE ON-SITE AUDITS

4.2.1 Part 1 Unannounced audit

Sites opting for the unannounced scheme shall be obliged to accommodate the auditor and allow the audit to start immediately on arrival at the site. The audit process will be focused on the production facility and some supporting documentation required to complete a particular audit trail. It is expected that after a brief opening meeting the auditor will start the production facility audit within 30 minutes of the auditor arriving on site.

The part 1 unannounced audit will focus largely on the clauses identified with the following colour code within the Standard:

Requirements assessed on part 1 – audit of good manufacturing practice	
Requirements assessed on both parts 1 and 2	

The part 1 unannounced audit consists of the following stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, including observing product changeover procedures, and interview of personnel.
- A review of documentation needed to complete the audit trail (e.g. pest control records).
- Final review of findings by the auditor(s) – preparation for the closing meeting.
- Closing meeting – to review audit findings with the site. (Note that non-conformities are subject to subsequent independent verification by the certification body management.)

4.2.2 Part 2 Announced audit

The part 2 announced audit will focus largely on the clauses identified with the following colour code within the Standard:

Requirements assessed on part 2 – audit of records, systems and documentation	
Requirements assessed on both parts 1 and 2	

The part 2 documentation audit consists of the following stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review the factory standards and in particular the corrective actions taken in response to non-conformities identified during the part 1 audit.

- Document review – a review of the documented HACCP and quality management systems.
- Traceability challenge – including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications). This is a vertical audit – as specified within the BRC guidance document on audit techniques.
- Final review of findings by the auditor(s) – preparation for the closing meeting.
- Closing meeting – to review audit findings with the site. (Note that non-conformities are subject to subsequent independent verification by the certification body management.)

The site shall fully assist the auditor(s) at all times. It is expected that at the opening and closing meetings those attending on behalf of the site will be senior managers who have the appropriate authority to ensure that corrective action can be progressed if non-conformities are found. The most senior operations manager on site or their nominated deputy shall be available at the audit and attend the opening and closing meetings.

During both parts of the audit, detailed notes shall be made regarding the site's conformities and non-conformities against the Standard and these will be used as the basis for the audit report. The auditor(s) shall assess the nature and severity of any non-conformity.

At the closing meetings the auditor(s) shall present their findings and reconfirm all non-conformities that have been identified during the audit, but shall not make comment on the likely outcome of the certification process. Information on the process and timescales for the company to provide evidence to the auditor(s) of the corrective action to close non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor(s) either at the closing meeting or within one working day after completion of each part of the audit.

At the final closing meeting the auditor(s) shall provide the site with an explanation of the BRC Global Standards Directory, which allows secure access to audit data to both the client and their nominated customers, together with the feedback systems available to communicate with the certification body and with the BRC.

The decision to award certification and the grade of the certificate will be determined independently by the certification body management, following a technical review of the audit report and the closing of non-conformities in the appropriate timeframe. The company will be informed of the certification decision following this review.

4.3 NON-CONFORMITIES AND CORRECTIVE ACTION

Non-conformities and corrective actions are the same as for the announced audit scheme (see section 2.3).

Evidence of the action taken to correct non-conformities identified at the part 1 audit shall be submitted to the certification body within 28 days of the part 1 audit and will be subject to further review at the part 2 audit.

If a critical non-conformity and/or the number and level of non-conformities identified at the part 1 audit would result in the failure to achieve a certificate, the existing certificate for the site shall be immediately withdrawn.

4.4 GRADING OF THE AUDIT

The process for grading is the same as for the announced audit scheme (see section 2.4).

The grade awarded following certification shall be based on the number and level of non-conformities, as outlined in Table 1. Note that the grade will have the addition of a plus symbol after the grade (i.e. AA+, A+, B+, C+ or D+).

The grade awarded is based on the combination of non-conformities identified at the part 1 and the part 2 audits. Although the non-conformities identified on the part 1 audit should have been corrected before the part 2 audit, these shall be included in calculating the grade.

4.5 AUDIT REPORTING

The audit reporting requirements are the same as for the announced audit scheme (see section 2.5). However, the report shall state 'Unannounced option 2'.

The full audit report will include information and non-conformities identified at both the part 1 and part 2 audits. The final report will not be produced until after completion of the part 2 audit.

4.6 CERTIFICATION

The certification requirements are the same as for the announced audit scheme (see section 2.6). However, the certificate shall state 'Unannounced option 2'.

This certificate will supersede the existing certificate. The certificate shall be issued within 42 days of the part 2 audit and will have an expiry date based on the expiry date of the previous certificate plus 12 months, providing the site remains within the unannounced audit scheme. If the site decides to return to the announced audit programme, the certificate expiry date will be 6 or 12 months depending upon the grade achieved.

4.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

4.7.1 Scheduling re-audit dates

The site can choose whether to:

- remain within the unannounced option 2 programme
- transfer to the unannounced option 1 programme
- revert to the announced audit programme.

If the site wishes to remain in the option 2 programme, the audits will be undertaken as indicated by the audit planning rules above.

If the site opts to move to unannounced option 1, the rules for that programme will apply and the full unannounced audit will occur between 3 and 12 months after the initial audit date.

If the site wishes to withdraw from the unannounced audit programme, the next audit will be scheduled to occur within the 28 days up to and including the audit due date indicated on the certificate.

It is the responsibility of the certification body to ensure that the unannounced part 1 audit is undertaken within the audit window. It is the responsibility of the company to ensure that the announced part 2 audit takes place within the certification window to avoid the late audit non-conformity clause (1.1.8).

4.7.2 Seasonal production sites

The option 2 unannounced programme may be applied to seasonal production sites (see the glossary for the definition of 'seasonal production sites'). The following rules will, however, apply:

- The expected seasonal production dates shall be notified to the certification body at the time of choosing the unannounced scheme.
- No dates may be excluded within the production season.
- Where the option 2 scheme is chosen, the documentation and systems audit will take place first at a pre-arranged date at least 28 days before the expected start to the season to allow for completion of any corrective actions. The part 1 good manufacturing practice audit will be carried out as an unannounced audit during the season.

The audit due dates for some sites producing seasonal products may occur towards the beginning of the product's season and this could limit the dates available to carry out the unannounced audit before the end of the re-audit window. Therefore, in the first year that the site is within the unannounced scheme the audit window is extended to allow the unannounced audit to be carried out up to 6 weeks after the audit due date. There will be no penalty for late audits.

The subsequent next audit due date and the certificate expiry date (42 days later) shall be based on the typical season end date agreed between the site and the certification body. In practice this will mean the issue of a certificate with duration of more than 1 year on occasions.

Unannounced audits in year 2 may then occur at any date during the season and meet normal certification rules.

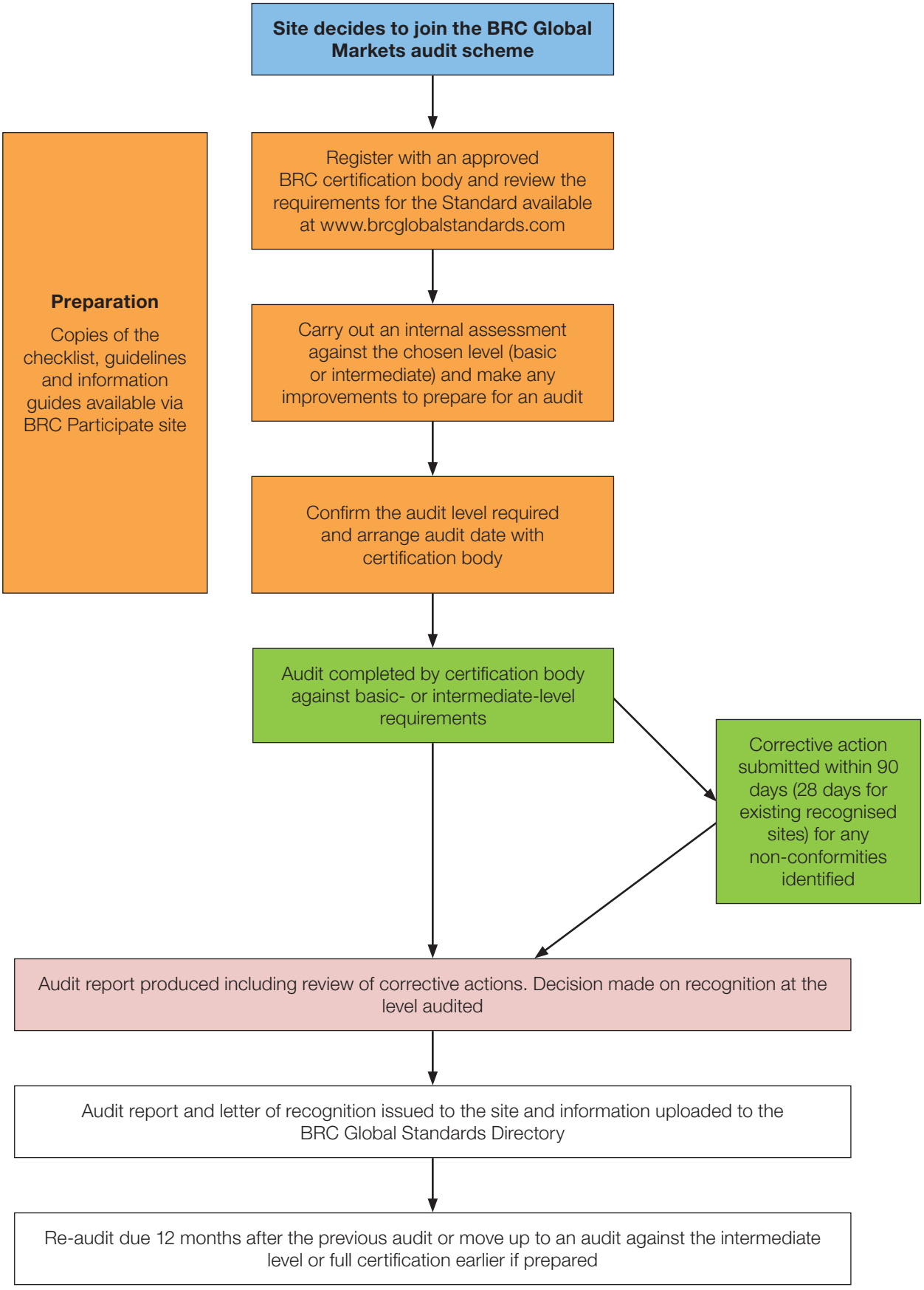


FIGURE 3 BRC GLOBAL MARKETS PROGRAMME

5 BRC GLOBAL MARKETS PROGRAMME

The BRC Global Markets programme is designed for sites which are either very small and for which the full Standard may not be appropriate or for sites which are in the development process of their food safety management systems.

The programme is based on the principles of the GFSI Global Markets programme. Requirements from the full BRC Global Standard for Food Safety have been identified that form audit requirements at the basic and intermediate levels, before progression to full certification. It allows an audit and recognition of attainment of compliance at two levels below full BRC certification (i.e. basic and intermediate levels):

- Basic requirements – cover the minimum requirements within the BRC Standard to enable the production of safe, legal food.
- Intermediate requirements – incorporate the basic requirements but in addition include more robust systems for food safety and product quality management from the full Standard.

A full guideline on the scheme together with the details of the requirements at each level and the appropriate audit checklists are available on the BRC Global Standards website and within the BRC Participate subscription service.

Audits for the BRC Global Markets programme must be undertaken by BRC-recognised certification bodies. The rules on scope and exclusions from scope in the general protocol apply (Part III, section 1.6). The BRC Global Markets programme is summarised in Figure 3.

5.1 AUDIT PLANNING

5.1.1 Preparation by the company

All audits for the BRC Global Markets programme at the basic and intermediate level are announced. The site shall agree a mutually convenient date, with due consideration given to the amount of work required to meet the requirements of the basic or intermediate level.

There is a requirement on the site to be prepared for the audit, to have appropriate documentation for the auditor(s) to assess, and to have appropriate staff available at all times during the on-site audit.

The site shall ensure that the production programme at the time of the audit covers products for the intended scope of the certification. Where possible, the widest range of these products shall be in production for the auditor(s) to assess. Where the product range is large or diverse, the auditor(s) has the discretion to continue the audit until sufficiently satisfied that the intended scope of the certification has been assessed. Where a significant production process is undertaken only during a different period of the year from the audit, a separate audit will be required to assess that production method.

5.1.2 Information to be provided to the certification body for audit preparation

The company shall supply the certification body with background information prior to the audit day to ensure the auditor(s) is fully prepared and to provide the best opportunity for the audit to be completed efficiently. The information will be requested by the certification body and may include but is not limited to:

- confirmation of the audit level (i.e. basic or intermediate)
- a summary of critical control points (CCPs)
- a simple process flow diagram or process description
- a simple site plan
- the main management contacts and positions
- the list of products or product groups included within the audit scope
- typical shift patterns
- production schedules, to allow audits to cover relevant processes (e.g. night-time manufacture or where production processes are not carried out each day)
- recent quality issues, withdrawals or customer complaints and other relevant performance data.

The company shall make the previous year's audit report and level of recognition available to the certification body, where this is a contract with a new certification body.

5.1.3 Audit duration

Before the audit takes place, the certification body shall indicate the approximate duration of the audit. The typical duration of the basic-level audit is 1 day (8 hours/day) at the site. The intermediate-level audit will typically take 1.5 days.

The audit duration is based on:

- the required audit level – basic or intermediate
- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of HACCP studies included within scope – a HACCP study corresponds to a family of products with similar hazards and similar production technology
- the complexity of the manufacturing process
- the number of product lines
- the age of the site and impact on material flow
- the labour-intensity of processes
- communication difficulties (e.g. language)
- the number of non-conformities recorded in any previous audit.

If additional storage facilities, locations or head office assessments are included within the audit process (see Appendix 4) then additional time shall be allocated for this over and above that indicated in the audit calculator.

The calculation for audit duration shall determine the amount of time to be expected to undertake the audit at the site. Additional time will be required for the review of any documentary evidence provided and completion of the final audit report.

5.2 THE ON-SITE AUDIT

The on-site audit consists of the following stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, including observing product changeover procedures, and interview of personnel.
- Document review – a review of the documented HACCP and applicable quality management systems.
- Traceability challenge.
- Review of production facility inspection – to verify and conduct further documentation checks.
- Final review of findings by the auditor(s) – preparation for the closing meeting.
- Closing meeting – to review audit findings with the site. (Note that non-conformities are subject to subsequent independent verification by the certification body management.)

The site shall fully assist the auditor(s) at all times. It is expected that at the opening and closing meetings those attending on behalf of the site will be senior managers who have the appropriate authority to ensure that corrective action can be progressed if non-conformities are found. The most senior operations manager on site or their nominated deputy shall be available at the audit and attend the opening and closing meetings.

The audit process gives emphasis to the practical implementation of food safety procedures and general good manufacturing practices. It is expected that at least 50% of the audit will be spent auditing production and site facilities, interviewing staff, observing processes and reviewing documentation in production areas with the relevant staff.

During the audit, detailed notes shall be made regarding the site's conformities and non-conformities against the Standard and these will be used as the basis for the audit report. The auditor(s) shall assess the nature and severity of any non-conformity and shall discuss this with the accompanying manager at the time.

At the closing meeting, the auditor(s) shall present their findings and reconfirm all non-conformities that have been identified during the audit. Information on the process and timescales for the company to provide evidence to the auditor(s) of the corrective action to close non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor either at the closing meeting or within one working day after completion of the audit.

At the closing meeting the auditor(s) shall provide the site with an explanation of the BRC Global Standards Directory, which allows secure access to audit data to both the client and their nominated customers, together with the feedback systems available to communicate with the certification body and with the BRC.

The decision to award basic or intermediate-level recognition will be determined independently by the certification body management, following a technical review of the audit report and the closing of non-conformities in the appropriate timeframe. The company will be informed of the decision following this review.

5.3 NON-CONFORMITIES AND CORRECTIVE ACTION

The levels of non-conformity and corrective actions required are the same as for the full BRC certification scheme.

5.3.1 Non-conformities

There are three levels of non-conformity:

- **Critical** Where there is a critical failure to comply with a food safety or legal issue.
- **Major** Where there is a substantial failure to meet the requirements of a 'statement of intent' or any clause of the Standard or a situation is identified which would, on the basis of available objective evidence, raise significant doubt as to the conformity of the product being supplied.
- **Minor** Where a clause has not been fully met but, on the basis of objective evidence, the conformity of the product is not in doubt.

The objective of the audit is to provide a true reflection of the standard of the operation and level of conformity against the BRC Global Markets basic or intermediate standard. Consideration should therefore be given to awarding a single major non-conformity where minor non-conformities are repeatedly raised against a particular clause of the Standard. Clustering of a significant number of minor non-conformities against a clause and recording this as a single minor non-conformity is not permitted.

5.3.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities during the audit, the company must undertake corrective action to remedy the immediate issue (correction). It is also strongly encouraged that an analysis of the underlying cause of the non-conformity (root cause) is undertaken to allow any preventive actions to be taken to prevent recurrence.

The process for 'closing out' non-conformities depends upon the level of non-conformity and the numbers of non-conformities identified.

Critical non-conformities

The grading of non-conformities will be reviewed by the certification body as soon as possible after the audit. Where the review confirms that a non-conformity is classed as critical, the site will be required to undertake another full audit before attainment of basic or intermediate level.

Where this occurs at a site which has previously been awarded basic or intermediate-level recognition, this recognition must be immediately withdrawn.

It is a requirement of some customers that they shall be informed when their suppliers have a critical non-conformity identified or fail to retain basic or intermediate-level recognition. In such circumstances the company shall immediately inform its customers and make them fully aware of the circumstances. Information on the corrective actions to be taken in order to address the non-conformities will also be provided to customers where required.

Major and minor non-conformities

No basic or intermediate-level recognition shall be issued until major and minor non-conformities have been demonstrated as having been corrected, either permanently or via a temporary solution that is acceptable to the certification body.

Close-out of non-conformities can be achieved either by objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken, or by the certification body undertaking a further on-site visit.

Where a high number of non-conformities are identified or the type of issues identified would make it very difficult to confirm compliance through documentary evidence alone the certification body would need to revisit the site to confirm correction.

Sites that have not yet achieved basic level are allowed up to 90 days after the audit date to correct and provide evidence of corrective action. Where sites have already achieved basic and/or intermediate level, 28 calendar days are allowed for submission.

If satisfactory evidence of correction is not provided within the timescale an award of basic or intermediate level cannot be granted and a further audit will be required for consideration of the award of basic or intermediate level.

5.4 GRADING OF THE AUDIT

There is no grading of the awards of basic or intermediate level. The numbers and type of non-conformity will, however, be indicated on the audit report.

5.5 AUDIT REPORTING

Following each audit, a full written report shall be prepared in the designated format. The report shall be produced in English or in another language, dependent upon user needs. Where the report is produced in a language other than English, the audit summary sections shall, in addition, always be reported in English.

The audit report shall provide the company and customers or prospective customers with a profile of the company and an accurate summary of the performance of the site against the requirements appropriate to the chosen level.

The audit report must assist the reader to be informed of:

- the food safety controls in place and improvements since the last audit
- 'best practice' systems, procedures, equipment or fabrication in place
- non-conformities and the corrective action taken.

The report shall accurately reflect the findings of the auditor during the audit.

Reports shall be prepared and dispatched to the company within 42 calendar days (104 days for sites that have not previously attained basic level) of the completion of the full audit.

The audit report shall be uploaded to the BRC Global Standards Directory in a timely manner irrespective of whether basic or intermediate level is attained. The owner of the audit report may allocate access to the audit report to customers or other parties in the directory.

The audit report and associated documentation including auditor's notes shall be stored safely and securely for a period of 5 years by the certification body.

5.6 BASIC OR INTERMEDIATE-LEVEL RECOGNITION

After a review of the audit report and documentary evidence provided in relation to the non-conformities identified, a decision shall be made on whether to award recognition of attainment of the basic or intermediate level. Please note attainment of a level is not certification; certification is only achieved by successful compliance with the full BRC Global Standard.

Where recognition is granted this shall be confirmed in writing by the certification body within 42 calendar days of the audit (104 days where sites have not previously achieved recognition).

The letter of recognition shall include the following details:

- company name
- address of the site audited
- scope of the audit and any permitted exclusions
- date(s) of the audit
- the level attained (i.e. BRC Global Markets basic or intermediate level)
- the name and address of the awarding certification body
- expiry date of recognition (i.e. 1 year and 42 days after the full audit date).

5.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

5.7.1 Scheduling re-audit dates

In order to maintain recognition at either basic or intermediate level the site shall be re-audited every 12 months. The due date of the re-audit shall be calculated from the date of the initial audit, irrespective of whether further site visits were made to verify corrective action arising from the initial audit.

The subsequent announced audit shall be scheduled to occur within a 28-day time period up to the next audit due date. This allows sufficient time for corrective action to take place in the event of any non-conformities being raised, without jeopardising continued recognition.

The BRC Global Markets programme is designed to encourage continuous improvement and assist sites in developing their food safety systems to a point where they can achieve full certification. Sites can at any time request an audit either to move from basic level to intermediate level or for full certification.

6 VOLUNTARY MODULES

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

It is expected that modules will be developed and become available for use throughout the life of this issue of the Standard. A list of the modules, the applicable requirements and any specific protocol issues for a module will be available on the BRC Global Standards website (**www.brcglobalstandards.com**) and on the BRC Participate subscription service.

The voluntary modules can be added to any of the full certification audit options.

The general protocol for the voluntary modules is as follows.

6.1 AUDIT PLANNING

6.1.1 Preparation by the company

The certification body shall be notified in advance of the audit that a particular voluntary module is intended to be added to the scope of the audit. This ensures sufficient additional time can be scheduled and that an auditor with the appropriate qualifications for the additional module is selected.

The site shall ensure that the production programme at the time of the audit covers products for the intended voluntary module where this is applicable.

6.1.2 Information to be provided to the certification body for audit preparation

The company shall supply the certification body with any additional background information requested prior to the audit day to ensure the auditor(s) is fully prepared to audit against the additional module, and to provide the best opportunity for the audit to be completed efficiently.

6.1.3 Audit duration

In order for the voluntary modules to be included within the audit programme additional time will be needed for the audit. The certification body shall indicate the expected additional time requirements at the time of planning the audit.

The actual additional time will depend upon the module or combination of modules chosen.

6.1.4 The on-site audit

Compliance with the requirements of the chosen voluntary modules shall be assessed as part of the audit against the requirement of the main Standard and is expected to be integrated into the audit programme as appropriate.

During the audit, detailed notes shall be made regarding the site's conformities and non-conformities against the requirements of the additional module, and these will be used as the basis for an addendum to the audit report. The auditor(s) shall assess the nature and severity of any non-conformity.

At the closing meeting, the auditor(s) shall present their findings and discuss all non-conformities that have been identified against the module during the audit. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor either at the closing meeting or within one working day after completion of the audit.

The decision to award certification for the voluntary module will be determined independently by the certification body management, following a technical review of the audit report and the closing of non-conformities in the appropriate timeframe. The company will be informed of the certification decision following this review.

6.2 NON-CONFORMITIES AND CORRECTIVE ACTION

The level of non-conformity assigned by an auditor against a requirement of a voluntary module is an objective judgement with respect to severity and risk and is based on evidence collected and observations made during the audit. This is verified by the certification body management.

6.2.1 Non-conformities

Non-conformities against requirements of a voluntary module shall be graded in the same way as non-conformities identified against requirements of the main Standard, namely:

- **Critical** Where there is a critical failure to comply with a product safety or legal issue within the scope of the module.
- **Major** Where there is a substantial failure to meet the requirements of a 'statement of intent' or any clause of the module or a situation is identified which would, on the basis of available objective evidence, raise significant doubt as to the conformity of the product or service to the module.
- **Minor** Where a clause of the module has not been fully met but, on the basis of objective evidence, the conformity of the product or service to the module is not in doubt.

6.2.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities against the requirements of the module during the audit, the company must undertake corrective action to remedy the immediate issue (correction). The process for 'closing out' non-conformities depends upon the level of non-conformity and the numbers of non-conformities identified.

Critical non-conformities

If a critical non-conformity is identified against a requirement of the module then the site cannot be certificated for this module without a further full audit of the module.

Where this occurs at a site which already holds certification for the module, certification of the module must be immediately withdrawn.

If it is a requirement of customers that they shall be informed when their suppliers have a critical non-conformity identified or fail to gain certification against a module the company shall immediately inform its customers.

Note a critical non-conformity against a requirement of a voluntary module does not necessarily prevent certification against the main Standard or other voluntary modules.

Major and minor non-conformities

A voluntary module cannot be included on a certificate until major and minor non-conformities have been demonstrated as having been corrected, either permanently or via a temporary solution that is acceptable to the certification body.

Close-out of non-conformities can be achieved either by objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken, or by the certification body undertaking a further on-site visit.

If satisfactory evidence is not provided within the 28 calendar-day period allowed for submission following the audit, certification for the module will not be granted. The site will then require a further full audit in order to be considered for certification of the module.

The certification body will review objective evidence of corrective action completed prior to awarding a certificate.

6.3 GRADING OF THE AUDIT

There will be no grading of the voluntary modules. The modules will either be certificated or not.

Any non-conformities identified when assessing a voluntary module **shall not** be taken into account when deciding the grade for certification against the Global Standard for Food Safety.

6.4 AUDIT REPORTING

Following each audit, a written report shall be prepared in the agreed format for the particular module and this will form an addendum to the Global Standard for Food Safety audit report. The addendum report shall be produced in English or in another language, dependent upon user needs. Where the report is produced in a language other than English, any applicable audit summary sections shall, in addition, always be reported in English.

The report addendum covering the requirements for the voluntary module shall be prepared and dispatched to the company within 42 calendar days of the completion of the full audit.

The full BRC audit report together with the addendum for the voluntary module shall be uploaded to the BRC Global Standards Directory in a timely manner irrespective of whether a certificate is issued. The owner of the audit report may allocate access to the audit report with addendum to customers or other parties in the directory.

The audit report and associated documentation including auditor's notes shall be stored safely and securely for a period of 5 years by the certification body.

6.5 CERTIFICATION

After a review of the audit report for the voluntary module and documentary evidence provided in relation to the non-conformities identified, a certification decision shall be made by the designated independent certification manager. Where certification is granted this shall be included on the certificate for the BRC Global Standard for Food Safety and issued by the certification body within 42 calendar days of the audit.

Note the voluntary modules are certificated as an addendum to the Global Standard for Food Safety. Where certification to the Global Standard for Food Safety is not achieved, certification for the module cannot be awarded irrespective of whether the requirements of the module have been met.

6.6 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

6.6.1 Scheduling re-audit dates

If certification to the voluntary module is to be maintained the module shall be included within each subsequent Global Standards for Food Safety audit. The rules for scheduling the next audit and maintaining certification will follow the audit choice for the Global Standards for Food Safety (i.e. Announced, Unannounced option 1 or Unannounced option 2).

7 GENERAL PROTOCOL – POST AUDIT

7.1 COMMUNICATION WITH CERTIFICATION BODIES

In the event that any circumstances change within the site that may affect the validity of continuing certification, the site must immediately notify the certification body. This may include:

- legal proceedings with respect to product safety or legality
- product recall
- significant damage to the site (e.g. natural disaster such as flood or damage by fire)
- change of ownership
- significant change to the operation or scope.

The certification body in turn shall take appropriate steps to assess the situation and any implications for the certification, and shall take any appropriate action.

Information shall be provided to the certification body by the site on request so that an assessment can be made as to the effect on the validity of the current certificate.

The certification body may as appropriate:

- confirm the validity of certification
- suspend certification pending further investigation
- require further details of corrective action taken by the site
- undertake a site visit to verify the control of processes and confirm continued certification
- withdraw certification
- issue a new certificate with the new owner's details.

Changes to certification status of a site shall be recorded in the BRC Global Standards Directory.

7.2 EXTENSION TO SCOPE

Once certification has been granted, any additional significant products manufactured or processes undertaken by the site, which are required to be included in the scope of certification, must be communicated to the certification body. The certification body shall assess the significance of the new products or processes and decide whether to conduct a site visit to examine the aspects of the required extension to scope.

A revisit is required before granting a scope extension in the following circumstances:

- inclusion of manufacturing facilities not taken into account in the original audit
- inclusion of a new processing technology (e.g. canning of low-acid products where formerly only high-acid products were within scope)
- inclusion of new products which introduce a significant new risk to the facility (e.g. addition of a nut-based product to a previously allergen-free site).

A revisit is less likely where new products are extensions to the existing ranges produced on existing equipment.

Where an extension to scope is required shortly before the certificate is due to expire, it may be more appropriate to undertake a full audit and issue a new certificate. This option should be agreed between the certification body and their client prior to undertaking the extension to scope audit.

When a revisit is considered necessary, the duration of this visit will vary depending on the aspects to be examined for the required extension to scope. The site visit should be conducted along the same principles as the original audit (i.e. including an opening meeting, inspection of the operation of the process, documentation trails and closing meeting). The revisit should be announced, irrespective of whether the site is certificated to the announced or unannounced scheme.

Identified non-conformities should be documented and actioned within the normal protocol of the Standard (i.e. the company has 28 days to provide appropriate evidence of close-out and the certification body should review the information and confirm the certification decision in the normal manner). The additional non-conformities raised at the site visit will affect neither the current certificated grade nor continued certification. However, if practices are seen that give the certification body cause to doubt continued certification (e.g. the identification of a critical non-conformity) then the certification body shall arrange a full re-audit of the site. In these circumstances the current certificate shall be withdrawn.

A visit report should be documented, but shall not be in the format of a standard BRC audit report. A short explanation of the nature of the visit, what was audited and the conclusions should be given. The visit report should document what controls are in place and confirm the effectiveness of these controls. It should be clear in the report what aspects were looked at and what was excluded.

The site's current certificate will be superseded by any new certificate issued. The certificate must use the same expiry date as detailed on the original certificate. The due date of the next full audit will therefore remain the same and this should be made clear to the supplier by the certification body when arranging extension to scope visits. The grade shall also remain the same.

The certificate should include identification that it was a scope extension and the date of the visit.

7.3 CERTIFICATION WITHDRAWAL

The certificate may be withdrawn by the certification body in a number of circumstances where the site may no longer comply with the requirements of the BRC certification scheme and ISO/IEC 17065 requirement. Examples of these instances are:

- evidence that the site no longer complies with the requirements of the Standard, raising significant doubt of the conformity of the products produced
- failure to implement adequate corrective action plans within appropriate timescales
- evidence of falsification of records.

7.4 APPEALS

The company has the right to appeal the certification decision made by the certification body and any appeal should be made in writing to the certification body within 7 calendar days of receipt of the certification decision.

The certification body shall have a documented procedure for the consideration and resolution of appeals against the certification decision. These investigative procedures shall be independent of the individual auditor and certification manager. Individual certification bodies' documented appeals procedures will be made available to the site on request. Appeals will be finalised within 30 calendar days of receipt. A full written response will be given after the completion of a full and thorough investigation into the appeal.

In the event of an unsuccessful appeal, the certification body has the right to charge costs for conducting the appeal.

7.5 SURVEILLANCE OF CERTIFICATED COMPANIES

For certificated companies, where appropriate, the certification body or the BRC may carry out further audits or question activities to validate continued certification at any time. These visits may take the form of announced or unannounced visits to undertake either a full or part audit. Refusal of access to the site may affect certification status.

Any non-conformities identified at a visit must be corrected and closed out within the normal protocol (i.e. within 28 days of the visit), and reviewed and accepted by the certification body. If there is no intention on behalf of the site to take appropriate corrective actions or the corrective actions are deemed inappropriate, certification shall be withdrawn. The ultimate decision to suspend or withdraw certification remains with the certification body. Any change in certification status shall be notified to the BRC by the certification body and the status in the BRC Global Standards Directory amended accordingly.

In the event that certification is withdrawn or suspended by the certification body, the company shall immediately inform its customers and make them fully aware of the circumstances relating to the withdrawal or suspension. Information on the corrective actions to be taken in order to reinstate certification status should also be provided to customers.

7.6 BRC LOGOS

Achieving BRC certification is something of which to be proud. Companies that achieve certification and have no exclusions from their scope are qualified to use the BRC logo on site stationery and other marketing materials. Information and conditions relating to the use of the BRC logo is available at **www.brcglobalstandards.com**.

If a site is no longer certificated because of certificate expiry, withdrawal or suspension it shall no longer use the logo or certificate claiming certification.

The BRC logo is not a product certification mark and shall not be used on products or product packaging. Any certificated site found to be misusing the mark will be subject to the BRC complaints/referral process (see Part IV) and may risk suspension or removal of its certification.

The BRC logo may not be used by companies that do not include all products within the audit scope.

7.7 THE BRC GLOBAL STANDARDS DIRECTORY

The BRC Global Standards Directory (**www.brcdirectory.com**) is the database of all audits conducted against a BRC Global Standard, all certification bodies, all auditors and their recognised audit categories.

The directory holds full copies of all audit reports in read-only PDF. This includes archived audit documents from 2008 onwards.

Certification bodies are responsible for maintaining site name, address, audit content and certificate status. All certification bodies are assessed and graded by the BRC on how quickly and accurately they update audit data.

Audit reports can only be accessed following secure sign-in.

The directory also features a publicly accessible search function which displays certification data only. The public directory lists only currently certificated sites, not those expired or withdrawn.

Sites wishing to be excluded from public listing should contact their certification body.

7.7.1 Site code

Each audited site is allocated a unique seven-digit reference number known as a site code. This can be used to authenticate the validity of any certificate.

A site code is created when a site is audited for the first time and remains unchanged regardless of subsequent auditing certification bodies or audit status.

Site codes are located on the top right-hand corner of the first page of the audit report and on the corresponding certificate.

The listing for any certificated site can be located in the public directory by adding the site code to the 'Site Code' search field. If no results are returned for a search, contact the BRC to confirm certification authenticity.

7.7.2 Audit sharing

The directory allows audit owners to share their audit reports with customers including retailers, manufacturers, suppliers and other specifiers.

When audit sharing is set up, customers can access full current, archived and future audit documents (as they become available) without any further administration.

An audit owner can cancel sharing at any time. All sharing changes take immediate effect.

Audit documents shared in the directory cannot be edited or doctored by the audit owner. As such, audits obtained via the directory can be considered as complete and authenticated.

7.7.3 Notification emails

The directory notifies audit owners, and anybody who has shared access to the audit, if a site's certification is suspended, withdrawn or expires without replacement.

Notifications are via automated email and can be turned off if not required.

For further information on the directory or audit sharing, contact the BRC Directory Services team via **submissions@brcglobalstandards.com**.

PART IV
MANAGEMENT AND GOVERNANCE OF THE SCHEME

REQUIREMENTS FOR CERTIFICATION BODIES

TECHNICAL GOVERNANCE OF THE GLOBAL STANDARD FOR FOOD SAFETY

ACHIEVING CONSISTENCY – COMPLIANCE

PART IV
MANAGEMENT AND GOVERNANCE OF THE SCHEME

REQUIREMENTS FOR CERTIFICATION BODIES

The Global Standard for Food Safety is a process and product certification scheme. In this scheme, businesses are certificated upon completion of a satisfactory audit by an auditor employed by an independent third party – the certification body. The certification body in turn shall have been assessed and judged as competent by a national accreditation body.

The process of certification and accreditation is outlined in Figure 4.

In order for a business to receive a valid certificate on completion of a satisfactory audit, the organisation must select a certification body approved by the BRC. The BRC lays down detailed requirements that a certification body must satisfy in order to gain approval.

As a minimum, the certification body must be accredited to ISO/IEC 17065 by a national accreditation body affiliated to the International Accreditation Forum and recognised by the BRC.

Further details are available in the document 'Requirements for organisations offering certification against the criteria of the BRC Global Standards', which is available from the BRC on request.

Companies looking to become certificated to the Standard should assure themselves that they are using a genuine certification body approved by the BRC. A list of all certification bodies approved by the BRC is available on the BRC Global Standards Directory (**www.brcdirectory.com**).

The BRC recognises that in certain circumstances, such as for new certification bodies wishing to commence auditing against the Standard, accreditation may not yet have been achieved. This is because the accreditation process itself requires some audits to have been completed which will then be reviewed as part of the accreditation audit of the certification body. The certification body must be able to conduct audits as part of the process of achieving accreditation and so some unaccredited audits will be performed. This will be permitted where the organisation can demonstrate:

- an active application for accreditation against ISO/IEC 17065 from an approved national accreditation body
- that accreditation will be achieved within 12 months of the date of application and the experience and qualifications of the auditors in the relevant product category are consistent with those specified by the BRC
- a contract is in place with the BRC and all other contracted requirements have been met
- the acceptability of audit reports generated by certification bodies awaiting accreditation but meeting the above criteria is at the discretion of individual specifiers.

TECHNICAL GOVERNANCE OF THE GLOBAL STANDARD FOR FOOD SAFETY

The Standard and associated scheme is managed by the BRC with governance and technical advice provided through a number of stakeholder groups (see Figure 5), each of which works to a set of defined terms of reference.

INTERNATIONAL ADVISORY BOARDS

The technical management and operation of the Standard is governed by the BRC International Advisory Boards. These consist of senior technical representatives of international retail and food manufacturing businesses in Europe, America and Asia.

The functions of the advisory boards are to provide strategic advice on the development and management of the BRC Global Standards and the activities to ensure the effective management of the certification bodies and audit process.

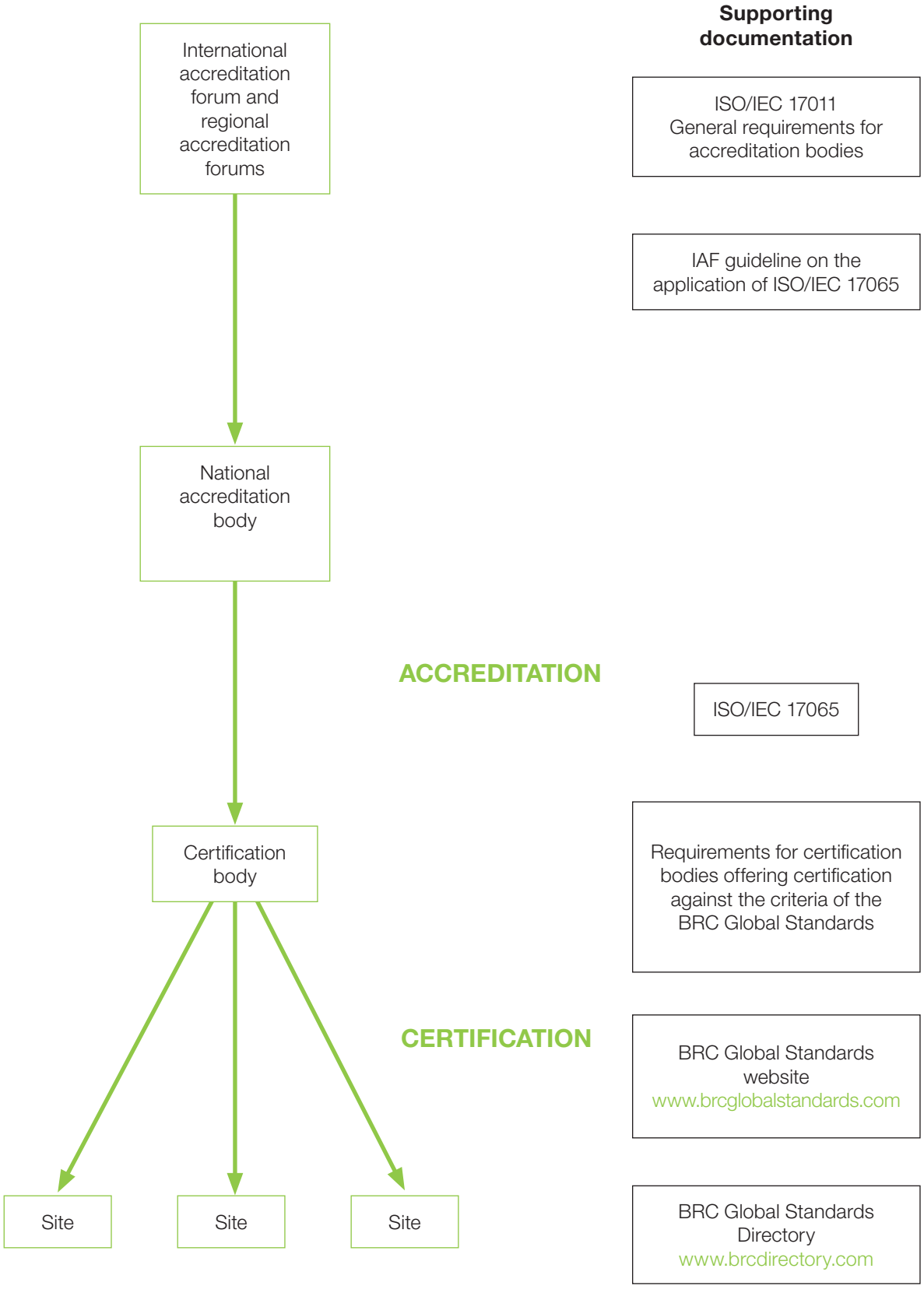


FIGURE 4 PROCESS FOR ACCREDITATION OF CERTIFICATION BODIES

TECHNICAL ADVISORY COMMITTEE

Each BRC Global Standard is supported by at least one Technical Advisory Committee (TAC), which meets regularly to discuss technical, operational and interpretational issues related to the Standard. The BRC provides the technical secretariat for these groups.

The TAC for the Global Standard for Food Safety is made up of senior technical managers representing the users of the Standard and includes representatives of retailers, food manufacturers, trade associations for each sector, certification bodies and independent technical experts.

The Standard is reviewed every 3 years to assess the need for updating or production of a new issue. This work is undertaken by the TAC, which is expanded for the purpose to include other available expertise.

The TAC also reviews auditor competence requirements, proposed training materials and supplementary technical documents supporting the Standards.

THE CERTIFICATION BODY CO-OPERATION GROUPS

The BRC encourages and facilitates meetings of the certification bodies participating in the scheme (co-operation groups) to discuss matters arising on the implementation of the Standard and discuss issues of interpretation. These groups report regularly to the BRC on operational issues, implementation and suggested improvements. Representatives from the co-operation groups attend the TAC meetings.

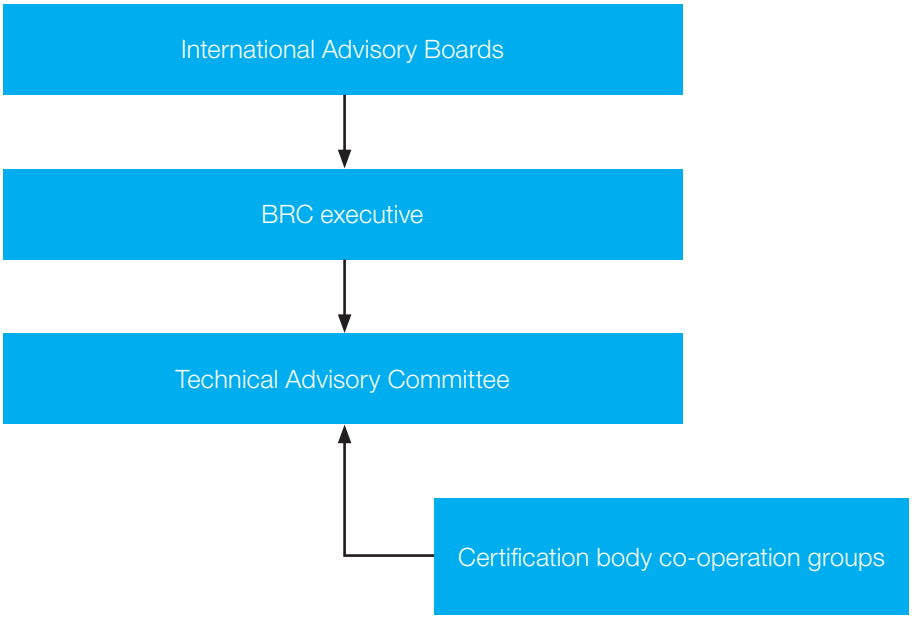


FIGURE 5 GOVERNANCE OF THE BRC SCHEMES

ACHIEVING CONSISTENCY – COMPLIANCE

The maintenance of a high and consistent standard of audit and certification, and the ability of the certificated sites to maintain the standards achieved at the audit, are essential to confidence in the scheme and to the value of certification. The BRC therefore has an active compliance programme to supplement the work of accreditation bodies and ensure high standards are maintained.

The BRC scheme may only be certificated by certification bodies registered and approved by the BRC and accredited by a BRC-recognised accreditation body. All auditors undertaking audits against the Standard must meet the BRC auditor competency requirements and shall be registered with the BRC. The qualifications, training and experience requirements for auditors who conduct audits against the BRC Global Standard for Food Safety are detailed in Appendix 5. All audits undertaken against the Standard shall be uploaded to the BRC Global Standards Directory, which provides the BRC with an oversight of the activity of the certification bodies and the opportunity to review the quality of the reports produced.

To support the Standard, the BRC operates a compliance programme which reviews the performance of the certification bodies, samples the quality of audit reports, assesses levels of understanding of the scheme requirements and investigates any issues or

complaints. As part of this programme the BRC provides feedback on the performance of each certification body through a key performance indicator (KPI) programme.

As part of the compliance programme the BRC audits the offices of certification bodies and accompanies auditors on audits at sites to observe the performance of auditors. The BRC may also undertake independent visits to certificated sites to ensure standards of food safety and quality are being maintained in line with its certification status and ensure that the audit and reporting process is to the expected standard.

CALIBRATING AUDITORS

A key component of the scheme is the calibration of the auditors to ensure a consistent understanding and application of the requirements. All certification bodies are required to have processes to calibrate their own auditors. An essential element of the training and calibration of auditors is the witnessed audit programme. Auditors are observed during an audit and provided with feedback on the performance of the audit. In order to ensure consistency between certification bodies and for the purposes of accreditation, an audit may be witnessed by a BRC representative or accreditation body auditor. Guidelines apply to these activities to ensure that sites are not disadvantaged by the presence of two auditors. This process forms an essential part of the scheme and sites are obliged to permit witnessed audits as part of the conditions for certification.

FEEDBACK

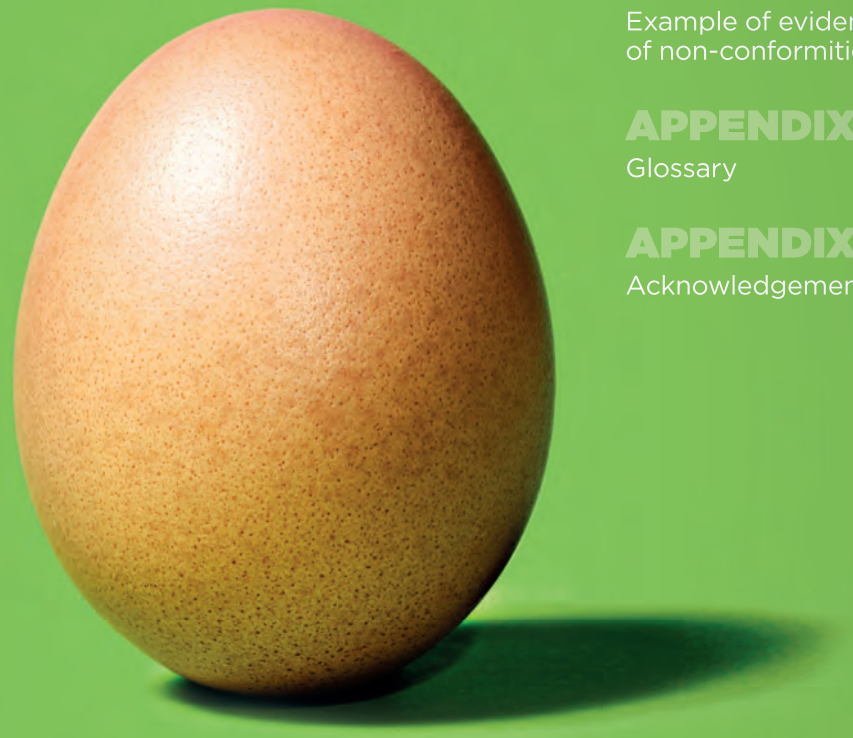
Companies audited against the Standard may wish to provide feedback to the certification body or the BRC on the performance of the auditor. Such feedback sent to the BRC will be considered in confidence. Feedback provides a valuable input to the BRC monitoring programme for certification body performance.

COMPLAINTS

The BRC has implemented a formal complaint process, which is available to organisations involved with the Global Standards. This is available on the website (**www.brcglobalstandards.com**).

From time to time, failure to apply the principles and criteria of the BRC Global Standards at certificated sites may be reported to the BRC by, for example, retailers and companies conducting their own audits. In this event, the BRC will conduct an investigation as appropriate and may undertake announced or unannounced visits to a certificated site.

APPENDICES



APPENDIX 1
OTHER BRC GLOBAL STANDARDS

The BRC has developed a range of Global Standards which set out the requirements for the manufacture of food and consumer products, the packaging used to protect the products and the storage and distribution of these products. The other BRC Standards complement the Food Safety Standard and provide a resource for the auditing and certification of suppliers.

The **BRC Global Standard for Packaging & Packaging Materials** is an auditing standard that lays down the requirements for the manufacturing of packaging materials used for food and consumer products. Food and non-food businesses may request this from their suppliers of packaging.

The **BRC Global Standard for Storage and Distribution** is an auditing standard that sets out the requirements for the storage, distribution, wholesaling and contracted services for packaged and unpackaged food products, packaging materials and consumer goods. The Standard is not applicable to storage facilities under the direct control of the production facility management, which is covered by the relevant manufacturing Standard (e.g. the BRC Global Standard for Food Safety).

The **BRC Global Standard for Consumer Products** is an auditing standard applicable to the manufacture and assembly of consumer products. This specifically excludes food-associated products such as vitamins, minerals and herbal supplements, which fall within the scope of the BRC Global Standard for Food Safety.

The **BRC Global Standard for Agents and Brokers** is an auditing standard which enables companies to be audited and certificated where they buy and sell products or provide services to other parties but are unable to gain certification to the production or storage and distribution standards because there is no product present to be audited.

APPENDIX 2
GUIDELINES ON DEFINING PRODUCTION RISK ZONES

The Standard identifies a number of different risk zones within the processing and storage facilities, with corresponding levels of hygiene and segregation to reduce the potential for product contamination. The decision trees (Figures 6 and 7) provide a guide to defining the risk zones. These are classified as:

- high risk (chilled and frozen)
- high care (chilled and frozen)
- ambient high care
- low risk
- enclosed product areas (e.g. warehouses and storerooms)
- non-product areas (e.g. canteens, laundries and offices).

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

OPEN PRODUCT AREAS

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

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

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

HIGH RISK (CHILLED AND FROZEN)

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

- The finished products require chilling or freezing during storage to preserve food safety.
- All components have received a full cook[1] process to a minimum of 70°C for 2 minutes or equivalent (see Appendix 3) before entry to the area.
- The finished products are vulnerable to the growth of pathogens (e.g. *Listeria* species) or the survival of pathogens, which could subsequently grow during the normal storage or use of the product (e.g. if a frozen product is defrosted but not immediately consumed).
- The finished products are ready to eat[2] or ready to heat[3] or, on the basis of known consumer use, are likely to be eaten without adequate cooking.

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

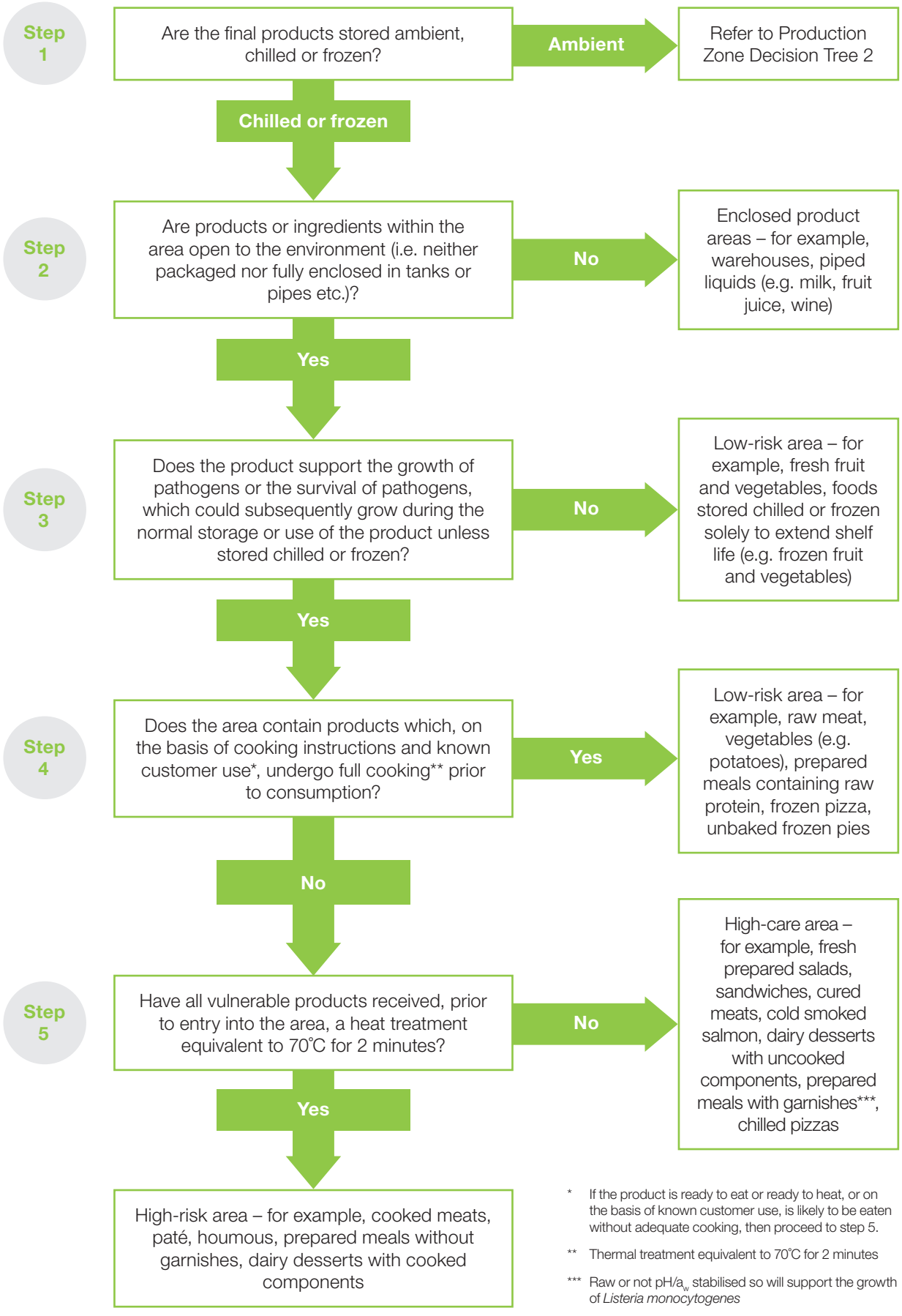


FIGURE 6 PRODUCTION ZONE DECISION TREE 1 – CHILLED AND FROZEN PRODUCTS

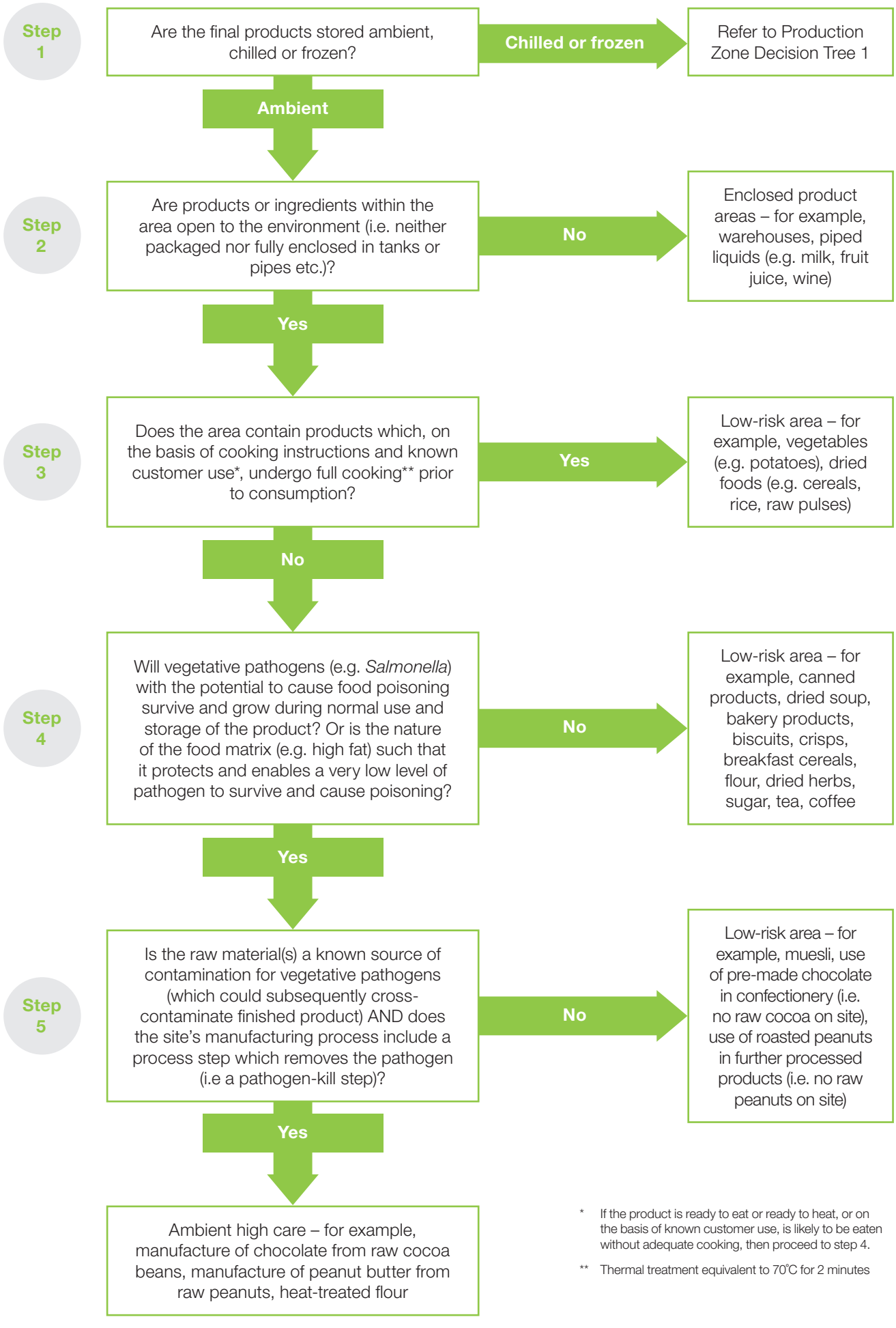


FIGURE 7 PRODUCTION ZONE DECISION TREE 2 – AMBIENT PRODUCTS

It should be noted that where the product has cooking instructions for the consumer that are equivalent to a full cook, then the product may be considered as low risk. In these situations, the site is expected to have a full validation, which the auditor can refer to, demonstrating that the cooking instructions are appropriate and that the product will achieve the correct temperature/time when the cooking instructions are used.

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

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

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

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

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

Time segregation is not an acceptable alternative to physical segregation for high-risk areas.

HIGH CARE (CHILLED AND FROZEN)

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

- The finished products require chilling or freezing during storage.
- All microbiologically susceptible components have received a process to reduce the microbiological contamination to acceptable levels (typically 1–2 log reduction of micro-organisms such as *Listeria* species) before entry to the area.
- The finished products are vulnerable to the growth of pathogens or the survival of pathogens, which could subsequently grow during the normal storage or use of the product (e.g. if a frozen product is defrosted but not immediately consumed).
- The finished products are ready to eat[2] or ready to heat[3] or, on the basis of known consumer use, are likely to be eaten without adequate cooking.

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

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

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

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

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

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

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

AMBIENT HIGH CARE

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

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

- A raw material(s) is prone to contamination with a vegetative pathogen (e.g. *Salmonella* species).
- The production process includes a process step which removes or reduces the pathogen (e.g. a microbiological kill step). (Where there is no effective step it is assumed that any risk associated with the raw material is controlled as part of the raw material risk assessment.)
- The finished products are stored at ambient temperatures (i.e. greater than 5°C).
- The finished products are ready to eat[2] or ready to heat[3] or, on the basis of known consumer use, are likely to be eaten without adequate cooking.
- The finished products are such that vegetative pathogens could survive and grow in normal use, subsequently causing food poisoning, or are of a nature (e.g. fatty foods) that enables food poisoning to result from a very low level of contamination with a pathogen.

Examples of processes that require an ambient high-care processing area include the manufacture of chocolate from raw cocoa beans, the production of milk powder from raw liquid milk or the manufacture of peanut butter from raw peanuts.

Ambient high-care products do not include those products where the risk of vegetative pathogen contamination from the raw material has been controlled at an earlier stage in the supply chain. For example, a biscuit manufacturer purchasing ready-made chocolate for incorporation into a biscuit would not be considered ambient high care as the risk is associated with raw cocoa beans and has been controlled by the chocolate supplier. The biscuit manufacturer would, however, be expected to have a raw material risk assessment process(es) in place that ensured the raw material received met the appropriate standards.

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

It should be noted that the BRC Standard includes only two clauses relating to specific requirements for ambient high care (clauses 4.3.1 and 4.3.7). Clauses which refer to either high risk or high care (without reference to ambient products) are not applicable to ambient high care.

LOW RISK

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

- do not support the growth of pathogens (either intrinsically or by design of the product) or the survival of pathogens, which could subsequently grow during the normal storage or use of the product
- are designed to undergo a later kill step that ensures the product is safe to eat.

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

Products manufactured in this area include the following:

- Products which will always require cooking by the consumer before consumption (e.g. raw meat and fish). Where consumer cooking instructions are provided, these must be fully validated.
- Products that are processed within the final container (e.g. canned).
- Products unsuitable for the growth and/or survival of pathogens which are stored and distributed as ambient products (e.g. preserves, pH-controlled products such as pickles, low a_w foods such as dried pasta and sugar confectionery).
- Ready-to-eat products stored chilled or frozen to preserve the quality of the product, but which have other controls to prevent the growth of pathogens (e.g. hard cheese).
- Raw materials or prepared products and mixes before undergoing a kill step prior to transfer into high-risk or high-care areas.

Examples of products considered as low risk include raw meat, sugar and flour.

ENCLOSED PRODUCT AREAS

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

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

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

NON-PRODUCT AREAS

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

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

PRODUCTION AREA DECISION TREES

The decision trees shown in Figures 6 and 7 provide a guide to the categorisation of production areas but cannot take account of specific product characteristics (e.g. pH or a_w) or the vulnerability of particular products to pathogens or spoilage that may result in exceptions. A detailed risk assessment should be undertaken where necessary to support the decision.

1 'Cook' is a thermal process which is designed to achieve typically a 6 log reduction in *Listeria monocytogenes* equivalent to 70°C for 2 minutes. Alternative cooking processes may be accepted or required where these meet recognised national guidelines and are validated by scientific data. Note that other processes achieving a 6 log reduction (e.g. irradiation, high-pressure processes) should be considered in the same way as conventional 'cook' processes.

2 Ready-to-eat food is food that is intended by the manufacturer for direct human consumption without the need for cooking or other processes to eliminate or reduce to an acceptable level micro-organisms of concern.

3 Ready-to-heat food products are designed to be safe to be consumed without the need for a full cook; the reheating of the product is intended to make it more palatable and is not a microbiological kill step.

APPENDIX 3
EQUIVALENT PROCESSES TO ACHIEVE 70°C FOR 2 MINUTES

Table 2 shows the equivalent cooking processes designed to achieve 70˚C for 2 minutes that have been calculated using a *z* value of 7.5˚C. For example, if heating at 68˚C, Table 2 indicates that 1 minute of heating at 68˚C is equivalent to 0.541 minutes at 70˚C. Therefore, to achieve the equivalent of 2 minutes at 70˚C, it would be necessary to heat at 68˚C for 3.70 minutes (2 ÷ 0.541 = 3.70).

This table is reproduced with permission from Campden BRI Guideline 51 – *Pasteurisation: A Food Industry Practical Guide* (second edition, 2006). It is for illustrative purposes only. The equivalent times given are dependent on the *z* value of the organism in question, which in this example is given as 7.5˚C. The *z* values vary from one strain to another, and can also change with temperature. Copies of the document are available from the Campden BRI publications section (telephone: +44 (0)1386 842048, email: **pubs@campden.co.uk**).

TABLE 2 EQUIVALENT PROCESSES TO ACHIEVE 70ºC FOR 2 MINUTES

TEMPERATURE AT THE SLOWEST HEATING POINT (°C)	LETHAL RATE (MIN) (EQUIVALENT TO 1 MIN AT 70°C)	TIME REQUIRED AT THE REFERENCE TEMPERATURE TO ACHIEVE AN EQUIVALENT PROCESS (MIN)
60	0.046	43.48
61	0.063	31.74
62	0.086	23.26
63	0.116	17.24
64	0.158	12.66
65	0.215	9.30
66	0.293	6.83
67	0.398	5.02
68	0.541	3.70
69	0.735	2.72
70	1.00	2.00
71	1.36	1.47
72	1.85	1.08
73	2.51	0.80 (48 s)
74	3.41	0.60 (36 s)
75	4.64	0.43 (26 s)
76	6.31	0.32 (19 s)
77	8.58	0.23 (14 s)
78	11.66	0.17 (10 s)
79	15.85	0.13 (8 s)
80	21.54	0.09 (5 s)

APPENDIX 4
MULTIPLE SITES AUDIT PROTOCOL

SCOPE OF AUDIT

The scope of a BRC audit needs to be agreed between the site and the certification body prior to the audit.

The audit, report and certificate shall be 'product' and 'site' specific. However, in some circumstances, more than one site may be included under a single certification. This will be considered exceptional, but allowable under the following rules.

Audits may cover multiple site addresses where **all** of the following rules apply:

- all sites are under the same organisation ownership
- all sites are operated against the same documented quality management systems
- sites manufacture product which is part of the same manufacturing process
- the sites solely supply the other sites with no additional customers
- the sites are no more than 30 miles/50 km apart.

AUDIT PLANNING

All sites must be visited as part of the same audit schedule (i.e. within the same timeframe).

The certification body's audit plan needs to clearly show the sites that shall be audited.

It must be clearly stated on the report and certificate that the audit has consisted of visits to more than one site address (e.g. the manufacture of cheese at Cheddar Industrial Estate, Wensleydale, Yorkshire, and maturation at Camembert Road, Ripon).

AUDITING OF ACTIVITIES WHERE THE HEAD OFFICE IS LOCATED SEPARATELY

When undertaking audits of sites which are part of a larger manufacturing group, it is not uncommon for some of the requirements within the scope of the Standard to be undertaken by a central or head office. Typically this may apply to activities such as purchasing, supplier approval, product development, product recall and, occasionally, this extends to a group-shared quality management system – document control and procedures.

All requirements within the scope of the Standard must be assessed as satisfactory before a certificate can be issued. This requires that any centrally managed systems are included within the audit process; however, there are alternative processes for achieving this.

There are two approaches to auditing the requirements which are managed at a central office:

- Request and review information while at the manufacturing site as part of the site audit – standard audit.
- Undertake a separate audit of the centrally managed processes at the group/head office location – two-stage audit.

APPROACH 1 – REQUESTING AND REVIEWING INFORMATION AT THE MANUFACTURING SITE

This is recommended only where:

- satisfactory links can be established with the central office (telephone or video conferencing links to allow interview of relevant personnel, fax or email links to allow documents to be requested and viewed), and arrangements in place to ensure availability of relevant personnel
- the amount and type of information can be effectively reviewed and challenged remotely.

Note: where a site elects for the information to be assessed during the manufacturing site audit and satisfactory information cannot be provided during the audit, unsubstantiated requirements shall be recorded as non-conformities on the site audit report.

Reporting
The audit report shall make it clear where a requirement is managed by a central office together with a comment on how the company complies with the requirement.

Non-conformities
Non-conformities raised against a centrally operated requirement shall be recorded on the audit report and included within the count of non-conformities contributing to the site grade.

Corrective action shall be assessed in the same way as for non-conformities raised at the manufacturing site and must be satisfactorily corrected before a certificate can be issued to the site.

Subsequent manufacturing site audits
The central system requirements shall be challenged and evidence of compliance be provided at each manufacturing site audit.

APPROACH 2 – TWO-STAGE AUDITS: CENTRAL SYSTEM AND SEPARATE MANUFACTURING SITE AUDITS

This approach is recommended where it is not practical to effectively assess requirements from the manufacturing site. For example where:

- practical arrangements to allow assessment cannot be provided
- there are too many centrally managed requirements to effectively review remotely.

This shall be offered to the site being audited and undertaken when requested by the site.

Stage 1 – Central system audit
The audit of the central system shall be completed before undertaking the manufacturing site audit.

The audit shall assess both how the central system complies with the relevant requirement of the Standard and how this links to the manufacturing site operation.

Reports for the central system audit
The certification body may produce a report of the central system audit for the benefit of the company. However, as this audit will only include some of the requirements of the BRC Standard:

- no grade may be allocated
- no certificate may be issued
- the report must be in a format which is clearly different from the full BRC audit report.

The central system report shall not be uploaded to the BRC Global Standards Directory but the findings of the central system audit shall be incorporated into the final audit report of each of the associated manufacturing sites.

Recording non-conformities identified at the central system audit
All non-conformities identified at the central office audit shall be recorded on the audit report of the first manufacturing site audited following the central systems audit – irrespective of whether these have been closed out before that audit or not.

However, only those non-conformities raised at the central office audit which have not been closed out to the satisfaction of the certification body at the time of the manufacturing site audit shall be counted when calculating the grade for the manufacturing site.

Any non-conformities identified at the head office audit which are still outstanding at the time of further manufacturing site audits (second, third etc.) shall be included on that manufacturing site report and be included when calculating the grade for the site.

Closure of central systems corrective actions
Corrective actions required following the central office audit shall be assessed in the same way as corrective actions raised at the manufacturing site and must be satisfactorily corrected before a certificate can be issued to the manufacturing sites. This may be by documentary evidence or a revisit, as appropriate.

Stage 2 – Manufacturing site(s) audit
Information from the central office audit (including any evidence of corrective actions taken) shall be made available to the auditors of the associated manufacturing sites by the certification body.

The auditor shall establish that the central systems components assessed are the same as those operating at the manufacturing site. The auditor shall verify any corrective actions already taken following the central systems audit.

Audit duration
It may be possible to reduce the duration of the manufacturing site audit to take account of systems already audited at a central office.

BRC audit report
The final audit report shall be applicable to the manufacturing site.

The central office audit shall be commented upon in the Company Profile; for example: 'An audit was carried out at the central office at ..... on the ..... to assess requirements as indicated in the report'.

The key personnel may include the names of key staff present at the central office audit.

The manufacturing site(s) audit report shall include information about how both the site and the central system comply with the requirements of the Standard. The report shall indicate where a requirement is managed by a central office and provide an explanation of how that requirement is satisfied.

Corrective action
The 28 days allowed for evidence of corrective action to be provided starts from the date of the manufacturing site audit.

It is the responsibility of the site to ensure that head office corrective actions have been provided to the certification body in order to allow the site to become certificated. This will require effective communication with the central systems office.

Where central systems corrective actions have been accepted prior to the first manufacturing site audit, this shall be indicated on the first manufacturing site audit report and the date of acceptance of the action indicated in the 'action taken' section of the non-compliance report.

Certificate
The certificate, where awarded, is issued to the manufacturing site. The re-audit date for the manufacturing site is based on the grade achieved and shall be 6 or 12 months from the initial audit date.

The central office audits shall be carried out every 12 months and shall occur before the anniversary of the audit of the first manufacturing site.

Audits of other manufacturing sites associated with the central system
Usually there will be several manufacturing sites associated with a central system. The information from the annual central system audit shall be used for each subsequent manufacturing site audit.

Non-conformities originally raised at the central office and effectively corrected before the audit of that manufacturing site shall not be recorded as non-conformities on the site audit report. Any outstanding non-conformities at the time of the manufacturing site audit shall, however, be included within that site's report and calculation for grading purposes.

The BRC shall be contacted for advice before carrying out audit programmes for more complex arrangements of sites and centralised systems.

APPENDIX 5
QUALIFICATIONS, TRAINING AND EXPERIENCE REQUIREMENTS FOR AUDITORS

The following identify the minimum requirements for auditors to conduct audits against the BRC Global Standard for Food Safety.

EDUCATION

The auditor shall have a degree in a food-related or bioscience discipline, or as a minimum have successfully completed a higher education course in such a discipline.

WORK EXPERIENCE

The auditor shall have a minimum of 5 years' post-qualification experience related to the food industry. This shall involve work in quality assurance or food safety functions within manufacturing, retailing, inspection or enforcement, and the auditor shall be able to demonstrate an understanding and knowledge of specific product categories for which they are approved. The verification of the auditor's ability to carry out work within specific product categories is the responsibility of the certification body.

QUALIFICATIONS

The auditor must have:

- Passed a registered Management System Lead Assessor Course (e.g. IRCA) or the BRC Third Party Auditor course delivered by a BRC-approved trainer.
- Completed a training course in HACCP (as evidenced by examination), based on the principles of Codex Alimentarius, of at least 2 days' duration, and be able to demonstrate competence in the understanding and application of HACCP principles. It is essential that the HACCP course is recognised by the industry (and its stakeholders) as being appropriate and relevant.

AUDIT TRAINING

Auditors must have successfully completed a period of supervised training (including witnessed audits) in practical assessment through 10 audits (minimum 15 audit days) involving third-party food safety audits against Global Food Safety Initiative (GFSI)-approved Standards or ISO 22000 of which at least five audits must be against the Global Standard for Food Safety.

Certification bodies must be able to demonstrate that every auditor has appropriate training and experience for the particular categories for which they are considered competent. Auditor competence shall be recorded at least at the level of each category, as indicated in Appendix 6.

Certification bodies must establish training programmes for each auditor that incorporate:

- a Global Standard for Food Safety awareness course delivered by a BRC-approved trainer
- a period of initial training covering product safety, HACCP and prerequisite programmes, and access to relevant laws and regulations
- a period of supervised training to cover quality management systems, audit techniques and specific category knowledge
- assessment of knowledge and skills for each category
- documented sign-off after the satisfactory completion of the training programme.

Each auditor's training programme shall be managed and approved by a technically competent person within the certification body who can demonstrate technical competence in the categories in which training is given.

Full detailed training records of the individual shall be maintained by the certification body throughout the term of employment, and retained for a minimum period of 5 years after leaving the employment of the certification body.

EXCEPTIONS

Where a certification body employs an auditor who does not fully meet the specific criteria but has been assessed as competent, there shall be a fully documented justification in place to support the employment of the auditor which is agreed by the BRC.

RESPONSIBILITY OF THE CERTIFICATION BODY

It is the responsibility of the certification body to ensure processes are in place to monitor and maintain the competence of the auditor to the level required by the Standard.

APPENDIX 6
PRODUCT CATEGORIES

The product examples listed in Table 3 are given as guidance only and this is not an exhaustive list. The BRC will publish updated examples on the BRC website at **www.brcglobalstandards.com**.

TABLE 3 PRODUCT CATEGORIES

FIELD OF AUDIT	CATEGORY NO.	CATEGORY DESCRIPTION	PRODUCT EXAMPLES	STORAGE CONDITIONS	EXAMPLES OF KNOWLEDGE OF TECHNOLOGY REQUIRED BY AUDITOR
Raw products of animal or vegetable origin that require cooking prior to consumption	1	Raw red meat	Beef/veal, pork, lamb, venison, offal, other meat	Chilled, frozen	Slaughter, primary cutting and butchery Vacuum packing Modified atmosphere packaging
	2	Raw poultry	Chicken, turkey, duck, goose, quail, farmed and wild game Shell egg	Chilled, frozen	Slaughter and primary cutting Vacuum packing Modified atmosphere packaging
	3	Raw prepared products (meat and vegetarian)	Bacon, comminuted meat products (e.g. sausages), meat puddings, ready-to-cook meals, ready prepared meat products, pizzas, vegetable prepared meals, steamer meals, chips	Chilled, frozen	Retail butchery, processing and packing Curing, vacuum packing, modified atmosphere packaging
	4	Raw fish products and preparations	Wet fish, molluscs, crustacea, comminuted fish products (e.g. fish fingers), cold smoked fish, ready-prepared fish products (e.g. fish pie)	Chilled, frozen	Stunning, harvesting Vacuum packing, modified atmosphere packaging
Fruit, vegetables and nuts	5	Fruit, vegetables and nuts	Fruit, vegetables, salads, herbs, nuts (unroasted)	Fresh	Washing, grading
	6	Prepared fruit, vegetables and nuts	Prepared/semi-processed fruit, vegetables and salads including prepared ready-to-eat salads, coleslaws, frozen vegetables	Chilled, frozen	Blanching, freezing High-care principles

Table continues

TABLE 3 PRODUCT CATEGORIES *continued*

FIELD OF AUDIT	CATEGORY NO.	CATEGORY DESCRIPTION	PRODUCT EXAMPLES	STORAGE CONDITIONS	EXAMPLES OF KNOWLEDGE OF TECHNOLOGY REQUIRED BY AUDITOR
Processed foods and liquids with pasteurisation or UHT as heat treatment or similar technology	7	Dairy, liquid egg	Liquid egg, liquid milk/drinks, cream, liquid tea and coffee creamers, yogurts, fermented milk-based products, fromage frais/crème fraîche, butter Ice cream Cheeses – hard, soft, mould ripened, unpasteurised, processed, cheese food Long-life milks, non-dairy products (e.g. soya milk), ambient yogurts, custards etc. Fruit juices (includes freshly squeezed and pasteurised, smoothies) Dried whey powder, dried egg, dried milk/ milk formulation	Chilled, frozen, ambient	Dairy technology – pasteurisation, separation, fermentation High-risk principles
Processed foods, ready-to-eat or heat	8	Cooked meat/fish products	Cooked meats (e.g. ham, meat pâté, hot eating pies, cold eating pies), molluscs (ready to eat), crustaceans (ready to eat), fish pâté Hot smoked fish, poached salmon	Chilled, frozen	High/low-risk principles Vacuum packs Heat treatment
	9	Raw cured and/or fermented meat and fish	Parma ham, cold smoked fish, cured fish (e.g. gravlax), air-dried meats/ salami, fermented meats, dried fish	Chilled	Curing, fermentation, smoking High/low-risk principles
	10	Ready meals and sandwiches, ready-to-eat desserts	Ready meals, sandwiches, soups, sauces, pasta, quiche, flans, meal accompaniments, cream cakes, trifles, assembled high-risk sweet desserts	Chilled, frozen	High/low-risk principles
Ambient stable products with pasteurisation or sterilisation as heat treatment	11	Low/high acid in cans/glass	Canned products (e.g. beans, soups, meals, fruit, tuna). Products packed in glass (e.g. sauces, jams, pickled vegetables) Pet food	Ambient	Canning Thermal processing UHT

TABLE 3 PRODUCT CATEGORIES *continued*

FIELD OF AUDIT	CATEGORY NO.	CATEGORY DESCRIPTION	PRODUCT EXAMPLES	STORAGE CONDITIONS	EXAMPLES OF KNOWLEDGE OF TECHNOLOGY REQUIRED BY AUDITOR
Ambient stable products not involving sterilisation as heat treatment	12	Beverages	Soft drinks including flavoured water, isotonics, concentrates, squashes, cordials, minerals, table waters, ice, herbal drinks, food drinks	Ambient	Water treatment Heat treatment
	13	Alcoholic drinks and fermented/ brewed products	Beer, wine, spirits Vinegars Alcopops	Ambient	Distilling, fermentation, fortification
	14	Bakery	Bread, pastry, biscuits, cakes, tarts, breadcrumbs	Ambient, frozen	Baking
	15	Dried foods and ingredients	Soups, sauces, gravies, spices, stocks, herbs, seasonings, stuffings, pulses, legumes, rice, noodles, nut preparations, fruit preparations, dried pet food, vitamins, salt, additives, gelatine, glacé fruit, home baking, syrups, sugar, tea, instant coffee and coffee creamers	Ambient	Drying, heat treatment
	16	Confectionery	Sugar, chocolate, gums and jellies, other sweets	Ambient	Heat treatment
	17	Cereals and snacks	Oats, muesli, breakfast cereals, roasted nuts, crisps, poppadoms	Ambient	Extrusion, heat treatment
	18	Oils and fats	Cooking oils, margarine, shortening, spreads, suet, ghee Salad dressings, mayonnaise, vinaigrettes	Ambient	Refining, hydrogenation

APPENDIX 7
CERTIFICATE TEMPLATE

Auditor number

CERTIFICATION BODY NAME OR LOGO

[Certification body name, certification body number] certifies that, having conducted an audit

For the scope of activities:

Including voluntary modules of:

Exclusions from scope:

Product categories:

At COMPANY NAME
SITE CODE
AUDIT SITE ADDRESS

Has achieved Grade:

Meets the requirements set out in the

BRC GLOBAL STANDARD for FOOD SAFETY

ISSUE 7: JANUARY 2015

Audit programme: [announced, unannounced option 1 or option 2, reissued after extension to scope]

Date(s) of audit: [include two date ranges for unannounced option 2. If an extension to scope, include original audit date and visit date]

Certificate issue date:

Re-audit due date: from to

Certificate expiry date:

Accreditation body logo

Authorised by

BRC logo

Name and full address of certification body

Certificate traceability reference

This certificate remains the property of [name of certification body]

If you would like to feedback comments on the BRC Global Standard or the audit process directly to BRC, please contact enquiries@brcglobalstandards.com or call the Tell BRC Hot line +44 (0)20 7717 5959.

APPENDIX 8
EXAMPLE OF EVIDENCE SUBMITTED FOR CORRECTION OF NON-CONFORMITIES AND PREVENTIVE ACTION

MAJOR						
NO.	REQUIREMENT REF.	DETAILS OF NON-CONFORMITY	CORRECTION	PROPOSED PREVENTIVE ACTION PLAN (BASED ON ROOT CAUSE ANALYSIS)	EVIDENCE PROVIDED (DOCUMENT/ PHOTOGRAPH/ VISIT/OTHER)	REVIEWED BY AND DATE
1	4.10.3.2	Metal detectors on both roll plants failed to reject ferrous and non-ferrous test pieces (synchronisation error)	Engineer called and adjusted synchronisation immediately Test method changed to include rejection of test packs Staff trained	Proposed preventive action plan: 1) Staff retrained in the importance of, and requirements for, metal detection. (This is not the same as the procedure training listed in correction) 2) Specific checks on all metal detectors included in the internal audit schedule 3) Review of all items in the internal audit programme to ensure all the relevant systems and processes have been included 4) Metal detection procedure and record sheets updated to include requirement for sign-off by a suitable manager (e.g. a shift or line manager)	Copy procedure and training record	M. Oliver 26/07/2015

APPENDIX 9
GLOSSARY

Accreditation	The procedure by which an authoritative body gives formal recognition of the competence of a certification body to provide certification services against a specified Standard.
Adulteration	The addition of an undeclared material into a food item for economic gain.
Agent	A company that facilitates trade between a site or company and their raw material or packaging suppliers or their customers through the provision of services, but does not at any point own or take title to the goods.
Allergen	A known component of food which causes physiological reactions due to an immunological response (e.g. nuts and others identified in legislation relevant to the country of production or sale).
Ambient high care	An ambient area designed to a high standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to minimise potential product contamination by pathogenic micro-organisms.
Announced audit	An audit where the company agrees the scheduled audit day in advance with the certification body.
Assured status	Products produced in accordance with a recognised product certification scheme, the status of which needs to be preserved through the BRC-certified production facility (e.g. GlobalGAP).
ATP bioluminescence techniques	A rapid test for cleanliness of surfaces based on ATP (adenosine triphosphate) – a substance used in energy transfer in cells and therefore present in biological material.
Audit	A systematic examination to measure compliance of practices with a predetermined system, and whether the system is implemented effectively and is suitable to achieve objectives, carried out by certified bodies.
Auditor	A person possessing the appropriate competence and skills to carry out an audit.
Authenticity	Food authenticity is ensuring that food or raw materials purchased and offered for sale, are of the nature, substance and quality expected.
Brand owner	The owner of a brand logo or name who places the said logo or name onto retail products.
Branded product	Products bearing the logo, copyright or address of a company that is not a retailer.
BRC Global Markets programme	A recognition and audit scheme designed for sites which are either very small and for whom the full Standard may not be appropriate or for sites which are developing their food safety management systems.
Broker	A company which purchases or 'takes title to' products for resale to businesses (e.g. manufacturers, retailers or food service companies) but not to the ultimate consumer.
Calibration	A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or reference material, and the corresponding values realised by standards.
Certificate suspension	Revocation of certification for a given period, pending remedial action on the part of the company.
Certificate withdrawal	Where certification is revoked. Certification may only be regained following successful completion of the full audit process.
Certification	The procedure by which an accredited certification body, based on an audit and assessment of a company's competence, provides written assurance that a company conforms to a standard's requirements.

Certification body	Provider of certification services, accredited to do so by an authoritative body and registered with the BRC.
Clause	A specific requirement or statement of intent that a site must comply with in order to achieve certification.
Cleaning in place (CIP)	The process of cleaning and sanitising food-processing equipment in its assembled position without the need for dismantling and cleaning the individual parts.
Codex Alimentarius Commission	A body responsible for establishing internationally recognised standards, codes of practice and guidelines, of which HACCP (Hazard Analysis and Critical Control Point) is one standard.
Company	The entity with legal ownership of the site which is being audited against a BRC Global Standard.
Competence	Demonstrable ability to apply skill, knowledge and understanding of a task or subject to achieve intended results.
Compliance	Meeting the regulatory or customer requirements concerning product safety, legality and quality.
Consumer	The end-user of the finished product, commodity or service.
Contamination	Introduction or occurrence of an unwanted organism, taint or substance to packaging, food or the food environment. Contamination includes physical, chemical, biological and allergen contamination.
Contract packer	A company that packages the final product into consumer packaging.
Contractor or supplier	A person or organisation providing services or materials.
Control	To manage the conditions of an operation to maintain compliance with established criteria, and/or the state wherein correct procedures are being followed and criteria are being met.
Control measure	Any action or activity that can be used to prevent or eliminate a product safety hazard or reduce it to an acceptable level.
Controlled document	A document which is identifiable and for which revisions and removal from use can be tracked. The document is issued to identified individuals and their receipt of the document is recorded.
Cook	A thermal process designed to heat a food item to a minimum of 70°C for 2 minutes or equivalent (see Appendix 3). Alternative cooking processes may be accepted or required where these meet recognised national guidelines and are validated by scientific data.
Correction	Action to eliminate the cause of a detected non-conformity.
Critical control point (CCP)	A step at which control can be applied and is essential to prevent or eliminate a food or product safety hazard or reduce it to an acceptable level.
Cross-docking	Material is unloaded at distribution premises, and handled, but not formally put away into storage. This may be a staging area where inbound materials are sorted, consolidated and temporarily stored until the outbound shipment is complete and ready to ship.
Customer	A business or person to whom a service or product has been provided, either as a finished product or as a component part of the finished product.
Customer focus	A structured approach to determining and addressing the needs of an organisation to which the company supplies products and which may be measured by the use of performance indicators.
Despatch/dispatch	The point at which the product leaves the factory site or is no longer the responsibility of the company.
Distribution	The transportation of goods within any container (goods on the move) by road, rail, air or ship.
End consumer	The ultimate consumer of a foodstuff, who will not use the food as part of any food business operation or activity.
Enclosed product area	An area of the factory where all products are fully enclosed and therefore not vulnerable to environmental contamination.
Flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.
Food defence	Procedures adopted to assure the safety of raw materials and products from malicious contamination or theft.

Food fraud	Fraudulent and intentional substitution, dilution or addition to a product or raw material, or misrepresentation of the product or material, for the purpose of financial gain, by increasing the apparent value of the product or reducing the cost of its production.
Food handler	Anyone who handles or prepares food, whether open (unwrapped) or packaged.
Food raw materials	Food ingredients, additives and processing aids used in the manufacture of a product.
Food safety	Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
Food security	Procedures adopted to assure the continued availability of raw materials and products.
Fundamental requirement	A requirement of the Standard that relates to a system which must be well established, continuously maintained and monitored by the company as absence or poor adherence to the system will have serious repercussions on the integrity or safety of the product supplied.
Genetically modified organism (GMO)	An organism whose genetic material has been altered by the techniques of genetic modification so that its DNA contains genes not normally found there.
Global Food Safety Initiative (GFSI)	Managed by the Consumer Goods Forum, a project to harmonise and benchmark international food safety standards (**www.mygfsi.com**).
Good hygiene practice	The combination of process, personnel and/or service control procedures intended to ensure that products and/or services consistently achieve appropriate levels of hygiene.
Good manufacturing practice (GMP)	Implemented procedures and practices undertaken using best practice principles.
Hazard	An agent of any type with the potential to cause harm (usually biological, chemical, physical or radiological).
Hazard Analysis and Critical Control Point (HACCP)	A system that identifies, evaluates and controls hazards which are significant for food safety.
High-care area	An area designed to a high standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to minimise product contamination by pathogenic micro-organisms.
High-care product	A product that requires chilling or freezing during storage, is vulnerable to the growth of pathogens, has received a process to reduce the microbiological contamination to safe levels (typically 1–2 log reduction) and is ready to eat or heat.
High-risk area	A physically segregated area, designed to a high standard of hygiene, where practices relating to personnel, ingredients, equipment, packaging and environment aim to prevent product contamination by pathogenic micro-organisms.
High-risk product	A chilled ready-to-eat/ready-to-heat product or food where there is a high risk of growth of pathogenic micro-organisms.
Identity preserved	A product which has a defined origin or purity characteristic which needs to be retained throughout the food chain (e.g. through traceability and protection from contamination).
Importer	A company facilitating the movement of products across an international border. Usually the first recipient of the products in that country.
Incident	An event that has occurred that may result in the production or supply of unsafe, illegal or non-conforming products.
Initial audit	The BRC audit at a company/site which is not in possession of a valid BRC certificate. This may be the first audit at a site or a subsequent audit of a site whose certification has lapsed.
Internal audit	General process of audit, for all the activity of the company. Conducted by or on behalf of the company for internal purposes.
Job description	A list of the responsibilities for a given position at a company.
Key staff	Those staff whose activities affect the safety, legality and quality of the finished product.
Legality	In compliance with the law in the place of production and in the countries where the product(s) is/are intended to be sold.

Lot	See definition of 'Batch'.
Low-risk area	An area where the processing or handling of foods presents minimum risk of product contamination or growth of micro-organisms, or where the subsequent processing or preparation of the product by the consumer will ensure product safety.
Manufacturer	A company that produces product from raw materials and/or components and packs the product into retail units or supplies product in bulk to a packing company that packs the product into retail units. A packer that packs product into retail units from bulk-supplied material can also be classed as a 'manufacturer'.
May	Indicates a requirement or text which provides guidance but is not mandatory for compliance to the Standard.
Monitoring	A planned sequence of observations or measurements of defined control parameters to assess whether predefined limits are being met.
Non-conformity	The non-fulfilment of a specified product safety, legal or quality requirement or a specified system requirement.
Open product area	An area in which product is open to the environment (i.e. not fully enclosed in packaging or within equipment/pipes).
Outer packaging	Packaging which is visible when the product is released from the site. For example, a cardboard box could be considered outer packaging even if wrapped in clear film.
Performance indicators	Summaries of quantified data that provide information on the level of compliance against agreed targets (e.g. customer complaints, product incidents, laboratory data).
Positive release	Ensuring a product or material is of an acceptable standard prior to release for use.
Potable water	Water being safe to drink, free from pollutants and harmful organisms and conforming to local legal requirements.
Premises	A physical building or place owned by the company and audited as part of a site.
Pre-packaged products	Products in their final packaging that is designed for sale to the consumer.
Prepared primary product	A food product which has undergone a washing, trimming, size-grading or quality-grading process and is pre-packed.
Prerequisite	The basic environmental and operational conditions in a food business that are necessary for the production of safe food. These control generic hazards covering good manufacturing practice and good hygienic practice and shall be considered within the HACCP study.
Preventive action	Action to eliminate the fundamental, underlying cause (root cause) of a detected non-conformity and prevent recurrence.
Primary packaging	That packaging which constitutes the unit of sale, used and disposed of by the consumer (e.g. bottle, closure and label).
Procedure	Agreed method of carrying out an activity or process which is implemented and documented in the form of detailed instructions or process description (e.g. a flowchart).
Processed food	A food product which has undergone any of the following processes: aseptic filling, baking, battering, blending, bottling, breading, brewing, canning, coating, cooking, curing, cutting, dicing, distillation, drying, extrusion, fermentation, freeze drying, freezing, frying, hot filling, irradiation, microfiltration, microwaving, milling, mixing, being packed in modified atmosphere, being packed in vacuum packing, packing, pasteurisation, pickling, roasting, slicing, smoking, steaming or sterilisation.
Processing aid	Any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of the residues of the substance or its derivatives in the final product – provided that these residues do not present any health risk and do not have any technological effect on the finished product.
Product recall	Any measures aimed at achieving the return of an unfit product from customers and final consumers.
Product withdrawal	Any measures aimed at achieving the return of out-of-specification or unfit products from customers, but not from final consumers.

Protective clothing	Clothing designed to protect the product from potential contamination by the wearer.
Provenance	The origin or the source of food or raw materials.
Quality	Meeting the customer's specification and expectation.
Quantity check/mass balance	A reconciliation of the amount of incoming raw material against the amount used in the resulting finished products, also taking into account process waste and rework.
Quantity control	Check on amount of product in the pack. May be related to weight, volume, number of pieces, size etc.
Quarantine	The status given to any material or product set aside while awaiting confirmation of its suitability for its intended use or sale.
Raw material	Any base material or semi-finished material used by the organisation for the manufacture of a product. Raw material includes packaging material.
Ready-to-cook food	Food designed by the manufacturer as requiring cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern.
Ready-to-eat food	Food intended by the manufacturer for direct human consumption without the need for a full cook.
Ready-to-heat food	Food designed by the manufacturer as suitable for direct human consumption without the need for cooking. The heating of the product is intended to make the product more palatable.
Recognised laboratory accreditation	Laboratory accreditation schemes that have gained national and international acceptance, awarded by a competent body and recognised by government bodies or users of the Standard (e.g. ISO/IEC 17025 or equivalents).
Reference sample	Agreed product or components for referral by the manufacturer for production.
Requirement	Those statements comprising a clause with which compliance will allow sites to be certificated.
Retail brand	A trademark, logo, copyright or address of a retailer.
Retailer	A business selling products to the public by retail.
Retailer-branded products	Products bearing a retailer's logo, copyright, address or ingredients used to manufacture within a retailer's premises. These are products that are legally regarded as the responsibility of the retailer.
Retained production sample	Representative product or components taken from a production run and securely held for future reference.
Risk	The likelihood of occurrence of harm from a hazard.
Risk analysis	A process consisting of three components: risk assessment, risk management and risk communication.
Risk assessment	The identification, evaluation and estimation of the levels of risk involved in a process to determine an appropriate control process.
Root cause	The underlying cause of a problem, which, if adequately addressed, will prevent a recurrence of that problem.
Sampling plan	A documented plan defining the number of samples to be selected, the acceptance or rejection criteria and the statistical confidence of the result.
Satellite depot	A warehouse/distribution site receiving products only from another site within the same company.
Schedule	A tabulated statement giving details of actions and/or timings.
Seasonal production site	A product harvested and processed on a site that is opened specifically for the duration of the short term of that harvest (typically 12 weeks or less) during a 12-month cycle.
Secondary packaging	Packaging that is used to collate and transport sales units to the retail environment (e.g. corrugated case).
Senior management	Those with strategic/high-level operational responsibility for the company and the capability to authorise the financial or human resources necessary for the implementation of the Standard.
Shall	Signifies a requirement to comply with the contents of the clause.
Should	Signifies that compliance with the contents of the clause or requirement is expected or desired.

Site	A unit of a company; the entity which is audited and which is the subject of the audit report and certificate.
Specification	An explicit or detailed description of a material, product or service.
Specifier	A company or person requesting the product or service.
Standard, the	The Global Standard for Food Safety Issue 7.
Supplier	The person, firm, company or other entity to which a site's purchase order to supply is addressed.
Suspension	Where certification is revoked for a given period, pending remedial action on the part of the company.
Traceability	Ability to trace and follow raw materials, components and products, through all stages of receipt, production, processing and distribution both forwards and backwards.
Traded goods	Goods not manufactured or part-processed on site but bought in and sold on.
Trend	An identified pattern of results.
Unannounced audit	An audit undertaken on a date unknown to the company in advance.
User	The person or organisation who requests information from the company regarding certification.
Utilities	Commodities or services, such as electricity or water, that are provided by a public body.
Validation	Obtaining evidence through the provision of objective evidence that a control or measure, if properly implemented, is capable of delivering the specified outcome.
Vehicle	Any device used for the conveyance of product that is capable of being moved upon highways, waterways or airways. Vehicles can be motorised (e.g. a lorry) or non-motorised (e.g. container or rail truck).
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control or measure is or has been operating as intended.
Where appropriate	In relation to a requirement of the Standard, the company will assess the need for the requirement and, where applicable, put in place systems, processes, procedures or equipment to meet the requirement. The company shall be mindful of legal requirements, best practice standards, good manufacturing practice and industry guidance, and any other information relating to the manufacture of safe and legal product.
Work in progress/ work in process	Partially manufactured products, intermediates or materials waiting for completion of the manufacturing process.
Workwear	Company-issued or authorised clothing designed to protect the product from potential contamination by the wearer.

APPENDIX 10
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Emma Adams	Morrisons
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Karen Betts	BRC Global Standards
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Kate Bown	Asda
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Andrew Clarke	Maple Leaf Foods
Alison Cousins	BRC Global Standards
Su Dakin	British Frozen Food Federation
Alain Dewael	Starbucks
Siarl Dixon	SAI Global Assurance Services
Andrew Donkin	The Co-operative Group
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Barry Eschbach	Land O'Lakes
Julia Ferrell	Bay State Milling Company
John Figgins	BRC Global Standards
Suzanne Finstad	Tyson Foods, Inc.
Alison Friel	Waitrose Ltd
Kaarin Goodburn	Chilled Foods Association
Lindsay Hay	PepsiCo
Michael Hayes	Del Monte Corporation

Brandon Headlee	ConAgra Foods
Daniel Herzog	Gonnella Baking Co.
Steve Hessey	Bakkavor
Nick Hodgson	PepsiCo
Juliette Jahaj	Sainsbury's Supermarkets Ltd
Sherri Jenkins	JBS
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Ron Kill	Micron2 Ltd (UK Co-operation Group)
Daniel Kingdon	Tesco PLC
Elizabeth Krushinskie	Mountaire Farms
John Kukoly	BRC Global Standards
Alec Kyriakides	Sainsbury's Supermarkets Ltd
Heidi Lammers	Land O'Lakes
Richard Leathers	Campden BRI
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Bruno Marberger	Whole Foods Market
Joseph Martin	ConAgra Foods
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Meghann McLeod	Yum! Brands, Inc.
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Tom Owen	BRC Global Standards
Sarah Oxendale	Target Corporation
Robert Prevendar	NSF
Alicia Pulings	Gonnella Baking Co.
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Sue Williams	SAI Global Assurance Services (UK Co-operation Group)

BRC Global Standards
21 Dartmouth Street
London SW1H 9BP
Tel: +44 (0)20 7854 8900
Fax: +44 (0)20 7854 8901
Email: enquiries@brcglobalstandards.com

To learn more about the BRC Global Standards certification programme please visit
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