Global Standard FOOD SAFETY ISSUE 9

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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 Food Safety.

The document consists of the following parts:

Part I Introduction
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 audit programmes available within the Standard, as well as information on the logos and the BRCGS Directory.

Part IV Management and governance
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
Introduction

Part I
Introduction

Welcome to Issue 9 of the Global Standard Food Safety (hereafter referred to as the Standard). Originally developed and published in 1998, the Standard has been updated at regular intervals since to reflect the latest thinking in food safety, and to encourage adoption of the Standard worldwide. The Standard provides a framework for food manufacturers to assist them in the production of safe, authentic, legal food and to manage product quality to meet customers' requirements.

Certification against the Standard is recognised globally by many retailers, food service companies, procurement companies, agents and brokers, and manufacturers when assessing the capabilities of their suppliers. In response to demand, the Standard has been translated into many languages to facilitate implementation by food businesses across the world.

The Standard has been developed to specify the food safety, authenticity, quality and operational criteria required 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 9?

The development of Issue 9 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:

- encouraging understanding and further development of product safety culture
- ensuring global applicability, compatibility with the Codex General Principles of Food Hygiene, and benchmarking to the Global Food Safety Initiative (GFSI) benchmarking requirements
- expanding the audit options to include the use of information and communication technology (ICT)
- updating the requirements associated with core product safety activities, such as internal audits, root cause analysis, preventive actions and incident management
- providing greater clarity for sites completing animal primary conversion and producing animal feed.

The requirements of Issue 9 represent an evolution from previous issues, with a continued emphasis on management commitment, a food safety programme (based on hazard analysis and critical control points (HACCP)), and a supporting quality management system. The continuing objective has been to direct the focus of the audit towards the implementation of good manufacturing practices.

Audits

There are a number of audit options available for sites and these have expanded for Issue 9.

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

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

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

All other aspects of the announced audit protocol remain unchanged. More details on the announced audit programme can be found in Part III, section 2.

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

The introduction of the blended announced audit option utilises the evolving role of ICT to incorporate remote assessment into the audit process.

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

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

- confirms that a robust audit is possible (e.g. availability of remote technology at the site)
- assesses the percentage of the audit that can be completed remotely, up to a maximum of 50% of the audit duration.

As explained above, sites opting for announced audits, including the blended announced audit, are required to have at least one unannounced audit within every 3-year period.

The significance of this audit option resides in the flexibility provided to the audit scheduling. At the time of publication, this option is only available for re-certification audits and not for initial audits (the first BRCGS audit at a site). More details on the blended announced audit protocol can be found in Part III, section 3.

Unannounced audit programme

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

For Issue 9, the audit may occur at any stage within the last 4 months of the audit cycle, including the 28 calendar days before the audit due date (i.e. the unannounced audit occurs within the 4 months prior to the audit due date). The audit will be unannounced and the date of the audit shall not be notified to the site in advance. Where justified, a site may select up to 10 days when an audit cannot take place (for example, due to a customer visit). These non-audit days must be notified to the certification body in advance of the audit.

More details on the unannounced audit programme can be found in Part III, section 4.

Additional modules

Issue 9 maintains the principles originally developed in Issue 7 that enable the incorporation of additional modules. These modules allow sites to include extra requirements during their audit to meet the needs of particular customers, regions or schemes and reduce the number of site audits. BRCGS will continue to develop such modules in response to market demand and make these available via its website.

The scope of the Standard

The Standard sets out the requirements for the manufacture, processing and packing of:

- processed foods, both own brand and customer-branded
- raw materials or ingredients for use by food service companies, catering companies and/or food manufacturers
- primary products, such as fruit and vegetables
- pet foods for domestic animals and animal feed
- products from animal primary conversion.

Certification applies to products that have been manufactured or prepared at the site where the audit has taken place and includes storage facilities that are under the direct control of the production site management.

Section 9 in Part II of this Standard details the requirements of traded products. These requirements allow the audit to include the management of products that would normally fall within the scope of the Standard and are stored at the site, but are not manufactured, further processed, packed or labelled at the site.

The Standard shall not apply to activities relating to the wholesale, importation, distribution or storage of food products that are outside the direct control of the company. BRCGS has developed a number of standards setting out the requirements for a 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 to facilitate the production of food products that are lawful and consistent with compositional and safety standards and good manufacturing practice
- satisfy themselves that their suppliers are competent to produce the specified product, comply with legal requirements, and operate appropriate systems of process control
- establish and maintain a risk-assessed programme for product examination, testing and/or analysis
- monitor and act upon customer complaints.

The Standard has been developed to assist businesses in meeting these requirements.

The food safety management system

Principles of the Standard

A food business must have a full understanding of the products it produces, manufactures and distributes, and have systems in place to identify and control the hazards that are significant for product safety, authenticity, legality and quality. The Standard is based on four key components:

- senior management commitment
- the development of a food safety plan – a HACCP-based hazard and risk assessment system (which provides a step-by-step approach to managing food safety risks)
- a product safety and quality management system
- the establishment of prerequisite programmes.

Senior management commitment

Within a food business, food safety must be seen as a cross-functional responsibility that draws on many departments, using different skills and levels of management expertise across the organisation. Effective food safety management extends beyond technical departments and involves commitment from production operations, engineering, distribution management, raw materials procurement, customer feedback and human resources (who organise and procure activities such as training).

The starting point for an effective food safety plan is the commitment of senior management to the development of an all-embracing policy to guide the activities that collectively ensure food safety. The Standard places a high priority on clear evidence of senior management commitment.

The requirements for senior management commitment are located in Part II, section 1.

A HACCP-based system (the food safety plan)

A HACCP-based system focuses on the significant food safety hazards related to products and processes that require specific controls to ensure the safety of individual food products or lines.

The Standard requires the development of a food safety plan incorporating all the Codex Alimentarius HACCP principles. Such a plan requires the input of all relevant departments and must be supported by senior management.

Specific terms (such as prerequisites or critical control points) are drawn from global terminology to describe expectations. Sites are not required to adopt the specific terminology used in the Standard. Alternative terminology may therefore be acceptable, providing it is evident that all the requirements have been fully met. For example, legislative requirements in the US (detailed in the Food Safety Modernization Act) use different terminology but still incorporate all the requirements of the Standard.

The requirements for a HACCP-based food safety plan are located in Part II, section 2.

A product safety and quality management system

Details of the organisational and management policies and procedures that provide a framework by which an organisation will achieve the requirements in this Standard are given in Part II, section 3.

Prerequisite programmes

These are the basic environmental and operational conditions in a food business that are necessary to produce safe food. They control the generic hazards covering good manufacturing and good hygienic practice, as detailed in Part II, sections 4–8.

Where a site handles traded products (see glossary in Appendix 10), these may be included in the scope of the audit using the requirements in Part II, section 9.

Position statements

During the lifetime of a published standard, the BRCGS technical advisory committee (TAC) may be asked to review the wording of a clause or provide an interpretation of a requirement or a detail of the protocol. The decision made by the TAC is known as a position statement. Position statements are binding on the way that the audit and certification process is carried out and are an extension of the Standard.

Further details are available in Part III, section 6.2, and Appendix 9.

Documented procedures

In many instances, the Standard specifically states that the requirements shall be satisfied by documented procedures, processes, plans or records; in other instances, documentation is implied. Further clarification is provided in the glossary definitions in Appendix 10 (e.g. 'procedure', which clearly states that documents are required in these situations). The company needs to be able to demonstrate that systems are in place, working consistently, and that documents are available for reference when required. Therefore, any policies and documents must be written in sufficient detail to satisfy their purpose and must reflect the activities that happen in practice. These documents can be hard copy (i.e. paper-based) or electronic.

The certification process

The Standard 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 BRCGS. BRCGS 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. A list of approved certification bodies is available in the **BRCGS Directory**.

Benefits of the Standard

The Standard impacts on US$800bn of product sales[2] and therefore plays a critical role on the provision of safe food. As a result, global organisations encourage the adoption of the Standard as a means of strengthening food safety systems and meeting regulations, including IFC (a member of the World Bank)[3] and UNECE (a regional commission of the United Nations).[4]

Adoption and use of the Standard, along with certification, provides a number of benefits to food businesses and their customers. These include:

- a comprehensive scope, covering product safety, authenticity, legality and quality
- a single standard and protocol that govern an accredited audit by third-party certification bodies, allowing a credible, independent assessment of a company's food safety and quality management systems
- meeting part of the 'due diligence' requirements for both the certificated food manufacturer and its customers
- enabling companies to ensure that their suppliers are following good food safety management practices
- the completion of corrective actions, root cause analysis and preventive actions on any non-conformities to the Standard, and within the site's product safety and quality management systems; this reduces the need for customers to follow up audit reports, and demonstrates continual improvement
- an internationally recognised and GFSI-benchmarked standard that provides a report and certification which can be accepted by customers in place of their own audits, thus reducing time and cost
- the option for certificated companies to appear in the publicly available section of the BRCGS Directory, providing recognition of their achievements and use of a logo for marketing purposes
- free access to an all-inclusive set of tools designed to drive continuous improvement
- a range of audit options, including announced, unannounced and blended 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.

[2] Lambert, R. and Frenz, M. (2021). **The economic impact for manufacturing sites operating to BRCGS certification**.

[3] International Finance Corporation (2021). **Food safety reforms, learning from the best: the New Zealand food safety system in case studies**.

[4] **The benefits of voluntary food safety standards in meeting national and regional regulation (UNECE case study)**.

Independent research[5] carried out by the University of Birkbeck, London, has demonstrated that food businesses with BRCGS certification demonstrate greater compliance with national regulations and are subject to less intervention. Additional research[6] demonstrates that certification to BRCGS standards generates extensive and positive business impacts for food businesses in relation to business growth, profitability, operational efficiency and innovation.

Guidance and training

BRCGS produces a range of guidance documents, training courses and a self-assessment tool designed to assist sites with the application of the Standard and an understanding of the core skills needed, such as risk assessment and root cause analysis. Further information about BRCGS training can be found on the **BRCGS website**.

BRCGS guidance covers a range of topics including (but not limited to):

- an interpretation guideline for Issue 9 which explains every requirement of the Standard
- product changeover (i.e. good practices when moving from the production of one product to another)
- effective internal audits
- vulnerability assessments
- high-risk, high-care and ambient high-care zones
- category-specific guidance for the red meat, poultry and fresh-produce sectors.

Certificated sites can download BRCGS publications from **BRCGS Participate** as part of their service package. For details, see Appendix 11.

Effective date of Issue 9

As with all revisions of the Global Standards, there must be a transition period 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 9 will commence on 1 February 2023. All certificates issued against audits carried out prior to this date will be against Issue 8 and be valid for the period specified on the certificate.

Acknowledgements

BRCGS wishes to acknowledge all those food industry experts who have contributed to the preparation of Issue 9 of the Standard or provided invaluable feedback through the consultation process. All those who participated in the working groups are listed in Appendix 12.

[5] Lambert, R. (2021). **A review of certification and its impact on regulatory intervention**.

[6] Ibid.

Part II
Requirements

Part II
Requirements

How the requirements are set out

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

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

Colour-coding of requirements

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

As an aid to this process, the requirements within the Standard have been colour-coded (see Table 1). Colour-coding shows the activities that would usually be audited as part of the assessment of the production areas and facilities, and those that would form part of an audit of records, systems and documentation.

Table 1 Key to colour-coding of requirements

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

Fundamental requirements

Within the Standard certain requirements have been designated as 'fundamental' requirements. These are marked with the word 'FUNDAMENTAL' and denoted with the following symbol: ☆. These requirements relate to systems that are crucial to the establishment and operation of an effective food quality and safety operation. The requirements deemed fundamental are:

- Senior management commitment and continual improvement (1.1)
- The food safety plan – HACCP (2)
- Internal audits (3.4)
- Management of suppliers of raw materials and packaging (3.5.1)
- Corrective and preventive actions (3.7)
- Traceability (3.9)
- Layout, product flow and segregation (4.3)
- Housekeeping and hygiene (4.11)

- Management of allergens (5.3)
- Control of operations (6.1)
- Labelling and pack control (6.2)
- Training: raw material-handling, preparation, processing, packing and storage areas (7.1).

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

Additional requirements

The requirements in sections 1–7 shall be applied to all operations with the following exceptions:

- Section 5.8 applies only to sites manufacturing, processing or packing pet food or animal feed, and section 5.9 applies only to animal primary conversion.
- Where a site's products require high-risk, high-care or ambient high-care production facilities (as defined in Appendix 2 of the Standard), these requirements are listed in section 8. Any site that requires high-risk, high-care or ambient high-care facilities must meet the requirements in section 8.
- Where a site also handles traded products (defined as food products or raw materials, that would normally fall within the scope of the Standard and are stored at the site's facilities, but that are not manufactured, processed, reworked or packed at the site being audited), the site can opt to include these products within the scope of its BRCGS audit. The requirements for traded products are detailed in section 9.

1 Senior management commitment

1.1 Senior management commitment and continual improvement

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

Clause	Requirements
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe, legal and authentic products to the specified quality, and its responsibility to its customers. This shall: • be signed by the person with overall responsibility for the site • be communicated to all staff • include commitment to continuously improve the site's food safety and quality culture.

1.1.2	The site's senior management shall define and maintain a clear plan for the development and continuing improvement of a food safety and quality culture. The plan shall include measures needed to achieve a positive culture change.
	This shall include:
	• defined activities involving all sections of the site that have an impact on product safety. As a minimum, these activities shall be designed around:
	  • clear and open communication on product safety
	  • training
	  • feedback from employees
	  • the behaviours required to maintain and improve product safety processes
	  • performance measurement of activities related to the safety, authenticity, legality and quality of products
	• an action plan indicating how the activities will be undertaken and measured, and the intended timescales
	• a review of the effectiveness of completed activities.
	The plan shall be reviewed and updated at least annually, at a minimum.

1.1.3	The site's senior management shall ensure that clear objectives are defined to maintain and improve the safety, authenticity, legality and quality of products manufactured, in accordance with the food safety and quality policy and this Standard. These objectives shall be: • documented and include targets or clear measures of success • clearly communicated to all staff • monitored and results reported at least quarterly to site senior management and all staff.

Clause	Requirements
1.1.4	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually at a minimum, to review the site performance against the Standard and objectives set in clause 1.1.3. The review process shall include the evaluation of: • previous management review action plans and timeframes • the results of internal, second-party and/or third-party audits • any objectives that have not been met, to understand the underlying reasons. This information shall be used when setting future objectives and to facilitate continual improvement • any customer complaints and the results of any customer feedback • any incidents (including both recalls and withdrawals), corrective actions, out-of-specification results and non-conforming materials • the effectiveness of the systems for HACCP, food defence and authenticity, and the food safety and quality culture plan • resource requirements. Records of the meeting shall be documented and used to revise the objectives, thereby encouraging continual improvement. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.
1.1.5	The site shall have a demonstrable meeting programme which enables food safety, authenticity, legality and quality issues to be brought to the attention of senior management. These meetings shall occur at least monthly.
1.1.6	The company shall have a confidential reporting system to enable staff to report concerns relating to product safety, authenticity, legality and quality. The mechanism (e.g. the relevant telephone number) for reporting concerns shall be clearly communicated to staff. The company's senior management shall have a process for assessing any concerns raised. Records of the assessment and, where appropriate, actions taken, shall be documented.
1.1.7	The company's senior management shall provide the human and financial resources required to produce safe, authentic, legal products to the specified quality and in compliance with the requirements of this Standard.
1.1.8	The company's senior management shall have a 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 in the country where the product will be sold (where known).
1.1.9	The site shall have a genuine, original hard copy or electronic version of the current Standard available and be aware of any changes to the Standard or protocol that are published on the BRCGS website.

Clause	Requirements
1.1.10	Where the site is certificated to the Standard, it shall ensure that announced or blended announced recertification audits occur on or before the audit due date indicated on the certificate.
1.1.11	The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for certification to the Standard. Relevant departmental managers or their deputies shall be available as required during the audit. A member of the senior management team on site shall be available during the audit for a discussion on effective implementation of the food safety and quality culture plan.
1.1.12	The site's senior management shall ensure that the root causes of any non-conformities against the Standard identified at the previous audit have been effectively addressed to prevent recurrence.
1.1.13	The BRCGS logo and references to certification status shall be used only in accordance with the conditions of use detailed in the audit protocol section (Part III, section 6.7) of the Standard.
1.1.14	Where required by legislation, the site shall maintain appropriate registrations with the relevant authorities.

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, authenticity, legality and quality.

Clause	Requirements
1.2.1	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, authenticity, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.
1.2.2	The site's senior management shall ensure that all staff are aware of their responsibilities and demonstrate that work is carried out in accordance with documented site policies, procedures, work instructions and existing practices for activities undertaken. All staff shall have access to relevant documentation.
1.2.3	Staff shall be aware of the need to report any risks or any evidence of unsafe or out-of-specification product, equipment, packaging or raw materials, to a designated manager to enable the resolution of issues requiring immediate action.
1.2.4	If the site does not have the appropriate in-house knowledge of food safety, authenticity, legality or quality, external expertise (e.g. food safety consultants) may be used; however, the day-to-day management of the food safety systems shall remain the responsibility of the company.

2 The food safety plan – HACCP

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

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

Clause	Requirements
2.1.1	The HACCP or food safety plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for quality assurance, technical management, production operations and other relevant functions (e.g. engineering, hygiene). The team leader shall have an in-depth knowledge of Codex HACCP principles (or equivalent) and be able to demonstrate competence, experience and training. Where there is a legal requirement for specific training, this shall be in place. The team members shall have specific knowledge of HACCP and relevant knowledge of products, processes and associated hazards.
2.1.2	The scope of each HACCP or food safety plan, including the products and processes covered, shall be defined.

2.2 Prerequisite programmes

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 disinfection (see section 4.11) • pest management (see section 4.14) • maintenance programmes for equipment and buildings (see sections 4.4 and 4.6) • personal hygiene requirements (see section 7.2) • staff training (see section 7.1) • supplier approval and purchasing (see section 3.5.1) • transportation arrangements (see section 4.16) • processes to prevent cross-contamination (see sections 4.9 and 4.10) • allergen management (see section 5.3). The prerequisite programmes for the particular areas of the site shall take into account the production risk zoning (see clause 4.3.1). The control measures and monitoring procedures for the prerequisite programmes shall be clearly documented and shall be included within the development and reviews of the HACCP or food safety plan.

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

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

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

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

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

Clause		Requirements
2.5.1		A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP or food safety plan scope, from raw material receipt through to processing, storage and distribution. As a guide, this should include the following, although this is not an exhaustive list: • plan of premises and equipment layout • raw materials, including introduction of utilities and other contact materials (e.g. water, packaging) • sequence and interaction of all process steps • outsourced processes and subcontracted work • potential for process delay • rework and recycling • low-risk/high-risk/high-care area segregation • finished products, intermediate/semi-processed products, by-products and waste.

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

Clause		Requirements
2.6.1		The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit at least annually, and whenever there are changes to the process, to ensure any changes have been considered as a part of the HACCP or food safety plan. 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 (equivalent to Codex Alimentarius Step 6, Principle 1)

Clause		Requirements
2.7.1		The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and consideration of the following types of hazard: • microbiological • physical contamination • chemical and radiological contamination • fraud (e.g. substitution or deliberate/intentional adulteration) (see section 5.4) • malicious contamination of products (see section 4.2) • allergen risks (see section 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 the significant hazards (i.e. those hazards that are reasonably likely to occur at an unacceptable level), which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to the following: • likely occurrence of hazard • severity of the effects on consumer safety • vulnerability of those exposed • survival and multiplication of micro-organisms of specific concern to the product • presence or production of toxins, chemicals or foreign bodies • contamination of raw materials, intermediate/semi-processed product, or finished product. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.
2.7.3	The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Consideration may be given to using more than one control measure.
2.7.4	Where the control of a specific food safety hazard is achieved through prerequisite programmes (see section 2.2) or control measures other than critical control points (CCPs; see clause 2.8.1), this shall be stated and the adequacy of the programme to control the specific hazard validated.

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

Clause	Requirements
2.8.1	For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. 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 validated critical limits for each CCP (equivalent to Codex Alimentarius Step 8, Principle 3)

Clause	Requirements
2.9.1	For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be: • measurable wherever possible (e.g. time, temperature, pH) • supported by clear guidance or examples where measures are subjective (e.g. photographs).
2.9.2	The HACCP food safety team shall validate each CCP, including critical limits. 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 (equivalent to Codex Alimentarius Step 9, Principle 4)

Clause		Requirements
2.10.1		A monitoring procedure shall be established for each CCP to ensure compliance with critical limits. The monitoring system shall be able to detect loss of control of CCPs and, wherever possible, provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list: • online measurement • offline measurement • continuous measurement (e.g. thermographs, pH meters). Where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.
2.10.2		Records associated with the monitoring of each CCP shall include the date, time and result of measurement, and shall be signed by the person responsible for the monitoring and verified, when appropriate, by a suitably competent and authorised person. Where records are in electronic form, there shall be evidence that records have been checked and verified.

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

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

2.12 Validate the HACCP plan and establish verification procedures (equivalent to Codex Alimentarius Step 11, Principle 6)

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

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

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

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

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 effective, consistent application, facilitate training, and support due diligence in the production of a safe product.

Clause	Requirements
3.1.1	The site's procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual.
3.1.2	The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to relevant staff.
3.1.3	All procedures and work instructions shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. This should include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language).

3.2 Document control

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

Clause	Requirements
3.2.1	The company shall have a procedure to manage documents which form part of the food safety and quality system. This shall include: • a list of all controlled documents indicating the latest version number • the method for the identification and authorisation of controlled documents • a record of the reason for any changes or amendments to documents • the system for the replacement of existing documents when these are updated. Where documents are stored in electronic form these shall also be: • stored securely (e.g. with authorised access, control of amendments, or password protection) • backed up to prevent loss.

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 the alteration shall be recorded. Where records are in electronic form these shall also be: • stored securely (e.g. with authorised access, control of amendments, or password protection) • suitably backed up to prevent loss.
3.3.2	Records shall be retained for a defined period with consideration given to: • any legal or customer requirements • the shelf life of the product. This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing). At a minimum, records shall be retained for the shelf life of the product plus 12 months.

3.4 Internal audits

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

Clause	Requirements
3.4.1	There shall be a scheduled programme of internal audits. At a minimum, the programme shall include at least four different audit dates spread throughout the year. The frequency at which each activity is audited shall be established in relation to the risks associated with the activity and previous audit performance. All activities that form a part of the site's food safety and quality systems, including those relevant to food safety, authenticity, legality and quality, shall be covered at least once each year. The scope of the internal audit programme shall include, although this is not an exhaustive list: • HACCP or food safety plan, including the activities to implement it (e.g. supplier approval, corrective actions and verification) • prerequisite programmes (e.g. hygiene, pest management) • food defence and food fraud prevention plans • procedures implemented to achieve the Standard. Each internal audit within the programme shall have a defined scope and consider a specific activity or a section of the HACCP or food safety plan.

Clause	Requirements
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 include objective evidence of the findings. The results shall be reported to the personnel responsible for the activity audited. Corrective and preventive actions, and timescales for their implementation, shall be agreed and their completion verified. All non-conformities shall be handled as detailed in section 3.7. A summary of the results shall be reviewed in the management review meetings (see clause 1.1.4).
3.4.4	In addition to the internal audit programme, there shall be a separate programme of documented inspections to ensure that the factory environment and processing equipment are maintained in a suitable condition for food production. At a minimum, these inspections shall include: • hygiene inspections to assess cleaning and housekeeping performance • fabrication inspections (e.g. doors, walls, facilities and equipment) to identify risks to the product from the building or equipment. The frequency of these inspections shall be based on risk and on any changes that may affect food safety, but shall be no less than once per month in open product areas. The results shall be reported to the personnel responsible for the activity or area audited. Corrective actions, and timescales for their implementation, shall be agreed and their completion verified. A summary of the results shall be reviewed in the management review meetings (see clause 1.1.4).

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 primary packaging) to the safety, authenticity, legality and quality of the final product are understood and managed.

Clause	Requirements
3.5.1.1	The company shall undertake a documented risk assessment of each raw material or group of raw materials, including primary packaging, to identify potential risks to product safety, authenticity, legality and quality. This shall take into account the potential for: • allergens (allergen content and potential contamination) • foreign-body risks • microbiological contamination • chemical contamination • variety or species cross-contamination • substitution or fraud (see clause 5.4.2) • any risks associated with raw materials which are subject to legislative control or customer requirements. Consideration shall also be given to the significance of a raw material to the quality of the final product. The risk assessment shall form the basis for the raw material acceptance and testing procedure and for the processes adopted for supplier approval and monitoring. The risk assessment for a raw material shall be updated: • when there is a change in a raw material, the processing of a raw material, or the supplier of a raw material • if a new risk emerges • following a product recall or withdrawal, where a specific raw material has been implicated • at least every 3 years.

Clause	Requirements

3.5.1.2	The company shall have a documented supplier approval procedure to ensure that all suppliers of raw materials, including primary packaging, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval procedure shall be based on risk and include either one or a combination of:
	• a valid certification to the applicable BRCGS Standard or GFSI-benchmarked standard. The scope of the certification shall include the raw materials purchased
	or
	• supplier audits, with a scope to include product safety, traceability, HACCP review, the product security and food defence plan, the product authenticity plan and good manufacturing practices. The audit shall ensure that these plans form part of the supplier's product safety management system and that any resultant actions are implemented. The supplier audit shall be undertaken by an experienced and demonstrably competent product safety auditor. Where the supplier audit is completed by a second or third party, the company shall be able to:
	  • demonstrate the competency of the auditor
	  • confirm that the scope of the audit includes product safety, product security and food defence plan, product authenticity, traceability, HACCP review and good manufacturing practices
	  • obtain and review a copy of the full audit report
	or
	• where a valid risk-based justification is provided and the supplier is assessed as low risk only, a completed supplier questionnaire may be used for initial approval. At a minimum, the questionnaire shall have a scope that includes product safety, product security and food defence, product authenticity, traceability, HACCP review and good manufacturing practices. The questionnaire shall have been reviewed and verified by a demonstrably competent person.

3.5.1.3	There shall be a documented process for ongoing supplier performance review, based on risk and defined performance criteria. The process shall be fully implemented. Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status. Records of the review shall be kept.
3.5.1.4	The site shall have an up-to-date list or database of approved suppliers. This may be on paper (hard copy) or it may be controlled on an electronic system. The list or relevant components of the database shall be readily available to the relevant staff (e.g. at goods receipt).
3.5.1.5	Where raw materials (including primary packaging) are purchased from companies that are not the manufacturer, packer or consolidator (e.g. purchased from an agent, broker or wholesaler), the site shall know the identity of the last manufacturer or packer, or for bulk commodity products the consolidation place of the raw material. Information to enable the approval of the manufacturer, packer or consolidator, as in clauses 3.5.1.1 and 3.5.1.2, shall be obtained from the agent/broker or directly from the supplier, unless the agent/broker is themselves certificated to a BRCGS Standard (e.g. Global Standard Agents and Brokers) or a standard benchmarked by GFSI.

Clause	Requirements
3.5.1.6	The company shall ensure that its suppliers of raw materials (including primary packaging) have an effective traceability system. Where a supplier has been approved based on a questionnaire instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least every 3 years. This may be achieved by a traceability test. Where the supplier is not the manufacturer, packer or consolidator of the raw material (e.g. purchased from an agent, broker or wholesaler) and approval is based on a questionnaire instead of certification or audit, the verification of the traceability system shall be carried out on the last manufacturer, packer or consolidator of the raw material. Where a raw material is received directly from a farm or fish farm, further verification of the farm's traceability system is not mandatory.
3.5.1.7	The procedures shall define the actions required in either of the following circumstances: • an exception to the supplier approval processes in clause 3.5.1.2 occurs (e.g. where raw material suppliers are prescribed by a customer) • information for effective supplier approval is not available (e.g. bulk agricultural commodity products). In both the above situations, product testing is used to verify product quality and safety. When a site produces customer-branded product, the customer shall be made aware of the relevant exceptions.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

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

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

3.5.3 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, authenticity, legality and quality have been evaluated to ensure effective controls are in place.

Clause	Requirements
3.5.3.1	There shall be a procedure for the approval and monitoring of suppliers of services. Such services shall include, as appropriate: • pest control • laundry services • contracted cleaning • contracted servicing and maintenance of equipment • transport and distribution • off-site storage of ingredients or packaging (other than at the supplier's facilities) prior to delivery to the site • off-site packing of products • laboratory testing • catering services • waste management • providers of product safety training • product safety consultants. This approval and monitoring process shall be risk-based and take into consideration: • risk to the safety and quality of products • compliance with any specific legal requirements • potential risks to the security of the product (i.e. risks identified in the vulnerability and food defence assessments).
3.5.3.2	Contracts or formal agreements shall exist with the suppliers of services that clearly define service expectations and ensure that the potential food safety risks associated with the service have been addressed.
3.5.3.3	There shall be a documented process for ongoing performance review of suppliers of services, based on risk and defined performance criteria. The process shall be fully implemented. Records of the review shall be kept.

3.5.4 Management of outsourced processing

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

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

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

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

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

Clause	Requirements
3.5.4.1	The company shall be able to demonstrate that, where part of the production process (i.e. any intermediate process step) is outsourced or undertaken off site, and subsequently returned to the site, this has been declared to the customer and, where required, approval granted.

3.5.4.2	The company shall ensure that outsourced processors are approved and monitored, to ensure that they effectively manage risks to product safety and quality and are operating effective traceability processes.
	
	The approval and monitoring procedure shall be based on risk and include either one or a combination of:
	
	• a valid certification to the applicable BRCGS Standard or GFSI-benchmarked standard. The scope of the certification shall include the activities completed for the site
	or
	• supplier audits, with a scope to include product safety, traceability, HACCP review, product security and food defence plan, product authenticity plan and good manufacturing practices. The audit shall ensure that these plans form part of the supplier's product safety management system and that any resultant actions are implemented. The supplier audit shall be undertaken by an experienced and demonstrably competent product safety auditor. Where this supplier audit is completed by a second or third party, the company shall be able to:
	  • demonstrate the competency of the auditor
	  • confirm that the scope of the audit includes product safety, traceability, HACCP review, product security and food defence plan, product authenticity plan and good manufacturing practices
	  • obtain and review a copy of the full audit report.
	
	There shall be a documented process for ongoing supplier performance review, based on risk and defined performance criteria. The process shall be fully implemented. Records of the review shall be kept.

3.5.4.3	Where any processes are outsourced, including production, manufacture, processing or storage, the risks to the product safety, authenticity and legality shall form part of the site's food safety plan (HACCP plan).
3.5.4.4	Requirements for outsourced processing shall be agreed and documented in a service specification (similar to a finished product specification). This shall include any specific handling requirements for the products.

Clause	Requirements
3.5.4.5	Any outsourced processing operations shall: • be undertaken in accordance with established contracts which clearly define any processing requirements • maintain product traceability.
3.5.4.6	The company shall establish inspection and test procedures for products where part of the processing has been outsourced, including visual, chemical and/or microbiological testing. The frequency and methods of inspection or testing shall depend on risk assessment.

3.6 Specifications

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

Clause	Requirements
3.6.1	Specifications for raw materials and primary packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements. The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological, physical or allergen standards).
3.6.2	Accurate, up-to-date specifications shall be available for all finished products. These may be in the form of a printed or electronic document, or part of an online specification system. They shall include key data to meet customer and legal requirements and assist the user in the safe usage of the product.
3.6.3	Where the company is manufacturing customer-branded products, it shall seek formal agreement of the finished product specifications. Where specifications are not formally agreed, the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place.
3.6.4	Specification review shall be sufficiently frequent to ensure that data is current or at a minimum every 3 years, taking into account product changes, suppliers, regulations and other risks. Reviews and changes shall be documented.

3.7 Corrective and preventive actions

Fundamental

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

Clause	Requirements
3.7.1	The site shall have a procedure for handling and correcting issues identified in the food safety and quality management system. The site procedures shall include the completion of root cause analysis and implementation of preventive action.
3.7.2	Where a non-conformity places the safety, authenticity or legality of a product at risk, or where there is an adverse trend in quality, this shall be investigated and recorded including: • clear documentation of the non-conformity • assessment of consequences by a suitably competent and authorised person • the corrective action to address the immediate issue • completion of root cause analysis to identify the fundamental cause (root cause) of the non-conformity • appropriate timescales for corrective and preventive actions • the person(s) responsible for corrective and preventive actions • verification that the corrective and preventive actions have been implemented and are effective. Root cause analysis shall also be used to prevent recurrence of non-conformities, and to implement ongoing improvements when analysis of non-conformities for trends shows there has been a significant increase in a type of non-conformity.

3.8 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 procedures for managing non-conforming products. These procedures shall include: • the requirement for staff to identify and report a potentially non-conforming product • clear identification of a non-conforming product (e.g. direct labelling or the use of IT systems) • secure storage to prevent accidental release (e.g. physical or computer-based isolation) • management of any product returned to the site • referral to the brand owner where required • defined responsibilities for decision-making on the use or disposal of products appropriate to the issue (e.g. destruction, reworking, downgrading to an alternative label or acceptance by concession) • records of the decision on the use or disposal of the product • records of destruction where a product is destroyed for food safety reasons.

3.9 Traceability

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

Clause		Requirements
3.9.1		The site shall have a documented traceability procedure designed to maintain traceability throughout the site's processes. At a minimum this shall include: • how the traceability system works • the labelling and records required. Where applicable, the traceability system shall meet the legal requirements in the country of sale or intended use.
3.9.2		Identification of raw materials (including primary packaging), intermediate/semi-processed products, part-used materials, finished products and materials pending investigation shall be adequate to ensure traceability.

Clause	Requirements
3.9.3	The site shall test the traceability system across the range of product groups to ensure traceability can be determined from the supplier of raw material (including primary packaging) to the finished product and vice versa. For food raw materials and finished products (i.e. including printed packaging and labels with food safety and legal information), the test of the traceability system shall include a quantity check/mass balance. The traceability test shall include a summary of the documents that should be referenced during the test, and clearly show the links between them. The test shall occur at a predetermined frequency, at a minimum annually, and results shall be retained for inspection. Traceability should be achievable within 4 hours.
3.9.4	Where rework or any reworking operation is performed, traceability shall be maintained.

3.10 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 and 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 procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, authenticity, legality or quality. This shall include consideration of contingency plans to maintain product safety, authenticity, legality and quality. Incidents may include: • disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications • events such as fire, flood or natural disaster • malicious contamination or sabotage • product contamination indicating a product may be unsafe or illegal • failure of, or attacks against, digital cyber-security. Where products which have been released from the site may be affected by an incident, consideration shall be given to the need to withdraw or recall products.
3.11.2	The company shall have a documented product withdrawal and recall procedure. This shall include, at a minimum: • identification of key personnel constituting the recall management team, with clearly identified responsibilities • guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained • an up-to-date list of key contacts (including out-of-hours contact details) or reference to the location of such a list (e.g. recall management team, emergency services, suppliers, customers, certification body, regulatory authority) • a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner • details of external agencies providing advice and support as necessary (e.g. specialist laboratories, regulatory authority and legal expertise) • a plan to handle the logistics of product traceability, recovery or disposal of affected product, and stock reconciliation • a plan to record timings of key activities • a plan to conduct root cause analysis and to implement ongoing improvements, to avoid recurrence. The procedure shall be capable of being operated at any time.
3.11.3	The incident management procedures (including those for product recall and withdrawal) 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.

Clause	Requirements
3.11.4	In the event of a significant food safety, authenticity or legality incident, including a product recall, regulatory food safety non-conformity (e.g. a regulatory enforcement notice) or food safety-related withdrawal, the certification body issuing the current certificate for the site against this Standard shall be notified within 3 working days. The company shall then provide sufficient information to enable the certification body to assess any effects of the incident on the ongoing validity of the current certificate within 21 calendar days. As a minimum, this shall include corrective action, root cause analysis and a preventive action plan.

4 Site standards

4.1 External standards and site security

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

Clause	Requirements
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site (from potential contaminants, flooding etc.), they shall be reviewed in response to any changes.
4.1.2	The external areas shall be maintained in good order. Where grassed or planted areas are located near buildings, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to mitigate the risk of contamination of the product.
4.1.3	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird-roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).
4.1.4	Policies and systems shall be in place to ensure that access to the site by staff, contractors and visitors is controlled. A visitor recording system shall be in place. Contractors and visitors, including drivers, shall be made aware of the procedures for access to the site. Only authorised personnel shall have access to production and storage areas. Contractors working in product processing or storage areas shall be the responsibility of a nominated person. Staff shall be trained in site security procedures.

4.2 Food defence

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

Clause	Requirements
4.2.1	Where personnel are engaged in threat assessments and food defence plans, the individual or team responsible shall understand potential food defence risks at the site. This shall include knowledge of both the site and the principles of food defence. Where there is a legal requirement for specific training, this shall be in place.

Clause	Requirements
4.2.2	The company shall undertake a documented risk assessment (threat assessment) of the potential risks to products from any deliberate attempt to inflict contamination or damage. This threat assessment shall include both internal and external threats. The output from this assessment shall be a documented food defence plan. This plan shall be kept under review to reflect changing circumstances and market intelligence. It shall be formally reviewed at least annually and whenever: • a new risk emerges (e.g. a new threat is publicised or identified) • an incident occurs where product security or food defence is implicated. Where applicable, the food defence plan shall meet the legal requirements in the country of sale or intended use.
4.2.3	Where raw materials or products are identified as being at particular risk, the food defence plan shall include controls to mitigate these risks. Where prevention is not sufficient or possible, systems shall be in place to identify any tampering. These controls shall be monitored, the results documented, and the controls reviewed at least annually.
4.2.4	Areas where a significant risk is identified shall be defined in the food defence plan, monitored and controlled. These shall include external storage and intake points for products and raw materials (including packaging). Staff shall be trained in food defence procedures.

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	The site shall assess the production risk zones required for the products manufactured, processed or packed at the site, using the definitions in Appendix 2 of the Standard.

Clause	Requirements
4.3.2	There shall be a map of the site. At a minimum, this map shall define: • production risk zones, where product is at different levels of risk from pathogen contamination – for example, high-risk, high-care, ambient high-care, low-risk and enclosed product areas (see clause 4.3.1 and Appendix 2) • access points for personnel • access points for raw materials (including packaging), semi-finished products and open products • routes of movement for personnel • routes of movement for raw materials (including packaging) • routes for the removal of waste • routes for the movement of rework • location of any staff facilities, including changing rooms, toilets, canteens and smoking areas • production process flows • any areas where time segregation is used to complete different activities (for example, time segregation for high-care areas).
4.3.3	Contractors and visitors, including drivers, shall be made aware of the requirements of the areas they are visiting, with special reference to hazards and potential product contamination.
4.3.4	The movement of personnel, raw materials, packaging, rework and/or waste shall not compromise the safety of products. The process flow, together with the use of demonstrably effective procedures, shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products.
4.3.5	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.
4.3.6	Temporary structures constructed during building work or refurbishment etc. shall be designed and located to avoid pest harbourage and ensure the safety and quality of products.

4.4 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.

Clause	Requirements
4.4.3	Drainage, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety. Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain. Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage.
4.4.4	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.
4.4.5	Where suspended ceilings or roof voids are present, adequate access to the void shall be provided to facilitate inspection for pest activity, unless the void is fully sealed.
4.4.6	Where elevated walkways, access steps or mezzanine floors are adjacent to or pass over production lines which have open products, they shall be: • designed to prevent contamination of products and production lines • easy to clean • correctly maintained.
4.4.7	Where there is a risk to product, windows and roof glazing which are designed to be opened for ventilation purposes shall be adequately screened to prevent the ingress of pests.
4.4.8	Doors (both internal and external) shall be maintained in good condition. At a minimum: • external doors and dock levellers shall be close fitting or adequately proofed • external doors to open product areas shall not be opened during production periods except in emergencies • where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.
4.4.9	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.
4.4.10	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.
4.4.11	Where plastic strip curtains are present, these shall be maintained in good condition, clean, fitted correctly (e.g. to prevent pest ingress or for temperature control), and shall not pose a food safety risk.

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

4.6 Equipment

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

Clause	Requirements
4.6.1	There shall be a documented purchase specification for any new equipment detailing the site requirements for the equipment. This may, for example, include: • any relevant legislation • where applicable, requirements for food contact surfaces to meet legal requirements • details of intended use of the equipment and the type of materials it will be handling. Depending on its intended use, new equipment to site (including second-hand equipment) may require authorisation from a multi-disciplinary team. The supplier should provide evidence that equipment meets these site requirements prior to supply.

Clause	Requirements
4.6.2	The design and construction of equipment shall be based on risk, to prevent product contamination. For example, the use of the correct seals, impervious surfaces or smooth welds and joints, where they are exposed to product and could otherwise result in foreign-body, microbiological or allergen contamination of the product. Equipment that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.
4.6.3	A documented, risk-based commissioning procedure shall be in place to ensure that food safety and integrity is maintained during the installation of new equipment to site. Installation work shall be followed by a documented hygiene clearance procedure. New equipment to site shall be inspected by an authorised member of staff before being accepted into operation. The commissioning procedure shall include the update of any other site procedures that are affected by the new equipment, for example, training, operating procedures, cleaning, environmental monitoring, maintenance schedules or internal audits. The design and placement of equipment shall ensure that it can be effectively cleaned and maintained.
4.6.4	A procedure shall be in place to manage the movement of static equipment in production areas, to ensure that food safety is managed and the integrity of the equipment is maintained.
4.6.5	Equipment that is not used or is taken out of service shall be cleaned and stored in a manner that does not pose a risk to the product. Equipment stored in internal production and storage areas shall be kept clean. Food contact equipment that has been stored but is not in daily use shall be cleaned and, where necessary, disinfected prior to use.
4.6.6	Mobile equipment (e.g. forklift trucks, pallet trucks, scissor lifts and ladders) used in open product areas shall not pose a risk to the product. Where the use of mobile equipment in external areas cannot be avoided and poses a risk to the product, the equipment shall be cleaned and disinfected prior to entering production areas.
4.6.7	Battery-charging equipment shall not be stored in open product areas (unless the batteries are fully sealed and/or maintenance-free) or where there is a risk to products.

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

4.8 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.
4.8.4	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-washing facilities shall provide, at a minimum: • advisory signs to prompt hand-washing • a sufficient quantity of water at a suitable temperature • water taps with hands-free operation • liquid/foam soap • single-use towels or suitably designed and located air driers.
4.8.5	Toilets shall be adequately segregated and shall not open directly into production or packing areas. Toilets shall be provided with hand-washing facilities comprising: • basins with soap and water at a suitable temperature • adequate hand-drying facilities • advisory signs to prompt hand-washing. Where hand-washing facilities within toilets are the only hand-washing facilities provided before re-entering production, the requirements of clause 4.8.4 shall apply and signs shall be in place to direct people to hand-washing facilities before entering production.
4.8.6	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations. Electronic cigarettes shall not be permitted to be used or brought into production or storage areas.

Clause	Requirements
4.8.7	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.
4.8.8	Where catering facilities (including vending machines) are provided on the premises, they shall be suitably controlled to prevent contamination of products (e.g. as a source of food poisoning, the use of allergenic ingredients or introduction of new 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, at a minimum: • an approved list of chemicals for purchase • availability of material safety data sheets and specifications • confirmation of suitability for use in a food-processing environment • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • a designated storage area (separate from chemicals used as raw materials in products) with access restricted to authorised personnel • use by trained personnel only • procedures to manage any spills • procedures for the safe, legal disposal or return of obsolete or out-of-date chemicals and empty chemical containers.
4.9.1.2	Where strongly scented or taint-forming materials have to be used, for instance for building work, procedures shall be in place to prevent the risk of taint contamination of products.

4.9.2 Metal control

Clause	Requirements
4.9.2.1	There shall be a documented policy for the controlled use and storage of sharp metal implements including knives, cutting blades on equipment, needles and wires. This shall include a record of inspection for damage and the investigation of any lost items. Snap-off blade knives shall not be used.

Clause	Requirements
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	Procedures for handling glass and other brittle materials (other than product packaging) shall be in place where open products are handled or there is a risk of product contamination. These procedures shall include, at a minimum: • a list of items detailing location, number, type and condition • recorded checks of the condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise the potential for product contamination.
4.9.3.3	Procedures detailing the action to be taken in the event of breakage of glass or other brittle items shall be implemented and include the following: • training of staff in the correct procedure • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising production to continue • changing of workwear and inspection of footwear • specifying those staff authorised to carry out the above points • recording the breakage incident • safely disposing of contaminated product.
4.9.3.4	Where they pose a risk to product, glass windows shall be protected against breakage.
4.9.3.5	Where they pose a risk to product, bulbs and strip lights (including those on electric fly-killer devices) shall be adequately protected. Where full protection cannot be provided, alternative management such as wire-mesh screens or monitoring procedures shall be in place.

4.9.4 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.

Clause	Requirements
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 given for production to restart following cleaning • the area around the line being 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, its condition shall be monitored on a risk-based frequency to ensure it is in good condition and free from damage or splinters which could contaminate products. Wood used for food contact purposes shall be fit for purpose (e.g. free from damage or splinters, free from taint; and wood treatments, where used, are used only in accordance with legislation and approved for food use).

4.9.6 Other physical contaminants

Clause	Requirements
4.9.6.1	Procedures shall be in place to prevent physical contamination of raw materials by raw material packaging (e.g. during debagging and deboxing procedures to remove the packaging).

Clause	Requirements
4.9.6.2	Portable handheld equipment, e.g. stationery items (pens, pencils etc.), mobile phones, tablets and similar portable items used in open product areas, shall be controlled by the site to minimise the risk of physical contamination. The site may consider, for example: • excluding non-approved items • restricting the use to site-issued equipment • ensuring stationery items such as pens are designed without small external parts and are detectable by foreign-body detection equipment, or are used in designated areas where contamination is prevented.
4.9.6.3	Based on risk, procedures shall be implemented to minimise other types of foreign-body contamination (i.e. types of contamination that are not specifically covered in section 4.9).

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 Selection and operation of foreign-body detection and removal equipment

Clause	Requirements
4.10.1.1	A documented assessment in association with the food safety plan (see section 2 – The food safety plan) shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination. Typical equipment to be considered may include: • filters and sieves • metal detection and X-ray detection equipment • magnets • optical sorting 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 packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified.
4.10.1.3	The site shall ensure that the frequency of the testing of the foreign-body detection and/or removal equipment is defined and takes into consideration: • specific customer requirements • the site's ability to identify, hold and prevent the release of any affected materials, should the equipment fail. The site shall establish and implement corrective action and reporting procedures in the event of a failure of the foreign-body detector and/or removal equipment. Action shall include a combination of isolation, quarantining and re-inspection of all products produced since the last successful test or inspection.

Clause	Requirements
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.
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage at a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified, this shall be recorded and the potential for contamination of products investigated and appropriate action taken.

4.10.3 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 food safety. Where metal detectors are not used, justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective method of protection (e.g. use of X-ray, fine sieves or filtration of products).
4.10.3.2	The metal detector or X-ray equipment shall incorporate one of the following: • an automatic rejection device, for continuous in-line systems, which shall divert contaminated product either out of the product flow or to a secure unit accessible only to authorised personnel • a belt stop system with an alarm where the product cannot be automatically rejected (e.g. for very large packs) • in-line detectors which identify the location of the contaminant to allow effective segregation of the affected product.
4.10.3.3	The site shall establish and implement procedures for the operation and testing of the metal detection or X-ray equipment. This shall include, at a minimum: • responsibilities for the testing of equipment • the operating effectiveness and sensitivity of the equipment and any variation to this for particular products • the methods and frequency of checking the detector • recording of the results of checks.

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

4.10.4 Magnets

Clause	Requirements
4.10.4.1	The type, location and strength of magnets shall be fully documented. Procedures shall be in place for the inspection, cleaning, strength testing and integrity checks of magnets used for food safety purposes, including final product testing, e.g. to remove product contamination. Records of all checks shall be maintained.

4.10.5 Optical sorting equipment

Clause	Requirements
4.10.5.1	Optical sorting equipment used for final product testing 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 from the packaging container (e.g. jars, cans and other pre-formed rigid containers). This may include the use of covered conveyors, container inversion and foreign-body removal through rinsing with water or air jets.
4.10.6.2	The effectiveness of the container-cleaning equipment shall be checked and recorded during each production. Where the system incorporates a rejection system for dirty or damaged containers, the check shall incorporate a test of both the detection and effective rejection of the test container.

4.10.7 Other foreign-body detection and removal equipment

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

4.11 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 and disinfection procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures for the processing equipment and food contact surfaces shall, at a minimum, include: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning, including dismantling equipment for cleaning purposes where required • cleaning chemicals and concentrations • cleaning materials to be used • cleaning records (including records for completion and sign-off) and responsibility for verification. The frequency and methods of cleaning shall be based on risk. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.
4.11.3	Limits of acceptable and unacceptable cleaning performance shall be defined for food contact surfaces and processing equipment. These limits shall be based on the potential hazards relevant to the product or processing area (e.g. microbiological, allergen, foreign-body or product-to-product contamination). Therefore, acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing, allergen testing or chemical testing as appropriate. The site shall define the corrective action to be taken when monitored results are outside of the acceptable limits. Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard, the cleaning and disinfection procedures and their frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.
4.11.4	The resources for undertaking cleaning shall be available. Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled and, where necessary, planned for non-production periods. Cleaning staff shall be adequately trained or engineering support provided where access within equipment is required for cleaning.

Clause	Requirements
4.11.5	The cleanliness of equipment shall be checked before equipment is released back into production. The results of checks on cleaning, including visual, analytical and microbiological checks, shall be recorded and used to identify trends in cleaning performance and to instigate improvements where required.
4.11.6	Cleaning equipment shall be: • hygienically designed and fit for purpose • suitably identified for intended use (e.g. colour-coded or labelled) • cleaned and stored in a hygienic manner to prevent contamination.

4.11.7 Cleaning in place (CIP)

Clause	Requirements
4.11.7.1	All CIP equipment shall be designed and constructed to ensure effective operation. This shall include: • validation confirming the correct design and operation of the system • an up-to-date schematic diagram of the layout of the CIP system • where rinse solutions are recovered and re-used, an assessment of the risk of cross-contamination (e.g. due to the re-introduction of an allergen or the existence of different production risk zones within the site). Alterations or additions to the CIP system shall be authorised by a suitably competent individual before changes are made. A record of changes shall be maintained. The system shall be revalidated at a frequency based on risk, and following any alteration or addition.
4.11.7.2	Limits of acceptable and unacceptable performance for key process parameters shall be defined to ensure the removal of target hazards (e.g. soil, allergens, micro-organisms, spores). At a minimum these parameters shall include: • times for each stage • detergent concentrations • flow rate and pressure • temperatures. These shall be validated and records of the validation maintained.
4.11.7.3	The CIP equipment shall be maintained by suitably trained staff to ensure effective cleaning is carried out. This shall include: • routine checking of detergent concentrations • monitoring of recovered post-rinse solutions for build-up of carry-over from the detergent tanks • cleaning and inspection of filters, where fitted, at a defined frequency • storing flexible hoses (where used) hygienically when not in use, and inspecting them at a defined frequency to ensure that they are in good condition.

Clause	Requirements
4.11.7.4	CIP facilities, where used, shall be monitored at a defined frequency based on risk. This may include: • monitoring of process parameters defined in clause 4.11.7.2 • ensuring correct connections, piping and settings are in place • confirming the process is operating correctly (e.g. valves are opening/closing sequentially, spray balls are operating correctly) • ensuring effective completion of the cleaning cycle • monitoring for effective results, including draining where required. Procedures shall define the action to be taken if monitoring indicates that processing is outside the defined limits.

4.11.8 Environmental monitoring

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

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

Clause	Requirements
4.11.8.3	The company shall review the environmental monitoring programme at least annually and whenever there are: • changes in processing conditions, process flow or equipment which could impact the environmental monitoring programme • new developments in scientific information (e.g. new pathogens of concern) • failures of the programme to identify a significant issue (e.g. regulatory authority tests identifying positive results which the site programme did not) • product failures (products with positive tests) • consistently negative results (e.g. a site with a long history of negative results should review its programme to consider whether the correct parts of the factory are being tested, whether the testing is being conducted correctly, whether the tests are for the appropriate organisms, etc.).

4.12 Waste and waste disposal

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

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

4.13 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 otherwise authorised by the customer.
4.13.2	Where customer-branded products which do not meet specifications are sold to staff or passed on to charities or other organisations, this shall be with the prior consent of the brand owner. Processes shall be in place to ensure that all products (own-branded and customer-branded) which are sold to staff or passed on to charities or other organisations are fit for consumption and meet legal requirements, and that their traceability is maintained.
4.13.3	By-products and downgraded/surplus products intended for animal feed shall be segregated from waste and protected from contamination during storage. Products for animal feed shall be managed in accordance with the relevant legislative requirements.

4.14 Pest management

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

Pest management programmes shall comply with all applicable legislation.

Clause	Requirements
4.14.1	If pest activity is identified, it shall not present a risk of contamination to products, raw materials or packaging. The presence of any infestation on site shall be documented in pest management records and be part of an effective pest management programme to eliminate or manage the infestation so that it does not present a risk to products, raw materials or packaging.

Clause	Requirements
4.14.2	The site shall either contract the services of a competent pest management organisation or have appropriately trained staff for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. The risk assessment shall be reviewed whenever: • there are changes to the building or production processes which could have an impact on the pest management programme • there has been a significant pest issue. Where the services of a pest management contractor are employed, the service scope shall be clearly defined and reflect the activities of the site. Service provision, regardless of the source, shall meet with all applicable regulatory requirements.
4.14.3	Where a site undertakes its own pest management, it shall be able to effectively demonstrate that: • pest management operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • staff undertaking pest management activities meet any legal requirements for training or registration • sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood and complied with • dedicated locked facilities are used for the storage of pesticides.
4.14.4	Pest management documentation and records shall be maintained. At a minimum, this shall include: • an up-to-date plan of the full site, identifying pest control devices and their locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for the site management and the contractor • details of pest control products used, including instructions for their effective use and action to be taken in the event of an emergency • any observed pest activity • details of pest control treatments undertaken. Records may be on paper (hard copy) or controlled on an electronic system (e.g. an online reporting system).
4.14.5	Bait stations or other rodent monitoring or control devices shall be appropriately located and maintained to prevent contamination risk to product. Toxic rodent baits shall not be used within production or storage areas where open product is present except when treating an active infestation. Where toxic baits are used, these shall be secured. Any missing bait stations shall be recorded, reviewed and investigated.

Clause	Requirements
4.14.6	Insect-killing devices, pheromone traps and/or other insect-monitoring devices shall be appropriately sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used.
4.14.7	The site shall have adequate measures in place to prevent birds from entering buildings or roosting above loading or unloading areas.
4.14.8	In the event of infestation, or evidence of pest activity, immediate action shall be taken to identify at-risk products and to minimise the risk of product contamination. Any potentially affected products should be subject to the non-conforming product procedure.
4.14.9	Records of pest management inspections, pest proofing and hygiene recommendations and actions taken shall be maintained. It shall be the responsibility of the site to ensure that all of the relevant recommendations made by its contractor or in-house expert are carried out in a timely manner.
4.14.10	An in-depth, documented pest management assessment shall be undertaken at a frequency based on risk, but at least annually, by a pest management expert to review the pest management measures in place. The assessment shall: • include an in-depth inspection of the site, equipment and facilities for pest activity • review the existing pest management measures in place and make any recommendations for change. The assessment shall be timed to allow access to equipment for inspection where a risk of stored product insect infestation exists.
4.14.11	Results of pest management inspections shall be assessed and analysed for trends on a regular basis. At a minimum, results of inspections shall be analysed: • annually **or** • in the event of an infestation. The analysis shall include results from trapping and monitoring devices to identify problem areas. The analysis shall be used as a basis for improving the pest management procedures.
4.14.12	Staff shall understand the signs of pest activity and be aware of the need to report any evidence of such 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 purpose.

Clause	Requirements
4.15.1	Procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment, understood by relevant staff and implemented accordingly. These may include, as appropriate: • managing chilled and frozen product transfer between temperature-controlled areas • segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake • storing materials off the floor and away from walls • specific handling or stacking requirements to prevent product damage.
4.15.2	Where appropriate, packaging shall be stored away from other raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified to maintain traceability before being returned to an appropriate storage area.
4.15.3	Where temperature control is required (e.g. for raw materials, semi-finished materials or final products), the storage area shall be capable of maintaining product temperature within specification and operated to ensure specified temperatures are maintained. Temperature recording equipment with suitable temperature alarms shall be fitted to all storage facilities or there shall be a system of recorded manual temperature checks, typically on at least a 4-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products.
4.15.4	Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions.
4.15.5	Where storage outside is necessary, items shall be protected from contamination and deterioration. Items shall be checked for suitability before being brought into the factory.
4.15.6	The site shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure that materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life.

4.16 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	Procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include, as appropriate: • controlling temperature of loading dock areas and vehicles • the use of covered bays for vehicle loading or unloading • securing loads on pallets to prevent movement during transit • inspection of loads prior to dispatch.
4.16.2	All vehicles or containers used for the transport of raw materials and the dispatch of products shall be fit for purpose. This shall ensure that they are: • in a clean condition • free from strong odours which may cause taint to products • in a suitable condition to prevent damage to products during transit • equipped to ensure any temperature requirements can be maintained throughout transportation. Records of inspections shall be maintained.
4.16.3	Where temperature control is required, the transport shall be capable of maintaining product temperature within specification, under minimum and maximum load. Temperature data-logging devices which can be interrogated to confirm time/temperature conditions, or a system to monitor and record at predetermined frequencies the correct operation of refrigeration equipment, shall be used and records maintained.
4.16.4	Maintenance systems and documented cleaning procedures shall be available for all vehicles and equipment used for loading/unloading. There shall be records of the measures taken.
4.16.5	The company shall have procedures for the transport of products, which shall include: • any restrictions on the use of mixed loads • requirements for the security of products during transit, particularly when vehicles are parked and unattended • clear instructions in the event of vehicle breakdown, accident or failure of refrigeration systems, which ensure that the safety of the products is assessed and records maintained.
4.16.6	Where the company uses contractors, it shall have a documented supplier approval procedure to ensure risks to food quality and safety are effectively managed during dispatch and transport operations. The approval procedure shall be based on risk and include either one or a combination of: • a valid certification to the applicable BRCGS Standard (e.g. Global Standard Storage and Distribution) or GFSI-benchmarked standard **or** • a completed contract or terms and conditions. At a minimum, this shall include all the requirements of clauses 4.16.1 to 4.16.5. This shall have been reviewed and verified by a demonstrably competent person.

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 have a procedure for new product development and changes to existing product, packaging and manufacturing processes. This procedure shall include any restrictions to the scope of new product development to control the introduction of hazards which would be unacceptable to the site or customers (e.g. the introduction of allergens, glass packaging, microbiological risks or the introduction of ingredients that may affect product claims).
5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or an authorised HACCP team member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.
5.1.3	Trials using production equipment shall be carried out where it is necessary to validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.
5.1.4	Initial shelf-life trials shall be undertaken using documented protocols that reflect conditions expected during manufacture, storage, transport/distribution, use and handling to determine product shelf life. Results shall be recorded and retained and shall confirm compliance with the relevant microbiological, chemical and organoleptic criteria or sensory analysis. Where shelf-life trials prior to production are impractical, for instance for some long-life products, a documented science-based justification for the assigned shelf life shall be produced.

5.2 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. The company shall have a procedure for artwork approval and sign-off.

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

5.3 Management of allergens

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

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

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

Clause	Requirements
5.3.1	The site shall carry out an assessment of raw materials to establish the presence and likelihood of contamination (cross-contact) by allergens. This shall include a review of the raw material specifications and, where required, the acquisition of additional information from suppliers (e.g. through questionnaires to understand the allergen profile of the raw material, its ingredients and the factory in which it is produced).
5.3.2	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products, and any new product development ingredients or products.

Clause	Requirements
5.3.3	A documented risk assessment shall be carried out to identify routes of contamination (cross-contact) and establish documented policies, and procedures for handling raw materials and intermediate and finished products, to ensure cross-contamination (cross-contact) is avoided. This assessment shall include: • consideration of the physical state of the allergenic material (e.g. powder, liquid, particulate) • identification of potential points of cross-contamination (cross-contact) through the process flow • assessment of the risk of allergen cross-contamination (cross-contact) at each process step • identification of suitable controls to reduce or eliminate the risk of cross-contamination (cross-contact).
5.3.4	Procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination (cross-contact) of products not containing the allergen. These shall include, as appropriate: • physical or time segregation while allergen-containing materials are being stored, processed or packed • the use of separate or additional protective overclothing when handling allergenic materials • use of identified, dedicated equipment and utensils for processing • scheduling of production to reduce changes between products containing an allergen and products not containing the allergen • systems to restrict the movement of airborne dust containing allergenic material • waste handling and spillage controls • restrictions on food brought onto site by staff, visitors and contractors and for catering purposes.
5.3.5	Where rework is used, or reworking operations are carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.
5.3.6	Where a justified, risk-based assessment demonstrates that the nature of the production process is such that cross-contamination (cross-contact) from an allergen cannot be prevented, a warning should be included on the label. Legislation, 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 individuals with a food allergy or food sensitivity (sometimes referred to as a 'food hyper-sensitivity'), the site shall ensure that the production process is fully validated to meet the stated claim and the effectiveness of the process is routinely verified. This shall be documented.
5.3.8	Equipment or area-cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination (cross-contact) by allergens. The cleaning methods shall be validated to ensure that they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be: • identifiable and specific for allergen use • single use • 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	Where personnel are engaged in vulnerability assessments, the individual or team responsible shall understand potential food fraud risks. This shall include knowledge of raw materials used by the site and the principles of vulnerability assessment.
5.4.2	The company shall have processes in place to access information on historical and developing threats to the supply chain which may present a risk of adulteration or substitution of raw materials (i.e. fraudulent raw materials). Such information may come from, for example: • trade associations • government sources • private resource centres • activities completed for clause 1.1.8.
5.4.3	A documented vulnerability assessment shall be carried out on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution. This shall take into account: • historical evidence of substitution or adulteration • economic factors which may make adulteration or substitution more attractive • ease of access to raw materials through the supply chain • sophistication of routine testing to identify adulterants • the nature of the raw material. The output from this assessment shall be a documented vulnerability assessment plan. This plan shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risks. It shall be reviewed annually and whenever there is: • a change in raw materials or a supplier of raw materials • emergence of a new risk (e.g. known adulteration of an ingredient or developments in scientific information associated with authenticity of the site's products or raw materials, for example, information obtained as part of clause 1.1.8) • following a significant product safety incident (e.g. a product recall) where the authenticity of the site's products or raw materials is implicated.
5.4.4	Where raw materials are identified as being at particular risk of adulteration or substitution, the vulnerability assessment plan shall include appropriate assurance and/or testing processes to mitigate the identified risks.

Clause	Requirements
5.4.5	Where products are labelled or claims are made on finished packs which are dependent on the status of a raw material, the status of each batch of the raw material shall be verified. These claims include: • specific provenance or origin • breed/varietal claims • assured status (e.g. GLOBALG.A.P.) • genetically modified organism (GMO) status • identity preserved • named specific trademarked ingredients. The facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The site shall undertake documented mass balance tests at a frequency to meet the particular requirements of any scheme it is certificated to, or in the absence of a scheme-specific requirement, at least one mass balance test every 6 months.
5.4.6	Where claims are made about the methods of production (e.g. organic, halal, kosher), the site shall maintain the necessary certification status in order to make such a claim.
5.4.7	Where a product is designed to enable a claim to be made, the company shall ensure that all claims are substantiated, and product formulation and the production process are fully validated to meet the stated claim and any legal requirements (in the country of intended sale) relating to the claim. The process flow (see clause 2.5.1) 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 and processes for the purchase of product packaging shall be appropriate for the intended use. Packaging shall be stored under conditions to prevent contamination and minimise deterioration.

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

Clause	Requirements
5.5.3	The company shall have a procedure to manage obsolete packaging (including labels). This shall include: • mechanisms to prevent accidental use of obsolete packaging • control and disposal of obsolete packaging • appropriate procedures for the disposal of obsolete printed materials (e.g. rendering trademarked materials unusable).

5.6 Product inspection, on-site product testing and laboratory analysis

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

Clause	Requirements
5.6.1	There shall be a scheduled programme of product testing which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, processes for obtaining product samples (including, where appropriate, their delivery to a laboratory), frequency and specified limits shall be documented.
5.6.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. The significance of on-site and laboratory results shall be understood and acted upon accordingly. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends. Where legal limits apply, these shall be understood and appropriate action taken promptly to address any exceedance of these limits. Where applicable, the measurement uncertainty associated with laboratory test results shall be considered.
5.6.3	The site shall ensure that a system of validation and ongoing verification of the shelf life is in place. This shall be based on risk and shall include sensory analysis and, as applicable, microbiological testing and relevant chemical factors such as pH and a_w. Records and results from shelf-life tests shall verify the shelf-life period indicated on the product.
5.6.4	Pathogen testing (including pathogens tested as part of the site's environmental monitoring programme) shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be fully segregated from the production and storage areas and have operating procedures to prevent any risk of contamination of products or production areas.

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

5.8 Pet food and animal feed

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

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

Clause	Requirements
5.8.1	The site shall ensure that pet food and animal feed is formulated/designed for the intended use (e.g. where products are designed for complete diet or as a complementary product).
5.8.2	Where a site's product range includes pet food or animal feed products for different animal species, the site shall have specific procedures for the management of any ingredients, raw materials, products or rework that could be harmful to unintended recipients.
5.8.3	Where the site manufactures, processes or packs pet food or animal feed products that contain medicinal substances, the site shall have specific procedures for the management of the medicated raw materials and finished products. At a minimum, these procedures shall include: • identification of medication-containing materials handled on site. These can be raw materials, processing aids, intermediate and finished products, rework or any new product or product development ingredients • supplier approval equivalent to section 3.5.1 for all medicated raw materials • specific staff training on the correct handling of medicated materials • mechanisms to ensure the correct concentrations of medicinal substances in finished products • procedures (e.g. cleaning procedures) to prevent contamination of non-medicated pet food or animal feed with materials containing medicinal substances • specific procedures to ensure the correct labelling of medicated pet food or animal feed • waste disposal mechanisms (see section 4.12) that include the safe and legal disposal of medicated raw materials and products.
5.8.4	Site procedures shall be designed and implemented to meet the relevant pet food and animal feed product safety legislation (both in the country of production and in the country of sale).

5.9 Animal primary conversion

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

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

Clause	Requirements
5.9.1	The company shall undertake a risk assessment for potential prohibited substances (i.e. those prohibited by legislation in the country of operation or intended country of sale). Example substances include pharmaceuticals, veterinary medicines (e.g. growth hormones), heavy metals and pesticides. The risk assessment may be completed as part of clause 3.5.1.1 or as a separate activity. The results of the risk assessment shall be included in raw material acceptance and testing procedures and in the processes adopted for supplier approval and monitoring (see clauses 3.5.1.2–3.5.2.2).
5.9.2	Where the site is in receipt of live animals, there shall be an inspection by a suitably competent individual at lairage and post-mortem to ensure that the animals are fit for human consumption.
5.9.3	The site shall operate procedures to ensure that the traceability of all edible parts of the carcass (i.e. all parts that are intended for the human food supply chain) is maintained.
5.9.4	The site shall establish defined time and temperature requirements for all post-slaughter processes (for example, post-slaughter cooling, processing, storage and distribution). These requirements shall be defined for all chilled or frozen, edible parts of the carcass.

6 Process control

6.1 Control of operations

Fundamental
The site shall operate to process specifications and work instructions/procedures that ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP or food safety plan.

Clause	Requirements
6.1.1	Documented process specifications and work instructions/procedures shall be available for the key processes in the production of products to ensure product safety, legality and quality. The process specifications and work instructions/procedures (as appropriate) shall include: • recipes – including identification of any allergens • mixing instructions, speed, time • equipment process settings • cooking times and temperatures • cooling times and temperatures • labelling instructions • coding and shelf-life marking • storage conditions (e.g. storage temperatures) • any additional critical control points identified in the HACCP or food safety plan. Process specifications shall be in accordance with the agreed finished product specification. The site shall review the process specifications and work instructions/procedures prior to any changes which may affect food safety, legality and quality.
6.1.2	Where equipment settings are critical to the safety or legality of the product, changes to the equipment settings shall only be completed by trained and authorised staff. Where applicable, controls shall be password-protected or otherwise restricted.
6.1.3	Process monitoring, such as temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification.
6.1.4	In circumstances where process parameters or product quality are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.
6.1.5	Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated and verified at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores).
6.1.6	In the event 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.

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

6.2 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 packing machines. Where offline coding or printing of packaging materials occurs: • setting and amendments to the printer parameters (e.g. the input of, or changes to, date codes) shall only be completed by an authorised member of staff • controls shall be in place to ensure that only correctly printed material is available at the packing machines. Processes shall be in place to check label use is reconciled with expected use and the cause of any inconsistencies investigated.
6.2.2	Documented checks of the production line shall be carried out before commencing production and following changes of product. These shall ensure that lines have been suitably cleared and are ready for production. Documented checks shall be carried out at product changes to ensure that all products and printed packaging and labels from the previous production have been removed from the line before changing to the next production.

Clause	Requirements
6.2.3	Procedures shall be in place to ensure that all products are packed into the correct packaging and correctly labelled. These shall include checks: • at the start of packing • during the packing run (e.g. at predefined intervals and when printed packaging or labels are brought to the line during the production run) • when changing batches of packaging materials at the end of each production run. The checks shall also include verification of any printing carried out at the packing stage including, as appropriate: • date coding • batch coding • quantity indication • pricing information • bar coding • country of origin • allergen information.
6.2.4	Where online verification equipment (e.g. bar code scanners) is used to check product labels and printing, the site shall establish and implement procedures for the operation and testing of the equipment to ensure that the system is correctly set up and capable of alerting or rejecting product when packaging information is out of specification. At a minimum, testing of the equipment shall be completed at: • the start of the packing run • the end of the packing run • a frequency based on the site's ability to identify, hold and prevent the release of any implicated materials should the equipment fail (e.g. during the packing run or when changing batches of packaging materials). The site shall establish and implement procedures in the event of a failure in the online verification equipment (e.g. a documented and trained manual checking procedure).

6.3 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 the appropriate legislation governing quantity verification, and records of checks shall be retained.
6.3.2	Where the quantity of the product is not governed by legislative requirements (e.g. bulk quantity), the product shall conform to customer requirements and records shall be maintained.

Clause	Requirements
6.3.3	Where used, the site shall establish procedures for the operation and testing of online check weighers. At a minimum, this shall include: • consideration of any legal requirements • responsibilities for testing the equipment • operating effectiveness and any variations for particular products • methods and frequency of testing the check weighers • processes for handling rejected packs • records of the test results.

6.4 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 and product safety, legality and quality. This shall include, at a minimum: • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration or misuse.
6.4.2	All identified measuring devices, including new equipment, shall be checked and, where necessary, adjusted: • at a predetermined frequency, based on risk assessment • to a defined method traceable to a recognised national or international standard where possible. Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform.
6.4.3	Reference measuring equipment shall be calibrated and traceable to a recognised national or international standard and records maintained. The uncertainty of calibration shall be considered when equipment is used to assess critical limits.
6.4.4	Procedures shall be in place to record actions to be taken when the prescribed measuring devices are found not to be operating within specified limits. Where the safety or legality of products is based on equipment found to be inaccurate, action shall be taken to ensure at-risk product is not offered for sale.

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 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 control measures and 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 personnel. These shall include, at a minimum: • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training • delivery of training in the appropriate language of trainees.
7.1.4	All personnel, including engineers, agency-supplied staff, temporary staff and contractors, shall have received general allergen awareness training and be trained in the site's allergen-handling procedures.
7.1.5	All relevant personnel (including relevant agency-supplied staff, temporary staff and contractors) shall have received training on the site's labelling and packing processes which are designed to ensure the correct labelling and packing of products.
7.1.6	Records of all training shall be available. These shall include, at a minimum: • the name of the trainee and confirmation of attendance • the date and duration of the training • the title or course contents, as appropriate • the training provider • for internal courses, a reference to the material, work instruction or procedure that is used in the training. Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
7.1.7	The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.

7.2 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. These shall include, at a minimum, the following: • watches and similar wearable devices shall not be worn • jewellery shall not be worn, with the exception of a single, plain wedding ring, wedding wristband or medical alert jewellery • rings and studs in exposed parts of the body, such as ears, noses and eyebrows, shall not be worn • fingernails shall be kept short, clean and unvarnished • false fingernails and nail art shall not be permitted • excessive perfume or aftershave shall not be worn. Compliance with the requirements shall be checked routinely.
7.2.2	Hand-washing shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.
7.2.3	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue) and contains a metal detectable strip. These shall be site-issued and monitored. Where appropriate, in addition to the plaster, a glove shall be worn.
7.2.4	Where metal detection equipment is used, a sample from each batch of plasters shall be successfully tested through the equipment and records shall be kept.
7.2.5	Processes and written instructions for staff shall be in place to control the use and storage of personal medicines, so as to minimise the risk of product contamination.

7.3 Medical screening

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

Clause	Requirements
7.3.1	The site shall make staff 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 staff (including temporary employees), contractors and visitors to the site, of any relevant symptoms, infection, disease or condition which they may have been in contact with or may be suffering from.

Clause	Requirements
7.3.2	Where there may be a risk to product safety, visitors and contractors shall be made aware of the types of symptoms, infection, disease or condition which would prevent a person visiting areas with open food. Where permitted by law, visitors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to entering the raw material, preparation, processing, packing and storage areas.
7.3.3	There shall be procedures for staff (including temporary 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: staff or visitors to production areas

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

Clause	Requirements
7.4.1	The company shall document and communicate to all staff (including agency and temporary personnel), contractors and visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. production areas, storage areas). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, and use of canteen and smoking areas).
7.4.2	Protective clothing shall be available that: • is provided in sufficient numbers for each employee • is of suitable design to prevent contamination of the product (at a minimum containing no external pockets above the waist or sewn-on buttons) • fully contains all scalp hair to prevent product contamination • includes snoods for beards and moustaches, where required, to prevent product contamination.
7.4.3	Protective clothing shall be laundered by an approved contracted or in-house laundry using defined criteria to validate the effectiveness of the laundering process. The laundry must operate procedures which ensure: • adequate segregation between dirty and cleaned clothes • effective cleaning of the protective clothing • cleaned clothes are supplied protected from contamination until use (e.g. by the use of covers or bags). Washing of protective clothing by the employee is exceptional but shall be acceptable where: • the protective clothing is not used for product safety purposes; for example, it is used to protect the employee from the products handled **and** • the protective clothing is worn in enclosed product or low-risk areas only.

Clause	Requirements
7.4.4	Protective clothing shall be changed at an appropriate frequency, based on risk.
7.4.5	If gloves are used, they shall be replaced regularly. Where appropriate, gloves shall be suitable for food use, of a disposable type, of a distinctive colour (blue where possible) and intact, and shall not shed loose fibres.
7.4.6	Where items of protective clothing that are not suitable for laundering are provided (such as chain mail, gloves and aprons), these shall be cleaned and disinfected at a frequency based on risk.

8 Production risk zones – high risk, high care and ambient high care

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

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

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

Clause	Requirements
8.1.1	The map of the site (see clause 4.3.2) shall include the location of the pathogen control step(s).
8.1.2	Where high-risk areas are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, the nature of the materials (including packaging), the equipment, the personnel, the chemicals, the disposal of waste, the flow of air, the air quality and the provision of utilities (including drains). The location of transfer points shall not compromise the segregation between high-risk areas and other areas of the factory. Practices shall be in place to minimise the risk of product contamination (e.g. the disinfection of materials on entry).
8.1.3	Where high-care areas are part of the manufacturing site, there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, the nature of materials (including packaging), the equipment, the personnel, the chemicals, the disposal of waste, the flow of air, the air quality and the provision of utilities (including drains). Where physical barriers are not in place, the site shall have undertaken a documented risk assessment of the potential for cross-contamination, and effective, validated processes shall be in place to protect products from contamination, including the procedures for changeover from low-risk to high-care.
8.1.4	Where ambient high-care areas are required, a documented risk assessment shall be completed to determine the risk of cross-contamination with pathogens. The risk assessment shall take into account the potential sources of microbiological contamination and include: • the raw materials and products • the flow of raw materials, packaging, products, equipment, personnel and waste • air flow and quality • the provision and location of utilities (including drains). Effective processes shall be in place to protect the final product from microbiological contamination. These processes may include segregation, management of process flow or other controls.

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

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

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

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

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

Clause	Requirements

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

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

Clause	Requirements
8.5.1	Environmental cleaning procedures in high-care/high-risk areas shall consider the different microbiological risks associated with each production risk zone. At a minimum, cleaning procedures in high-risk and high-care areas shall include all of the requirements in clause 4.11.2. The frequency and methods of cleaning shall be based on risk, and the procedures shall be implemented to ensure that appropriate standards of cleaning are achieved.

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

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

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

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

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

9 Requirements for traded products

Traded products are defined as food products that would normally fall within the scope of the Standard and are stored at the facilities of the site being audited, but that are not manufactured, processed, reworked, packed or labelled at that site.

The site's management of these products is covered by the requirements in this section.

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

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

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

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

9.1 The food safety plan – HACCP

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

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

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

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

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

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

9.2.3	Records shall be maintained of the manufacturer's/packer's approval process, including audit reports or verified certificates confirming the product safety status of the manufacturing/packing sites supplying the products traded. There shall be a process of review and records of follow-up of any issues identified at the manufacturing/packing sites with the potential to affect food products traded by the company.

Clause	Requirements
9.2.4	There shall be a process for the ongoing review of manufacturers/packers, based on risk and using defined performance criteria, which may include complaints, results of any product tests, regulatory warnings/alerts, customer rejections or feedback. The process shall be fully implemented. Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status. Records of the review shall be kept.

9.3 Specifications

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

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

9.4 Product inspection and laboratory testing

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

Clause	Requirements
9.4.1	The site shall have a product sampling or assurance programme to verify that the products are in accordance with buying specifications and meet legal and safety requirements. Where verification is based on sampling, the sample rate and assessment process shall be risk-based. Records of the results of assessments or analysis shall be maintained.
9.4.2	Where verification of conformity is provided by the supplier (e.g. certificates of conformity or analysis), the level of confidence in the information provided shall be supported by commissioning periodic independent product analysis.
9.4.3	Where claims are made about the products being handled, including the provenance, chain of custody and assured or 'identity preserved' status of a product or raw materials used, supporting information shall be available from the supplier or independently to verify the claim.
9.4.4	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025. Documented justification shall be available where non-accredited test methods are used.
9.4.5	Test and inspection results shall be retained and reviewed to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.

9.5 Product legality

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

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

9.6 Traceability

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

Clause	Requirements
9.6.1	The site's traceability procedure (see clause 3.9.1) shall include details of the system used for the traceability of traded products. The traceability system shall ensure that, for all batches of product, the site can identify the last manufacturer or, in the case of primary agricultural products, the packer or place of last significant change to the product. Records shall also be maintained to identify the recipient of each batch of product from the company.
9.6.2	The company shall test the traceability system at least annually to ensure that traceability can be determined back to the last manufacturer and forward to the recipient of the product from the company. This shall include identification of the movement of the product through the chain from the manufacturer to receipt by the company (e.g. each movement and intermediate place of storage).
9.6.3	The traceability test shall include the reconciliation of quantities of product received by the company for the chosen batch or product lot. Traceability should be achievable within 4 hours (1 day when information is required from external parties).

Part III
Audit protocol

Part III
Audit protocol

Introduction

The Global Standard Food Safety (the Standard) 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 audit protocol describes how these audit processes operate and explains the rules around the audit and certification to the Standard. This is an essential element of the Standard and should be read and fully understood.

Every effort has been made to ensure that the content of the Standard is accurate at the time of publication. However, it may be subject to minor change. Any additions or amendments to this normative document will be published as 'position statements' (see section 6.2). Reference should be made to the **BRCGS website**, where changes will be published.

Conformance by the company to the requirements of the Standard 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.

Figure 1 summarises the steps to be followed for all companies wishing to gain certification.

Learn

- Visit www.brcgs.com
- Download a copy of the Standard
- Review any appropriate guidelines

Audit preparation

- Select an audit option (announced, unannounced or blended), with or without additional modules
- Self-assess compliance with the Standard
- Select a certification body
- Define scope of the audit

Audit planning

- Ensure information and appropriate personnel are available for the audit, even in the event of an unannounced audit
- Provide information to certification body for audit preparation
- Define audit date (or parameters if unannounced) and agree audit duration based on audit duration calculator

Audit

The audit will consist of several different audit techniques, including:

- Opening meeting
- Production facility inspection
- Document review
- Vertical audit (including traceability challenge and mass balance)
- Final review of findings
- Closing meeting

Non-conformities and corrective action

- Carry out corrective action, root cause analysis and develop a preventive action plan for any non-conformities identified. Evidence must be submitted within 28 days of the end of the audit
- Certification body reviews evidence in 14 days
- If corrective action, root cause analysis and preventive action plan are deemed satisfactory, a certificate, audit report and corresponding grade will be issued within 42 days of the audit

Post-audit

- Ongoing maintenance of the Standard and continual improvement
- Get login details for the BRCGS Directory and share audit report
- Use of BRCGS logo
- Ongoing communication with certification body
- Schedule re-audit date before the next audit is due

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 Standard, as summarised in Figure 2.

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

This is available for existing certificated sites and those new to certification. For announced audits, 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. Once every 3 years, the audit will be unannounced; the certification body will notify the site within 3 months of the previous audit due date. This will ensure that the site is aware that an unannounced audit will take place in the coming year. However, the actual date of the unannounced audit will not be communicated to the site in advance.

For an announced audit, successful sites are awarded a certificate with a grade of AA, A, B, C or D, depending on the number and type of non-conformities identified. For a mandatory unannounced audit, successful sites will receive an unannounced 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 section 2.

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

The blended announced audit programme uses information and communication technology (ICT) to remotely audit documented systems and records.

The audit is split into two separate parts: a remote audit followed by an on-site audit. The remote audit (first part) uses ICT to focus predominantly on documented systems and records, while the on-site audit (second part) focuses predominantly on production, storage and other on-site areas.

A blended audit can only be offered by the certification body following a risk assessment which:

- confirms that a robust audit is possible (e.g. remote technology is available at the site)
- assesses the percentage of the audit that can be completed remotely.

More details on the risk assessment can be found in section 3.1.5.

At the time of publication, the blended audit option is available for announced recertification audits only and not for initial audits (i.e. the first BRCGS audit at a site). Successful sites are awarded a certificate with grade AA, A, B, C or D, depending on the number and type of non-conformities identified.

More details on the blended announced audit protocol can be found in section 3.

1.1.3 Unannounced audit programme

The unannounced audit option is 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 option provides 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.

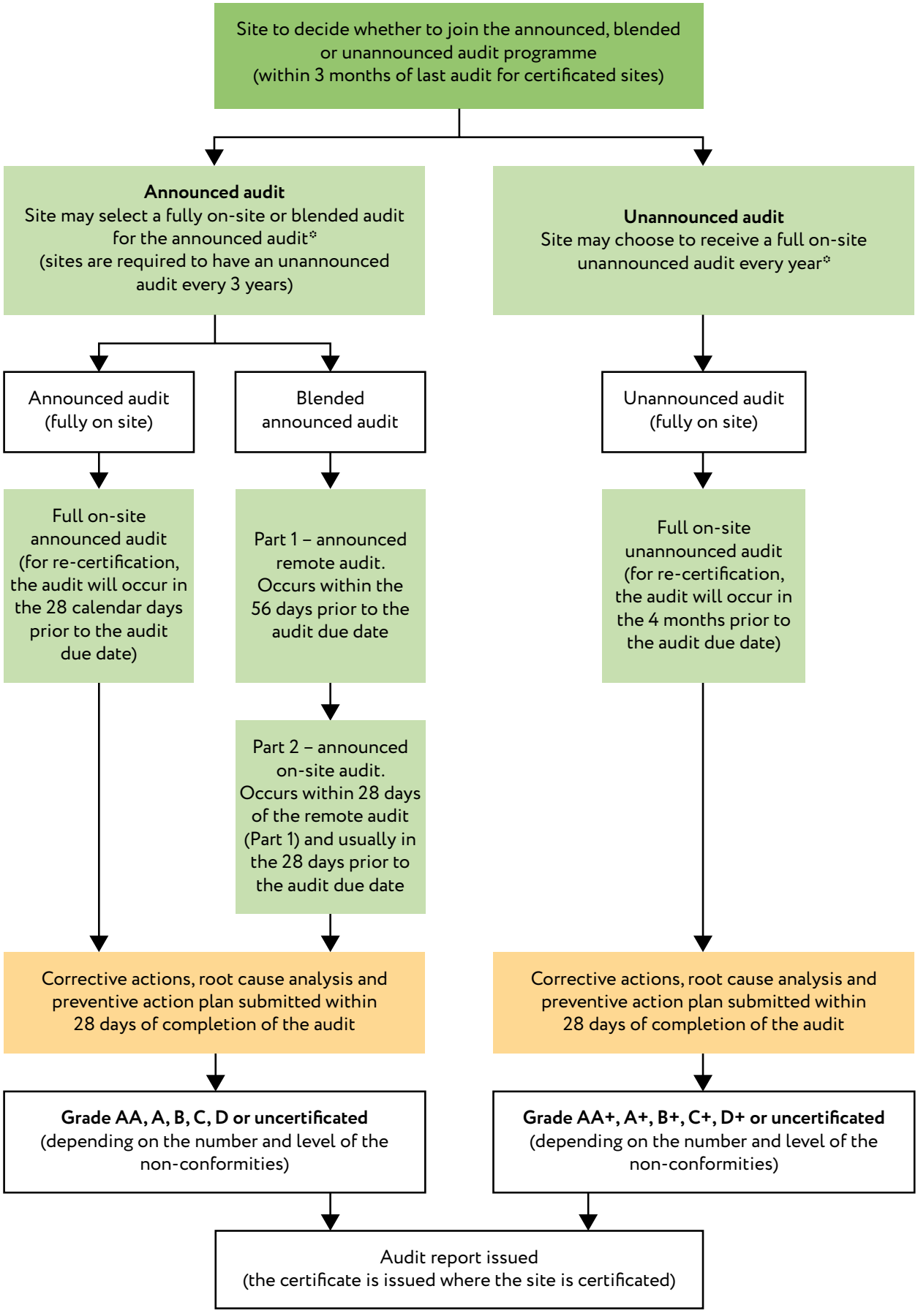

Figure 2 Audit options flow diagram

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.

More details on the unannounced audit programme highlighting the differences between the announced and unannounced protocols can be found in section 4.

1.2 Self-assessment of compliance with the Standard

It is essential that the site is assessed against the current issue of the Standard and any current position statements, all of which are available on the **BRCGS website**.

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 that need to be improved to meet the requirements should be addressed by the company to prevent a non-conformity being raised at the audit.

Further information, guidance and training to ensure compliance with the Standard, including a downloadable self-assessment tool, are available from the **BRCGS website**. BRCGS also has a full range of further guidelines and supporting materials available through the website or, for certificated sites, from **BRCGS Participate**.

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.

Certification bodies shall ensure that any pre-assessment meets the requirements for accreditation. For example, consultancy cannot be provided by the certification body that will later undertake the certification audit, so the same auditor cannot be used for both the pre-assessment and the certification audit.

Manufacturing units that are newly built or 'commissioned' shall ensure that systems and procedures in place are compliant before an initial audit is undertaken. It is at the discretion of the company when it wishes 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. Timescales for audits shall be agreed between the site and the certification body.

1.3 Selection of a certification body

Audits against a Global Standard are only recognised if these are undertaken by certification bodies that are recognised and approved by BRCGS.

BRCGS cannot advise on the selection of a specific certification body; however, they have 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 approved certification bodies in the **BRCGS Directory**. The company should ensure that its selected certification body is accepted by its customers (e.g. only 4- or 5-star-rated certification bodies may be accepted by some customers).

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 BRCGS 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 BRCGS and may be supplied to the accreditation body in the agreed format for the Standard. As a GFSI-benchmarked standard, records may be viewed in conjunction with any GFSI compliance audit. Other documents in relation to the audit shall be made available to BRCGS upon request. All documents submitted to BRCGS shall be copies of original documents. Documents provided will be treated as confidential.
- Where agreements are in place, BRCGS may make audit reports and certificates available to customers of sites or the authorities for earned recognition purposes. Sharing can be removed by the site at any time through the BRCGS Directory.
- 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 BRCGS.

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

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

This publication sets out the requirements against which sites will be audited. 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 shall be communicated to BRCGS and may result in additional compliance activities being undertaken. Non-compliance may also affect the certification status of the site.

1.5 Service fee

BRCGS requires a service fee to be collected by the certification body from the company for every audit undertaken. This covers the service package that allows the company to access a suite of BRCGS products, including **BRCGS Participate**, **BRCGS Professional** and the **BRCGS Directory**. The certificate and audit report shall be uploaded to the BRCGS Directory but shall not be valid until the service fee and the certification body's audit fees have been received, irrespective of the outcome of the certification process.

For more information about what is available in your service package, see **www.brcgs.com**.

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 an auditor (or auditors) 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 and unambiguous both on the audit report and on any certificate issued.

The scope description on reports and certificates shall include:

- the product groups and products manufactured
- a description of the processing activities undertaken at the site that fall within the scope of the Standard
- the packaging format, where applicable (i.e. where the packaging makes a significant difference to the product, e.g. canned products)
- clear identification of products purchased for resale by a site ('traded products')
- clear indication of where the site uses outsourced processing.

The description shall enable a recipient of the report or certificate to clearly identify whether the products supplied have been included in the audit scope.

The wording of the scope will be verified by the auditor during the site audit.

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 BRCGS 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 shall include an audit of the entire process from raw materials 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 shall assess any hazards presented by excluded areas or products (e.g. the introduction of allergens or foreign-body risks) and will therefore need to audit those processes, products and production areas (see Part II, clause 6.1.7). Non-conformities may be raised relating to the excluded area where this poses a risk to the products within the audit scope.

Traded products can be excluded from the audit scope; in that situation the requirements of section 9 will not be applicable. Where excluded, this will be recorded as an exclusion from scope on the audit report and on the certificate. It should be noted that the BRCGS 'food' logo cannot be used for promoting traded products even when they form part of the certificated scope.

1.6.3 Defining the limits of a site

Audit reports and certificates, and therefore audit scopes, are expected to be site-specific. However, in some circumstances, a company may own additional facilities or storage at more than one location, all operated under common management as a single operation, and these may be included under a single certification. This will be considered exceptional, but allowable, where all of the following conditions are met:

- All sites are under the same organisation's ownership
- All sites operate within the same documented quality management systems
- The sites manufacture product which is part of the same manufacturing process (i.e. sequential steps in the manufacture are completed at different sites)
- The sites solely supply the other sites, with no additional customers
- The sites are no more than 30 miles/50 km apart.

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

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).

1.6.4 Auditing 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.

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

1.6.5 Storage facilities – off-site

While 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.

1.6.6 Additional modules

In addition to the core Standard, BRCGS has developed a range of additional modules which may be added to the routine audit. These modules are voluntary and designed to enable sites to demonstrate compliance with specific sets of requirements in order to reduce multiple audits or to meet specific geographic or customer requirements.

A list of the modules, the applicable requirements and any specific protocol for a module is available on the BRCGS website, BRCGS Participate and the BRCGS Store.

The modules can be added to any of the full certification audit options (i.e. announced, blended or unannounced).

The general protocol for the modules is set out in section 5.

1.7 Auditor 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 auditor (or 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 shall be aware of the need to avoid a conflict of interest when arranging for auditors 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 in the native language of the site, an appropriate translator shall be provided who has knowledge of the technical terms used during the audit.

2 Announced audit protocol (with mandatory unannounced audit every 3 years)

This is a full announced audit with one mandatory unannounced audit every 3 years.

All sites shall have at least one unannounced audit every 3 years. For sites with annual (12-month) audits, this will result in at least every third audit being unannounced. Sites that receive a grade C or D at any of their audits will still be expected to undergo an unannounced audit at least every 3 years, but there will be a larger number of announced audits in the interim.

Sites that have opted into the fully unannounced audit programme are not affected by this change; they will continue to follow the unannounced audit protocol outlined in section 4. However, where a site chooses to revert to the announced audit programme, the requirements in this section will apply.

2.1 Audit planning

2.1.1 Preparation by the company

For announced 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 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 to assess. Where the product range is large or diverse, the auditor 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 during a different period of the year from the audit, a separate audit will be required to assess that production method.

For the mandatory unannounced audit, the certification body shall notify the site of the year when the unannounced audit will take place. The actual date of the unannounced audit will not be communicated to the site. This discussion shall occur within 3 months of the previous audit to ensure that the site is aware of the year in which the unannounced audit will take place.

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 (or audit team) 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:

- the background and structure of the company
- a summary of the site's HACCP plan (or food safety plan) and 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
- a description of any special handling requirements (e.g. for allergens, claims or other certifications)
- a description of the site and building fabrication
- typical staff 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 or are only carried out at certain times of the day)

- an outline of any outsourced processes
- any recalls that have occurred since the last BRCGS audit
- any recent quality issues, withdrawals or customer complaints, and other relevant performance data
- an outline of operational controls, such as internal audits, testing and traceability
- any significant changes since the last BRCGS audit.

Where the site is contracted with a new certification body, the site shall make the previous audit report and certificate available to the certification body, even if this was more than a year ago.

Submitting detailed information prior to the audit, and in the format requested by the certification body, may reduce the duration of the on-site audit and the time required to produce the final audit report; therefore sites are encouraged to fulfil such requests in a timely manner.

The time needed for the auditor and certification body to assess all the submitted documentation is additional to the duration of the audit.

Additional information will be required for the unannounced audit (see section 4.1.3).

2.1.3 Scheduling the mandatory unannounced audit

The certification body is responsible for managing the audit process and ensuring that within the 3-year period, all certificated sites receive at least one unannounced audit. The certification body shall notify the site of the year when the unannounced audit will take place, without communicating the actual date of the unannounced audit. This discussion shall occur within 3 months of the previous audit to ensure that the site is aware of the year in which the unannounced audit will take place.

The unannounced audit will replace the normal scheduled (announced) audit. It can occur at any stage within the last 4 months of the audit cycle, including the last 28 calendar days before the date that the announced audit is due (i.e. the unannounced audit must occur within the 4 months leading up to the audit due date). The audit must take place during normal site operation, unless other arrangements have been agreed with the site.

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

2.1.4 Nominating non-audit days for the mandatory unannounced audit

Applicable only to the mandatory unannounced audit.

Compliance with the Standard is expected to be maintained at all times, so the site should always be 'audit ready'. However, there may be dates when an audit genuinely cannot take place, such as when there is a planned customer visit. Therefore, a site may nominate up to 10 days when it is not available for an audit. Sites on a 6-month audit schedule (e.g. sites certificated to the Standard with grade C or D) may nominate up to 5 days.

Days when the site is not operating (e.g. public holidays and site shutdowns) are not included with the nominated 10 days (or 5 days). The certification body must be notified of any such non-operational days, including the dates and reasons, at least 4 weeks in advance. The certification body may challenge the reason where this does not appear appropriate, and at its discretion accept these nominated dates. Certification bodies are expected to operate discretion in the case of emergencies.

It is a condition of the unannounced audit that the auditor shall be granted access to the site for the audit on arrival (see section 2.7.4).

2.1.5 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 2–3 days (typically 8–9 hours/day, but never in excess of 10 hours/day) at the site. Announced audits are usually on consecutive days, although there may be circumstances when this is not the case. A calculator has been developed to assess the expected time required to undertake an audit of any site to ensure consistency, and this shall be used as the basis for calculating the total audit duration. The calculator is available on the BRCGS website.

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 on-site storage facilities
- the number of HACCP plans (or food safety plans) included within the scope. For the purpose of the calculator, a plan corresponds to a family of products with similar hazards and similar production technology.

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

- whether it is an initial certification audit
- shortfalls in the information provided prior to the audit, as specified in section 2.1.2
- the complexity of the manufacturing process
- the number of product lines
- the age of the site and the impact on material flow
- the labour intensity of the processes
- communication difficulties (e.g. language)
- the number of non-conformities recorded in the previous audit (requiring additional time to review the relevant systems and confirm implementation of effective preventive action)
- 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, additional time shall be allocated for this over and above that indicated by the audit calculator.

In the event that the audit against the Standard includes 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 the audit is expected to take 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 stages:

- **Opening meeting** To confirm the scope and process of the audit
- **Production facility inspection (e.g. site, production and storage)** To review practical implementation of the systems, including, for example, auditing good manufacturing practices, accuracy of process flow diagrams, product changeover and line start-up procedures, and observing product changeover procedures
- **Discussions with site staff and managers** For example, to confirm on-site procedures and the implementation of product safety and quality culture plans

- **Document review** To review the documented HACCP and quality management systems
- **Vertical audit, traceability challenge and mass balance** Including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications)
- **Verification of the product safety management system** Including the HACCP plan (e.g. CCPs and CCP monitoring)
- **Label review** Including a review of examples of product labels to check against specifications, the site's label development processes, and legislation
- **Review of production facility inspection** To verify and conduct further documentation checks
- **Final review of findings** Conducted by the auditor in preparation for the closing meeting
- **Closing meeting** To review the 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 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, attend the opening and closing meetings, and be available for a discussion on food safety and quality culture (see Part 11, clause 1.1.11).

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 shall assess the nature and severity of any non-conformity and discuss this with the accompanying manager at the time.

At the closing meeting, the auditor 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 of the corrective action to close any 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 1 working day of completion of the audit.

After completion of the certification process, BRCGS will email the site contact with instructions on how to manage the site's entry in the BRCGS Directory and the BRCGS compliance programme, and how to register for service package benefits. The BRCGS Directory allows both the client and its nominated customers secure access to audit data, and the BRCGS compliance programme provides feedback systems enabling sites to communicate with the certification body and the BRCGS team.

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 (including non-conformities) and confirmation of the site's post-audit actions, including:

- closing out of any non-conformities
- completion of root cause analysis
- development of a preventive action plan.

All site actions shall be completed within the appropriate timescale.

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 level and risk. It 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 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. The certification body shall justify a high number (more than 20) of minor non-conformities where one or no major non-conformities are 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 shall undertake corrective action to remedy the immediate issue, analyse 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 number 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 shown in Table 2.

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-calendar-day period, although there may be some exceptions. Therefore, the re-audit shall not take place any earlier than 28 calendar 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 a preventive action plan to correct it, including timescale, shall be provided to the certification body. A summary of the root cause and proposed preventive action shall be included in the audit report.

Close-out of non-conformities can be achieved in any of the following ways:

- objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken
- remote audit techniques being used to assess corrective actions
- the certification body undertaking a further on-site visit.

An example of evidence submitted for the correction of a non-conformity is given in Appendix 8.

Where the audit would result in a grade of C or C+ with two major non-conformities, or a D or D+ grade being awarded, the closure of non-conformities shall be by means of a further site visit or remote assessment (see section 2.4.1) 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 of corrective action, the root cause analysis and a preventive action plan are 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 previous certification audit shall also be checked during the next site audit to verify effective close-out. For each non-conformity at the last audit, the auditor will therefore expect to see the following:

- **Corrective actions** The site is required to implement corrective actions and report them to the certification body within 28 calendar days of the audit. The auditor shall therefore expect to see the corrective actions from the previous audit in operation (e.g. that the updated procedure submitted to the certification body as evidence of corrective action following the last audit is in use).
- **Root cause analysis** After being completed by the site following the last audit, the root cause analysis will have been submitted to the certification body, and full details should be available if the auditor requires them.
- **Preventive action** At the time of the previous certification decision, the site will have submitted a preventive action plan to the certification body but might not have completed the actual preventive action. The auditor will therefore expect to see evidence that the site has been effective in preventing recurrence of the non-conformity.

Where the corrective action or preventive action has been ineffective, a non-conformity shall be raised against clause 1.1.12 in Part II.

The certification body shall 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 2 Summary of grading criteria, action required and audit frequency

Grade		Critical	Major	Minor	Corrective action	Audit frequency
Announced	Unannounced					
AA	AA+			5 or fewer	Objective evidence within 28 calendar days	12 months
A	A+			6–10		
B	B+			11–16		
B	B+		1	10 or fewer		
C	C+			17–24	Objective evidence within 28 calendar days	6 months
C	C+		1	11–16		
C	C+		2	10 or fewer	Revisit required within 28 calendar days	6 months
D	D+			25–30		
D	D+		1	17–24		
D	D+		2	11–16		
Not certificated		1 or more			Certificate not granted. Re-audit required	
				31 or more		
			1	25 or more		
			2	17 or more		
			3 or more			

Note that shaded cells indicate zero non-conformities.

2.4.1 Revisits

Where a revisit is required to review the action taken in response to the non-conformities identified at the audit (i.e. some sites with grade C and all sites with grade D), this will be scheduled to be completed within 28 calendar days.

The certification body shall assess whether a physical revisit is required or whether a remote audit will provide an effective assessment of the actions taken to close out the non-conformities. Where a remote assessment is considered effective, the certification body can offer this option to the site.

The primary focus of the revisit (whether physical or remote) will be on reviewing the effectiveness of the corrective actions taken. However, if any new non-conformities are identified then these must also be satisfactorily resolved before a certificate can be issued, although they will not affect the grading. The action taken to correct the non-conformity shall be recorded in the final audit report.

2.4.2 Documentary evidence and remote auditing

Where a revisit is not required, suitable evidence of corrective action shall be provided to the certification body within 28 calendar days. The evidence shall clearly demonstrate that adequate corrective actions have been taken and implemented. There are two options for submitting this evidence:

- **A remote audit of the corrective action** To confirm that effective corrective action has been implemented (e.g. a review of documents, discussions with site staff, using webcams)
- **Provision of suitable documentary evidence** For example, updated procedures, records, photographs, and invoices for work completed.

If satisfactory corrective action cannot be effectively demonstrated to the satisfaction of the certification body, a revisit may be required before a certificate can be issued.

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 always be reported in English in addition to the other language.

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 issued so that the certification decision is confirmed within 42 calendar days of the completion of the full audit. Subsequently, the audit report shall be uploaded to and available from the BRCGS Directory within 49 days of the final day of the audit.

The BRCGS Directory is the source of accurate, authenticated and up-to-date certification status information. It enables a one-click audit report sharing option. Audit reports shall remain the property of the company commissioning the audit and shall not be released, whole or in part, to a third party unless the company has given prior consent or the release is otherwise required by law.

The audit report shall be uploaded to the BRCGS 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 BRCGS 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. the BRCGS and accreditation body logos) shall comply with their respective usage rules.

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 re-audit due date shall be calculated from the date of the first day of the initial audit (irrespective of whether further site visits were made to verify corrective actions arising from the initial audit) and not from the certificate issue date.

Subsequent audits of certificated sites shall be carried out either 6 or 12 months after the previous audit due date, depending on the number and type of non-conformities identified at that audit (see Table 2). If it is an announced audit, it shall be scheduled to occur within a 28-calendar-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.

Table 3 provides worked examples in accordance with the announced and mandatory unannounced recertification audits.

It is the responsibility of the site to maintain certification, and the BRCGS Directory sends automatic reminders. Where an audit is delayed beyond the due date, except in justifiable circumstances (see section 2.7.3), this shall result in a major non-conformity being awarded at the next audit. Justifiable circumstances shall be documented in the audit report.

For details on scheduling the mandatory unannounced audit, see section 2.1.3. The unannounced audit shall take place during normal site operations unless other arrangements have been agreed in advance with the site. However, the site must not be notified of the proposed audit date in advance.

The unannounced audit certificate will supersede the existing certificate. It will be issued within 42 days of the audit, assuming that certification is achieved (based on the number and severity of non-conformities and completion of corrective actions). The certificate will have an expiry date based on the expiry date of the previous certificate, plus 6 or 12 months (depending on the grade achieved).

The site shall be responsible for maintaining valid certification, while the certification body shall assume responsibility for maintaining the ongoing audit programme.

Where a site cannot be certificated because of the number or level of non-conformities identified during the audit, the site will require a further full audit before certification can be considered. Once the site has addressed the non-conformities that were raised, the new audit can be arranged. The reaudit shall not take place any sooner than 28 calendar days from the audit date. If the audit was a mandatory unannounced audit, the re-audit may be announced. The re-audit shall be completed by the same certification body unless a concession is granted by BRCGS for a change of certification body during this period.

It should be noted that the site must have at least one unannounced audit every 3 years, and this frequency is not expected to change as a result of a failed audit.

Table 3 Worked examples of an initial audit followed by announced and unannounced recertification audits

Announced/unannounced	Audit date	Next audit due date
Initial audit at site (announced)	1–2 June 2020	1 June 2021
Re-audit (announced)	20–21 May 2021 (audit within 28 calendar days prior to the audit due date)	1 June 2022
Re-audit (1 in 3 unannounced)	1–2 March 2022 (audit within 4 months prior to the audit due date)	1 June 2023
Re-audit (announced)	20–21 May 2023 (audit within 28 calendar days prior to the audit due date)	1 June 2024
Re-audit (announced)	20–21 May 2024 (audit within 28 calendar days prior to the audit due date)	1 June 2025
Re-audit (1 in 3 unannounced)	10–11 March 2025 (audit within 4 months prior to the audit due date)	1 June 2026

If the site chooses to change certification body or GFSI-benchmarked scheme, this does not change the requirement for the site to receive an unannounced audit. Therefore, the site must ensure that the new certification body is aware that the site is already certificated and provide the date of its last unannounced audit. The certification body will also require evidence of the site's audit history (e.g. a copy of the most recent audit report) so that the 3-year cycle can be maintained.

Sharing the last audit report is a mandatory requirement of the BRCGS audit protocol (see section 2.1.2). Where a site fails to share its last report in a timely manner, the new certification body will have access to the last audit report through the BRCGS Directory. If a site fails to have an unannounced audit within the 3-year period, its final audit may be refused by BRCGS and the site will become uncertificated until an unannounced audit has been completed.

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 (Part II, clause 1.1.12), are applicable when the site is:

- situated in a specific country or an area within a specific country where there is government advice not to 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 season (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 are not acceptable reasons 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 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 a renewal audit occurs within a 28-calendar-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 the due date; for example, to reset the audit dates to allow combined audits with another scheme, or to include a product that is produced during 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 next audit due date will be 'reset' to the 12 months (or 6 months, depending on grade) from this 'new' audit date
- The certificate (should it be issued) shall have an expiry date of 12 months (or 6 months, depending on grade) plus 42 calendar days from the new audit date.

2.7.4 Refusal of a company to undertake the unannounced audit

Sites are obliged to accommodate the auditor and allow the audit to commence upon the auditor's arrival at the site. Sites can nominate days when the audit cannot take place; however, they must do so in advance (see section 2.1.4).

Therefore, if the auditor arrives for the audit and is denied access, the site's certification will be suspended. The site shall remain suspended until a new unannounced audit can be completed. Since the new audit will be unannounced, the site shall not be told the new audit date, which may occur at any time within the 4 months following the refused audit. The audit shall be completed by the same certification body unless a concession is granted by BRCGS for a change of certification body during this period.

Liability for the auditor's time shall be covered by the certification body's contract with the site. Therefore, if access is denied, the site may also be liable for the auditor's costs.

2.7.5 Non-availability of key staff at the opening and closing meetings or during the audit

The Standard requires the most senior production or operation manager (i.e. the person who is responsible for the 'hands on' running of the site) to be present at the opening and closing meetings (see Part 11, clause 1.1.11) and for relevant staff to be available during the audit.

Where a key member of staff (e.g. the senior production manager, senior operation manager or technical manager) is genuinely absent on the day of the audit due to other commitments, a nominated deputy must be available (see Part 11, clause 1.2.1).

Therefore, the absence of a key member of staff shall not be accepted as a reason to prevent an audit going ahead.

2.7.6 No production activity on the day of the unannounced audit

As part of the audit planning, the site must notify the certification body of any days or times when operations are not undertaken. If the unannounced audit takes place on a date when the site is supposed to be operational, but on arrival the auditor finds that there is either no production or the only products being handled are outside the scope of the audit, then the audit cannot go ahead. A further unannounced audit will need to be arranged.

Liability for the auditor's time shall be covered within the certification body's contract with the site (see section 2.7.4).

2.7.7 Changing the certification body for an early re-audit

In addition to the situations described in section 2.7.3, an early re-audit may occasionally be requested by a site – usually shortly after the previous audit or following a failure to be certificated. This often occurs because the site wants to improve its audit grade. In this situation, the early re-audit must be completed by the certification body that issued the current certificate.

However, in exceptional circumstances and if agreed in advance by BRCGS, a site may be permitted to change the certification body for this early reaudit. Justification for changing the certification body in this situation shall be provided in writing to the certification body, who in turn shall submit it to BRCGS for consideration through the formal concession process. Where a change in certification body in this instance has not been agreed in advance, a re-audit by the new certification body will be null and void and will not be accepted in the BRCGS Directory.

This requirement applies only when an early re-audit has been requested; it does not change the process for re-audits completed to the normal 6- or 12-month schedule.

2.7.8 Seasonal production sites

The glossary defines a seasonal production site as 'a site that is opened for a short duration (typically 12 weeks or less) during a 12-month cycle. For example, to specifically harvest and process a product.'

For seasonal sites, the scheduling of audits needs to be carefully planned so that:

- certification does not lapse: where the product harvest is dictated by weather and this affects the actual audit date (e.g. the season is later than expected), there is no penalty for a delay to the audit, although justification for this delay must be included in the audit report
- the site is in production, so that all of the requirements of the Standard can be assessed
- there is a minimum of 1 week's production records for the auditor to review.

Corrective actions can be closed out within 28 calendar days and therefore within the current season. In the event that the harvest is unavoidably early (e.g. due to weather conditions) and, as a consequence, there are fewer than 28 calendar days before the end of the season, it may not be possible to close out identified non-conformities within the season. In this situation, the same rules apply as for sites with very short seasons (see below).

The scope of the certification may include a variety of products where these can be 'grouped' because they use the same processing systems. For example, the audit may be undertaken during the harvest of apricots, but certification could include other stone fruits that are known to be packed at the site at the time of the audit. Where products are packed during different seasons, the audit will take place during one season so that the auditor can assess the good manufacturing practice requirements of the Standard. During the audit, the auditor will also review documentation and/or traceability associated with both the product currently in production and those produced in different seasons.

For very short seasons (i.e. less than 4 weeks), it may not be possible to close out identified non-conformities within the season. However, where major non-conformities are identified, these must be resolved before the end of the season or within 28 calendar days of the audit if the site is to gain certification. Where minor non-conformities cannot be closed out within the season, they may be accepted by the certification body if a suitable action plan is provided. These actions will be assessed prior to the beginning of the next season and verified at the next audit. Any non-conformities that are not adequately closed out by the next audit will have the potential to be raised as non-conformities against management commitment (see section 2.3.2). This will apply whether the certificate has lapsed or not.

Where a site is awarded a grade C, C+, D or D+, it is likely that the site will not be in production when the next audit would normally fall 6 months later. In such circumstances, the next audit shall take place as soon as production has started in the new season. In this situation, the site may be required to agree a course of action with its customers, since it will not be certificated at the beginning of the season, until the scheduled re-audit has taken place. Under no circumstances will the validity of the certificate be extended to accommodate this situation.

For true seasonal production sites there may be circumstances where the frequency of audits is reduced, occurring at intervals of 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.

It is particularly important that seasonal sites are well organised to ensure that systems are in place prior to start-up; for example, pest control must be effective from day 1 of operations. The systems shall include internal audits completed prior to start-up.

For seasonal sites it is assumed that the site is not operational 'out of season' and therefore the requirements of the Standard concerning specified meetings or audits which would normally occur at monthly or quarterly intervals throughout the year would not be appropriate during the out-of-season period. However, as a general principle, the site must be able to demonstrate that these activities have taken place in a timely manner (i.e. before the start of the season and at appropriate regular intervals during the season). Sites will need to consider the timing of these activities so that actions, targets or objectives can be completed within meaningful timescales. A schedule must be in place and records available to demonstrate the outcomes.

A site that is open for 12 months of the year may process different products or complete different processes in different seasons, but it would not be classed as a seasonal production site because it operates all the year round. Wherever possible the audit date shall be selected to include the higher-risk or more complex production processes. For example, in a winery the audit date is organised so that the bottling or packing operations are running at the time of the audit. Where the processes are significantly different and there are different product risks, it may be necessary for both products or processes to be audited. However, where the product safety risks are low, the higher-risk process shall be audited as normal and the other processes or products shall be audited by using historical records, with the auditor seeing sufficient objective evidence to confirm compliance with requirements that occurred at other times of the year.

3 Blended announced audit protocol – two-part announced audit

This is a two-part audit consisting of a remote audit followed by an on-site audit.

The blended announced audit scheme allows the certification body to consider which requirements of the Standard may be audited using ICT to conduct an off-site remote assessment. This divides the audit requirements into two separate audits, comprising:

- **the off-site remote audit** – predominantly based on a review of documents and records, and may be planned to ensure that the appropriate staff are available to retrieve and discuss the records
- **the subsequent on-site audit** – mainly focused on the site's operating practices, such as hygiene, production, storage and product handling.

The certification body shall have a documented process for undertaking blended audits that ensure compliance with IAF MD4:2018.

Additional information on the processes for blended audits is available in BRCGS080: Blended Audits – Remote Auditing Using ICT (available from the BRCGS website).

Sites opting for the blended announced audit option are also required to have an unannounced audit at least once every 3 years (see section 2).

3.1 Audit planning

3.1.1 Selection of the blended audit option

This option is available for recertification audits only, not for the first BRCGS audit at a site or for audits at sites not holding a current BRCGS certificate.

The blended audit can be used irrespective of the site's previous grade (i.e. all grades from AA to D are eligible); however, the grade will be taken into account during the pre-audit risk assessment (see section 3.1.5).

The certification body can decide whether to offer and/or accept the blended audit option following the risk assessment.

Before planning the remote audit element of the audit, the certification body shall consider the willingness of the site to consent to the use of remote auditing by ICT. The availability of ICT is also a factor in the effective completion of this audit. It is important that both parties mutually agree to this option.

3.1.2 Preparation by the company

The preparation by the company is mainly the same as for the announced audit scheme (see section 2.1.1).

However, additional consideration is needed for the remote part of the audit. Examples include ensuring the availability of appropriate IT systems, agreement on any confidentiality, security and data protection (CSDP) requirements (see section 3.1.6), and the need to facilitate the audit in a quiet environment to avoid background noises and interference (e.g. considering the availability of office space and the use of noise-cancelling technology such as 'mufflers on microphones' or headsets).

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

The information to be provided to the certification body is same as for the announced audit scheme (see section 2.1.2).

3.1.4 Scheduling the mandatory unannounced audit

Sites opting for the blended announced audit option are required to have an unannounced audit at least once every 3 years. Details of the protocol for the mandatory unannounced audit are given in section 2, especially sections 2.1.3 and 2.1.4.

3.1.5 Pre-audit risk assessment

The certification body shall undertake a full risk assessment to determine whether audit objectives can be achieved remotely. The risk assessment shall include the ability of the company to receive a remote audit, including the:

- historical audit performance of the site, including the risks from complaints and recalls
- availability of documentation and records in electronic form, and the site's willingness to share these remotely (including any limitations)
- capability of the certification body to conduct the remote audit (e.g. trained auditors, access to an IT system that both the certification body and the company will be able to use)
- capability of the site staff to utilise technologies used in remote audit techniques, including on-site video.

Any limitations on document-sharing and record-sharing shall be understood before the audit.

The pre-audit risk assessment is not included in the calculation of the audit duration.

3.1.6 Confidentiality, security and data protection

The certification body shall consider local data protection and privacy laws (as stated in IAF MD4:2018, clause 4.1). It is important that, if ICT (such as video) is utilised, the relevant consents have been sought from the individuals involved to ensure compliance with local privacy regulations.

To prepare for the use of ICT, all requirements (certification, legal and customer) related to confidentiality, security and data protection shall be identified, and actions taken to ensure their effective implementation. Evidence of agreements related to confidentiality, security and data protection (CSDP) must be available. The CSDP criteria shall be acknowledged by all participants, and measures to ensure confidentiality and security shall be confirmed during the opening meeting.

Where documented information is analysed, it shall be shared in a secure and agreed system, such as a cloud-based, virtual private network or other file-sharing system utilising CSDP guidelines. Once the audit is complete, the auditor shall delete from their system, or remove access to, any documented information and records that are not required to be retained as objective evidence.

Auditors must not take screenshots or record videos of auditees as audit evidence. Any screenshots of documents, records or other kinds of evidence must be authorised in advance by the site being audited. In the case of non-fulfilment of these measures or non-agreement of information security and data protection measures, the certification body shall not use the blended audit option.

3.1.7 Selection of clauses for remote and on-site audits

As a minimum, the on-site audit shall include inspection/physical verification of good manufacturing practices and implementation of the food safety management system, including HACCP activities (e.g. the effective operation of prerequisite programmes, verification of the process flow diagram, CCP monitoring and verification) and the traceability challenge.

In addition, the requirements in the Standard are colour-coded to indicate which requirements may be audited remotely and which requirements must be audited during the on-site audit (see Table 4).

Table 4 Key for colour-coding of requirements

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

Clauses that are dual-coloured must be audited during both parts of the audit.

It is important to note that although the colour-coding indicates the clauses that may be audited remotely, the certification body's pre-audit risk assessment (see section 3.1.5) may identify clauses that require on-site assessment, even though they relate to documents or records.

3.1.8 Duration of the blended audit

The total audit duration is the same regardless of whether the audit is completed fully on site (announced or unannounced) or as a blended audit using both remote and on-site auditing (see section 2.1.5).

The duration does not include time spent on audit planning, the risk assessment or report writing.

The remote part of the audit shall not exceed 50% of the total audit duration. It should be noted that 50% represents the maximum proportion of the audit that may be completed remotely. The actual duration of the remote audit will be dependent on the certification body assessment (i.e. the risk assessment in section 3.1.5). Therefore, it may be significantly less than the maximum permitted in some circumstances; for example, if:

- additional risks are identified
- specific documents are not available for the remote audit
- the nature or volume of complaints or recalls is a concern
- the historical performance of the site has been a concern
- the certification body identifies clauses that need to be audited on site, even when they relate to documents or records.

If additional storage facilities, locations or head office assessments are included within the audit process (see sections 1.6.3–1.6.5 and Appendix 4) then additional time shall be allocated for this.

The time allocated for the on-site audit may also be adjusted based on the findings from the remote audit; for instance, more time may be required if a large number of non-conformities require an on-site review of corrective actions.

For the head office or central function, the remote audit can be completed using the colour-coding of the relevant clauses of the Standard. In some situations, this may mean that the auditor does not need to visit the head office as all the clauses are appropriate for remote audits. If the head office contains a mixture of clauses (i.e. some that require on-site audit and others that may be audited remotely), the site may elect to have either:

- a full on-site head office audit or
- a remote head office audit with the remaining on-site elements being assessed at each of the site audits.

The expected audit duration shall be notified to the site by the certification body in advance of the audit. Deviation from the expected audit duration must be justified and specified in the audit report.

3.1.9 Auditor selection

The auditor conducting the blended audit shall be fully competent and qualified in the appropriate product categories (i.e. the same auditor category requirements apply to both the remote and on-site audits).

Where audit teams are used, the audit report shall indicate whether each auditor has completed remote and/or on-site activities.

If a technical expert is used during the audit, the documents shared by the site shall also be made accessible to the expert.

Where different auditors are used for the remote and on-site audits, there shall be a clear handover process prior to the on-site audit to ensure that the auditor has all the necessary information to complete the audit in full and that all the requirements of the Standard are fully covered, either remotely or on site.

3.2 The site audit

3.2.1 The off-site remote audit

Scheduling the remote audit

The audit shall be announced, and the site shall agree a mutually convenient date with the certification body.

The remote audit shall be conducted first (i.e. before the on-site audit). However, where the BRCGS audit is combined with the audit for another GFSI-benchmarked standard, the sequence of the two parts of the audit may be reversed (i.e. the on-site audit would be completed first, followed by the remote audit).

The remote audit shall take place within the 56 calendar days before the audit due date. This is to ensure that:

- there is sufficient time to complete the on-site audit before the audit due date (and within 28 calendar days of the remote audit, although it is recommended that the remote and on-site audits are as close to each other as possible)
- the site has sufficient time (28 calendar days) to close out any non-conformities raised (see section 3.3)
- the certification body has sufficient time (42 calendar days) to make a certification decision after the on-site audit and before the site's current certificate expires.

Preparation for the remote audit

Preparation for the audit can be summarised in the following steps:

- The certification body shall prepare a clear audit plan which highlights the documents that will be needed remotely. This plan shall be shared with the site prior to the audit.
- The certification body shall set up the technical requirements for the remote audit – for example, internet access, meeting software that is usable by both site and auditor, and hardware (including webcams/cameras and microphones).
- BRCGS recommends that the certification body tests the compatibility of the ICT platform with the site, especially prior to the first blended audit at the site or when new ICT platforms will be used. If testing reveals issues that cannot be rectified then the audit shall be completed as a full on-site audit.
- Use of webcams/cameras shall be agreed.
- When assigning work to audit team members, including technical experts, this should take into consideration their ability to utilise the remote technologies.
- The remote audit shall be facilitated in a quiet environment wherever possible to avoid background noise and interference. The use of noise-cancelling technology (e.g. 'mufflers on microphones' or headsets) should be considered.
- When no agreement is reached for the use of ICT for a remote audit, the audit will revert to a full on-site audit.

If it is not possible to maintain satisfactory conditions during the scheduled time of the remote audit, the auditor may decide to terminate it. This shall be recorded in the report. The remote audit may continue at a later date agreed between the two parties within the period described above.

In the event of the technology failing during the remote audit, the certification body and the site can reschedule, providing this occurs within the 28-calendar-day window. The site may be liable to pay for the lost audit day where the failure is a site issue, and this should be covered in the contract between the certification body and the site. Ultimately, if the audit cannot be completed remotely then the auditor will need to complete the audit on site. This on-site audit will follow the protocol for the announced audit option (see section 2) and shall be completed prior to the audit due date.

Completing the remote audit

The remote audit consists of the following stages:

- **Opening meeting** To confirm the scope and process of the audit
- **Document review** The documents will have been confirmed by the certification body; for example, verification of the product safety management system (e.g. HACCP plan, CCPS and CCP monitoring)
- **Interviews/discussions with personnel** For example, to discuss the document, policy or record being audited
- **Label review** Including a review of examples of product labels to check against specifications, the site's label development processes, and legislation

- **Final review of findings** Conducted by the auditor in preparation for the closing meeting
- **Closing meeting** To review the audit findings with the site and confirm any non-conformities.

Good practice is to include sufficient breaks in the audit plan, so that site personnel and auditors are not continuously using a computer screen for a prolonged period.

The remote audit may also include a live video if required. Any live video shall not be recorded, but a record shall be kept of its duration and what was covered. This information is to be recorded in the audit report.

The site shall fully assist the auditor at all times. It is expected that the opening and closing meetings will be attended by the site's senior managers or their nominated deputies (see Part II, clause 1.1.11) who have the appropriate authority to ensure that corrective actions can be progressed if any non-conformities are found.

A closing meeting at the end of the remote audit shall conclude the audit findings, confirm any non-conformities and discuss the next steps. Information shall be given on the process of providing evidence for closing out any non-conformities and the timescale within which the company must provide it.

A written summary of the non-conformities discussed will be documented by the auditor either at the closing meeting or within 1 working day after completing the audit. Any non-conformities are subject to subsequent independent verification by the certification body management.

If a critical non-conformity or the number and level of non-conformities would result in failure to achieve a certificate, the existing certificate for the site shall be immediately withdrawn. A new audit shall be arranged, which shall be fully on-site. (This process is identical to the protocol for on-site audits, which is documented in section 2.)

3.2.2 The on-site audit

Planning for the on-site audit

This is the same as for the announced audit option (see section 2.1).

The on-site audit shall be conducted within 28 calendar days of the remote audit and during the audit due window of the current certificate (i.e. during the 28 calendar days prior to the audit due date). It is recommended that the time between the remote and on-site audits is as short as practicable. In exceptional (but justifiable) circumstances, the certification body may ask BRCGS for an extension of up to 90 days.

Completing the on-site audit

In order to have consistency, it is strongly recommended that the on-site audit should be carried out by the same auditor who carried out the remote audit. If this cannot be arranged, a clear handover process shall be in place prior to the on-site audit to ensure that the auditor has all the necessary information to fully complete the audit and that all the requirements of the Standard are covered, either remotely or on site. All auditors shall be qualified in the appropriate product categories (i.e. the same auditor category requirements apply to the remote audit and the on-site audit).

The on-site audit consists of the following stages:

- **Opening meeting** To confirm the scope and process of the audit
- **Audit of site and storage facilities** To audit practical implementation of systems, including, for example, auditing good manufacturing practices, accuracy of process flow diagram, product changeover and line start-up procedures
- **Any requirements identified** For on-site audit during the risk assessment and remote audits
- **Discussions with site staff and managers** For example, to confirm on-site procedures, the implementation of product safety and quality culture plans, and the site's label review mechanisms

- **Vertical audit, traceability challenge and mass balance** Including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications)
- **Verification of the product safety management system** Including the HACCP plan (e.g. CCPs and CCP monitoring)
- **Review of production facility inspection** To verify and conduct any further comparison of documentation with actual practice
- **Final review of findings by the auditor** Preparation for the closing meeting
- **Closing meeting** To review the 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 at all times. It is expected that the opening and closing meetings will be attended by the site's senior managers or their nominated deputies (see Part II, clause 1.1.11) who have the appropriate authority to ensure that corrective actions can be progressed if any non-conformities are found.

At the closing meeting, the auditor shall present their findings and reconfirm all the non-conformities that have been identified during the audit; however, they 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 of the corrective action needed to close any 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 1 working day after completion of the audit.

At the closing meeting, the auditor will also provide the site with an explanation of the BRCGS Directory (which allows both the client and its nominated customers secure access to audit data) and the BRCGS compliance programme (including the feedback systems available to communicate with the certification body and the BRCGS team).

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 identified in both audits in the appropriate timeframe. The company will be informed of the certification decision following this review.

3.3 Non-conformities and corrective action

Any non-conformities identified during the remote and on-site audits shall follow the existing requirements of the scheme (see section 2.3). Evidence of the action taken to correct any non-conformities shall be submitted to the certification body within 28 calendar days of the on-site audit (i.e. within 28 calendar days of the completion of the blended audit).

Verification of the preventive action plan and implementation of the corrective actions may take various forms (including further on-site assessment or the scrutiny of evidence submitted through ICT). Verification must be carried out by the certification body's technically competent personnel, who must use appropriate methods.

If a critical non-conformity or the number and level of other non-conformities identified at the remote audit (i.e. the first part of the audit) or the on-site audit (i.e. the second part of the audit), or as a result of the sum of both parts of the audit, would result in failure to achieve a certificate, the existing certificate for the site shall be immediately withdrawn. Where the critical non-conformity and/or number of non-conformities occurs during the remote (first) part of the audit, the existing certificate shall still be withdrawn immediately (i.e. after the remote audit) and not delayed until the second part of the audit has been completed.

3.4 Grading of the audit

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

However, the grade awarded is based on the combination of non-conformities identified at the two audits (i.e. the sum of the non-conformities identified at the remote audit and the on-site audit).

Any non-conformities identified during the remote audit that were closed out and corrected before the on-site audit are still counted when calculating the grade.

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 'Blended announced audit'.

The audit report shall clearly identify the extent to which any ICT has been used in carrying out the audit and the effectiveness of ICT in achieving the audit objectives. The audit report shall include all the summarised information and findings of the remote audit and the on-site audit so that a single report can be uploaded to the BRCGS Directory.

The report shall also reference the dates and the duration of the two audits, including the records of the people who attended them. The requirements assessed during the remote audit shall be identified by an asterisk placed at the beginning of the information.

The final report will not be produced until the on-site audit has been completed.

3.6 Certification

The certification requirements are the same as for the announced audit scheme (see section 2.6).

The design of and information on the certificate are the same as for all audits against the Standard, except that the certificate shall state 'Blended announced audit'. The dates of both audits (remote and on-site) shall be included on the certificate.

This certificate will supersede any existing certificate. It shall be issued within 42 days of the on-site audit and will have an expiry date based on the expiry date of the previous certificate plus 6 or 12 months, depending on the grade achieved.

3.7 Ongoing audit frequency and recertification

This is the same as for the announced audit option (see section 2.7).

Sites that have opted into the blended announced audit option are required to complete a mandatory unannounced audit every 3 years (see section 2.1.3).

3.7.1 Scheduling re-audit dates

Subsequent announced audits can remain in the blended announced audit programme, irrespective of the site's previous grade (i.e. sites graded from AA to D can receive a remote audit). However, the certification body will include the previous grade within the pre-audit risk assessment (see section 3.1.5).

4 Unannounced audit protocol

This is a fully on-site unannounced audit.

The protocol of unannounced audits generally follows that of announced audits above; where it differs, this is outlined as follows.

This audit option involves a single unannounced audit against all the relevant 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. It can occur at any stage within the last 4 months of the audit cycle, including the 28 calendar days before the audit due date (i.e. at any point from 4 months before the audit due date).

4.1 Audit planning

4.1.1 Selection of the unannounced audit 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 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.

Non-certificated sites may opt into the unannounced audit programme on the understanding that the initial audit may not occur for up to 12 months from the request.

4.1.2 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.

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

In addition to the information specified in section 2.1.2, the certification body will require 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
- any health and safety or other company information that needs to be reviewed by the auditor on arrival (e.g. health and safety video) to avoid unnecessary delays before entering production.

4.1.4 Nominating non-audit days

Compliance with the Standard is expected to be maintained at all times and the site should therefore always be 'audit ready'. However, there may be dates when an audit genuinely cannot take place, such as a planned customer visit. The unannounced audit programme therefore allows sites to nominate up to 10 days when they are genuinely not available for an audit. Sites on a 6-month audit schedule (e.g. sites certificated to the Standard with grades C or D) may nominate a maximum of 5 days.

The dates and the reasons must be provided to the certification body within 3 months of opting into the programme. At the discretion of the certification body, other unavailable dates may be accepted when provided at least 4 weeks in advance of the next unavailable date. The certification body may challenge the reason where this does not appear appropriate and at its discretion accept these nominated dates.

Days when a site is not operating (e.g. weekends, public holidays and planned shutdowns for site holidays or maintenance) are not included within the 10 days (or 5 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 audit programme 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

The typical duration of an audit does not differ from that of an announced audit, subject to the variances described in section 2.1.5.

4.2 The on-site audit

Sites opting for the unannounced audit programme 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 will follow the same stages as an announced audit (see section 2.2).

4.3 Non-conformities and corrective action

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

4.4 Grading of the audit

The process for grading is the same as for the announced audit (see section 2.4). The grade awarded following certification shall be based on the number and severity of the non-conformities, as outlined in Table 2. Note that the grade will have the addition of a plus symbol after the grade (i.e. AA+, A+, B+, C+ or D+) to indicate that the audit was unannounced.

4.5 Audit reporting

The audit reporting requirements are the same as for the announced audit; however, the report shall state 'unannounced option' (see section 2.5).

4.6 Certification

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

This certificate will supersede the existing certificate. The certificate shall have an expiry date based on that of the previous certificate plus 6 or 12 months, depending on the grade, provided that the site remains within the unannounced audit programme. If the site decides to return to the announced audit programme, the certificate expiry date will be 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 programme, it is not disadvantaged by a shorter certificate life and increased frequency of audits.

4.7 Ongoing audit frequency and recertification

4.7.1 Scheduling re-audit dates

The site can choose whether to:

- remain within the unannounced programmes (fully on site)
- revert to the announced audit programme (fully on site or blended).

If the site wishes to remain in an unannounced programme, the next audit will be unannounced. The audit may occur at any stage within the last 4 months of the audit cycle, including the 28 calendar days before the 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 certification body to ensure that the audit is undertaken within the certification window so that the late audit non-conformity clause (Part II, clause 1.1.10) shall not apply.

If the site wishes to withdraw from an unannounced audit programme, the next audit will be scheduled to occur within the 28 calendar 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. Where the site received a grade of C+ or D+ at the last audit and wishes to withdraw from an unannounced audit programme, the next audit due date will be 6 months after the last audit date, and the audit will occur within the 28 calendar days prior to this date.

4.7.2 Seasonal production sites

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

- The expected seasonal production dates shall be notified to the certification body at the time of choosing the unannounced programme
- 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 programme, the audit window will be 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 audit due date and certificate expiry date (42 calendar 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 occasional issue of a certificate with a duration of more than 1 year.

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

5 Additional modules

The Standard has been designed to enable additional modules to be included with the routine audit. The additional modules will enable sites to demonstrate compliance with 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 for a module will be available on the BRCGS website and on BRCGS Participate.

The modules can be added to any of the full certification audit options (i.e. announced, blended or unannounced).

The general protocol for the additional modules broadly follows the principles of the Standard; however, details will be given with each module.

The site should inform the certification body that an additional module is to be included within the scope of the audit. This ensures that sufficient extra 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 announced audit covers products for the intended additional module where this is applicable. Where the site has opted into the unannounced audit programme, detailed information shall be given to the certification body regarding production planning so that an appropriate audit date can be selected. At its discretion, where there is a lack of information or no potential for choice of audit dates, the certification body may be unable to accommodate the request for the additional module at the unannounced audit.

There will be no grading of the additional modules. The modules will either be certificated or not. Any non-conformities identified when assessing a module shall not be taken into account when deciding the grade for certification against the Standard.

Note that the modules are certificated separately from the Standard; however, where certification to the Standard is not achieved, certification for the module cannot be awarded, irrespective of whether the requirements of the module have been met.

6 General protocol – post audit

6.1 Communication with certification bodies

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

- legal proceedings with respect to product safety or legality, or that which significantly affects the operation of the site
- enforcement by authorities related to product safety or legality (e.g. an enforcement notice)
- product recalls, food safety-related product withdrawals, any significant public food safety incidents, or any significant regulatory food safety non-conformities
- significant damage to the site (e.g. natural disaster such as flood or damage by fire)
- change of ownership (see glossary)
- any significant change to the operation or scope
- significant staff changes or prolonged shutdowns (e.g. considerable staff losses or the loss of key product safety roles).

The certification body in turn shall take appropriate steps to assess the situation and any implications for the certification, and shall take 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 the certificate is not affected
- suspend certification pending further investigation
- require further details of the corrective action, root cause analysis and preventive action plan implemented 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 the certification status of a site shall be recorded in the **BRCGS Directory**.

In the event of an incident, the effectiveness of corrective and preventive actions taken by the site will also be reviewed at the next scheduled BRCGS audit to confirm their implementation and continued effectiveness.

6.2 Position statements

During the lifetime of the Standard, the BRCGS technical advisory committee (TAC) (see Part IV) may be asked to:

- review the wording of a requirement in the Standard or protocol
- provide an interpretation for a requirement
- rule on the grading of a non-conformity against a clause.

The outcome will be published on the BRCGS website as a 'position statement'. Position statements are binding on how the audit and certification processes are carried out. They are considered to be an extension of the Standard.

Sites shall be aware of any published position statements relating to the Standard and, where necessary, ensure that the information is transferred into action. Non-compliance with a relevant position statement may result in a non-conformity against clause 1.1.9 or a specific clause of the Standard.

Position statements are published on the **BRCGS website** and on **BRCGS Participate**. They are also communicated electronically to companies and certification bodies (e.g. in bulletins and newsletters).

More information on the development and publication of position statements can be found in Appendix 9.

6.3 Extension to scope

Once certification has been granted, any subsequent changes that are required to be included in the scope of certification (e.g. additional significant products manufactured or processes undertaken by the site) 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 its 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 programme.

Identified non-conformities should be documented and actioned within the normal protocol of the Standard (i.e. the company has 28 calendar 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 an 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 site 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.

6.4 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 Global Standards certification scheme and ISO/IEC 17065. Examples of these instances are:

- evidence that the site no longer complies with the requirements and protocol 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
- failure to fulfil contractual obligations (e.g. payment failure).

6.5 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. The documented appeals procedure of the relevant certification body 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.

It should be noted that where an appeal is made against a non-conformity, this does not delay or postpone the corrective action, root cause analysis or development of a preventive action plan (see section 2.3.2). The relevant information is still expected within 28 calendar days of the completion of the audit. In the event of an unsuccessful appeal, the certification body has the right to charge costs for conducting the appeal.

6.6 Surveillance of certificated companies

For certificated companies, the certification body or BRCGS 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. These audits form part of the BRCGS compliance programme with random visits to certificated sites. Refusal of access to the site or unwillingness to cooperate with the auditor 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 calendar 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 BRCGS by the certification body and the status in the BRCGS Directory shall be 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.

6.7 BRCGS logos

Achieving BRCGS certification is something of which to be proud. Companies that achieve certification and have no exclusions from their scope (see section 1.6.2) are qualified to use the BRCGS food logo on site stationery and other marketing materials. Note that the food logo shall not be used in promoting products purchased for resale by a site (traded products). Information and conditions relating to the use of the BRCGS logo is available from brcgs.com/resources/brcgs-brand-guidelines.

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 BRCGS logo is not a product certification mark and neither it nor any reference certification may be used on products or product packaging. Any certificated site found to be misusing the logo will be subject to the BRCGS complaints and referral process (see Part IV) and may risk suspension or removal of its certification.

The BRCGS logo may not be used by companies that do not include all products that are manufactured, processed, packed or labelled on site within the audit scope.

6.8 BRCGS Directory

The BRCGS Directory is the database of all audits conducted against a BRCGS Standard and all BRCGS-approved certification bodies and their auditors. The Directory hosts all audit reports and certificates in PDF format, including archived audit documents from 2008 onwards.

Audit data can be added to or edited on the Directory by BRCGS-approved certification bodies only. Audit reports and associated confidential content can only be accessed following secure sign-in.

Certification bodies are also responsible for maintaining all details about a site, including the site's name, address and contact details. All certification bodies are assessed and graded by BRCGS according to how quickly and accurately they update audit data.

The Directory also features a publicly accessible search function displaying certification data for currently certificated sites. Sites wishing to be excluded from public listing should contact their certification body.

6.8.1 Site code

All audited sites are allocated a unique 6-, 7- or 8-digit reference number known as a site code. Site codes are generated when a site record is initially created and added to the Directory by a certification body. The site code remains unchanged, regardless of subsequent auditing certification bodies, Standard status or audit status.

Site codes can be located on the top right-hand corner of the first page of all audit reports and on corresponding certificates.

The listing for any certificated site can be located in the public area of the Directory by adding the site code to the 'site code' search field. If no results are returned for a search, contact BRCGS to confirm certification authenticity.

6.8.2 Audit-sharing

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

Once audit-sharing has been configured, customers can access the full current, archived and future audit documents (as they become available) without any further administration. An audit owner can cancel sharing at any time. Audit documents shared in the Directory cannot be edited or otherwise changed by the audit owner; therefore, audits obtained from the Directory can be considered as complete and authenticated.

6.8.3 Site-sharing

Only certification bodies authorised by the site owner can edit a site record. In the event of a transfer from one certification body to another, the new certification body must be given access to the site's records before a new audit can be added for that site or any edits to the site details can be made. Site-sharing can be arranged by the site owner on the Directory or by BRCGS upon request.

6.8.4 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.

6.8.5 Directory assistance and contacting BRCGS

For further information regarding the BRCGS Directory, including how to configure audit-sharing with a customer or site-sharing with a certification body, visit the BRCGS Directory and click on the 'Audit & Site Sharing' and 'Contact' tabs.

Part IV
Management and governance

Part IV
Management and governance

1 Requirements for certification bodies

The Global Standard 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 3.

In order for a business to receive a valid certificate on completion of a satisfactory audit, the organisation shall select a certification body approved by BRCGS. BRCGS lays down detailed requirements that a certification body shall satisfy in order to gain approval. As a minimum, the certification body shall be accredited to ISO/IEC 17065 by a national accreditation body affiliated to the International Accreditation Forum (IAF) and recognised by BRCGS. Further details are available in the document 'Requirements for organisations offering certification against the criteria of BRCGS' (BRCGS004), which is available on request.

Companies looking to become certificated to the Standard should assure themselves that they are using a genuine, approved certification body. A list of all certification bodies approved by BRCGS is available in the **BRCGS Directory**.

BRCGS recognises that in certain circumstances (for example, when new standards are introduced or there are 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 shall be able to conduct audits as part of the accreditation process and so some unaccredited audits will be performed. This will be permitted where the organisation can demonstrate that:

- it has an active application for accreditation against ISO/IEC 17065 from an approved national accreditation body
- accreditation will be achieved within 12 months of the date of application, and the experience and qualifications of the auditors in the relevant product categories are consistent with those specified by BRCGS
- a contract is in place with BRCGS, and all other contracted requirements have been met.

The acceptance of audit reports and certificates generated by certification bodies awaiting accreditation (but meeting the above criteria) is at the discretion of individual specifiers. Full details of the BRCGS requirements for certification bodies and auditors are published separately from this document; copies are available from the BRCGS website or on request.

2 Requirements for accreditation bodies

2.1 General requirements

BRCGS recognises accreditation bodies that are signatories to the IAF Multilateral Agreement (MLA) for product certification and therefore work in accordance with the requirements of ISO/IEC 17011 'Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies'.

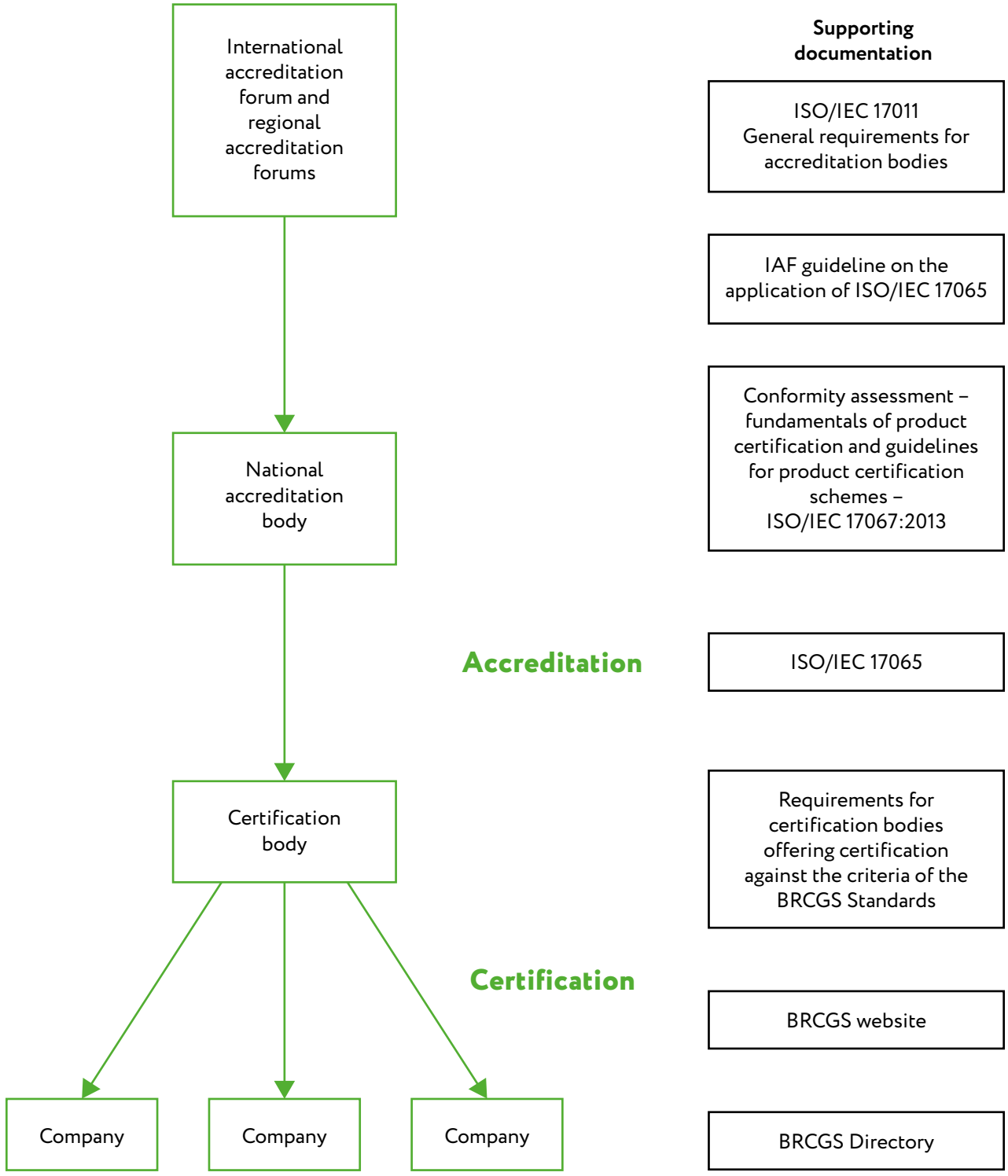

Figure 3 Process for the accreditation of certification bodies

2.2 Communication

Accreditation bodies shall have a working relationship with BRCGS, with interactive communication through a nominated contact within their organisation. BRCGS will:

- keep accreditation bodies up to date with relevant information and developments related to the certification programme
- provide an annual accreditation body conference
- share information through regular update bulletins
- provide specific data on its accredited certification bodies' performances.

Up-to-date information shall be available to BRCGS on initial and accreditation extensions granted, and any withdrawals or suspensions of accreditation of a certification body from the scheme. The scope of accreditation of the certification bodies shall be publicly available, up to date and defined in terms of the exact name of the Standard and its issue number.

Communications shall respect confidentiality requirements at all times.

2.3 Accreditation body personnel competencies

Accreditation body assessors shall have a working knowledge of ISO/IEC 17065:2012 and the Standard's normative documents, as well as the food industry in general, to undertake their role.

BRCGS operates an 'Approved Training Provider' scheme where authorised trainers deliver BRCGS-developed training material together with a corresponding examination. This training may be optionally utilised.

Witness assessors shall be competent, have a working knowledge of, and be trained in, the Standard (either internally or externally), and have a recognised HACCP qualification.

Head office assessors shall, as a minimum, have a detailed knowledge of the Standard and its normative documents, having been trained internally or externally.

2.4 Accreditation processes

Accreditation bodies shall implement processes that aim to complete any initial application for accreditation to the Standard within 12 months. Unaccredited certificates can be issued during this time with no limit on maximum numbers. Accreditation shall be completed prior to the new issue of the Standard becoming 'live' (i.e. before the certification body issues any certificates).

Accreditation bodies shall be able to demonstrate an approach which ensures that the requirements of the BRCGS Global Standards are understood and effectively assessed as a part of the accreditation process.

Initial assessments shall include a head office assessment, with a review of at least two full certification processes for the Standard, as well as a minimum of one accreditation witness assessment.

During the surveillance of the 5-year accreditation cycle for accredited certification bodies, a head office assessment against ISO/IEC 17065 shall be completed annually. The sampling of activities and files shall sufficiently cover the breadth of activities conducted by the certification body, considering audit and auditor volume, geography and product categories.

A minimum of one accreditation witness assessment every 2 years shall be completed. The planning and scheduling of activities shall be based on risk, taking into account the breadth of product categories, geography, and the audit and auditor volume held by the certification body.

3 Technical governance of the Standard

The Standard and associated scheme is managed by BRCGS with governance and technical advice provided through a number of committees (see Figure 4), each of which works to a set of defined terms of reference.

3.1 International advisory boards

The technical management and operation of the Standard is governed by BRCGS international advisory boards. These consist of senior technical representatives of international retail and food manufacturing businesses in Europe, North America and Asia.

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

3.2 Technical advisory committee

Each 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. BRCGS provides the technical secretariat for these groups.

The TAC for the Global Standard 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 the 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.

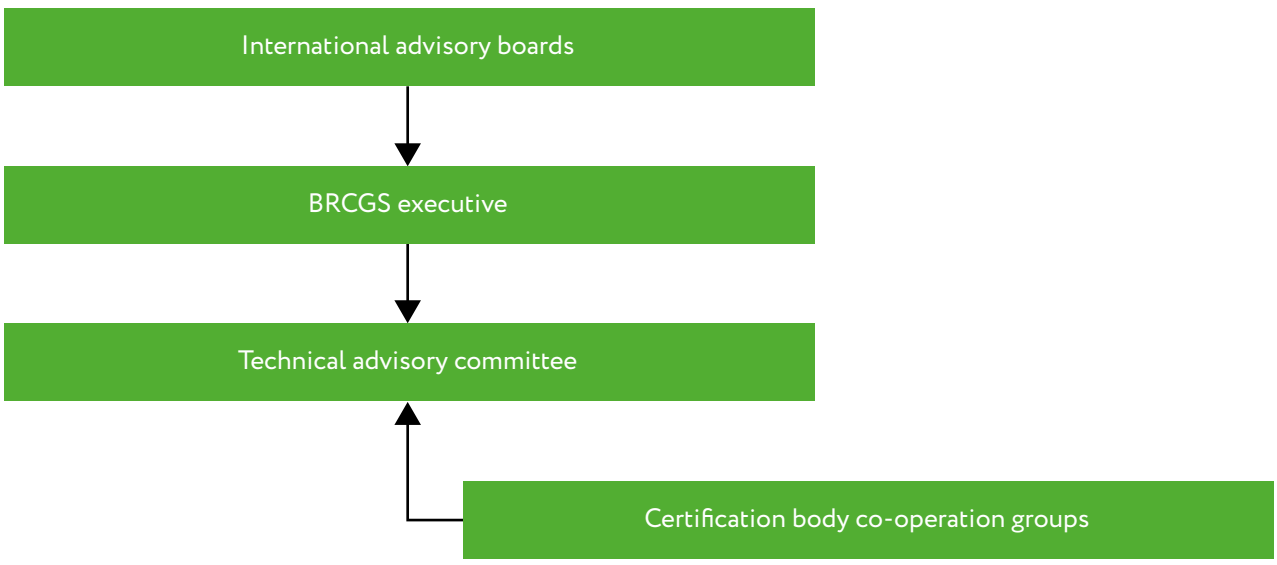

Figure 4 Technical governance structure for management of the Standard

3.3 The certification body co-operation groups

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

3.4 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 provide confidence in the scheme and the value of certification. BRCGS therefore has an active compliance programme to supplement the work of accreditation bodies and ensure high standards are maintained.

The Global Standards may only be certificated by certification bodies registered and approved by BRCGS and accredited by an accreditation body recognised by BRCGS. All auditors undertaking audits against the Standard shall meet the BRCGS auditor competency requirements and shall be registered with BRCGS. All audits undertaken against the Standard shall be uploaded to the **BRCGS Directory**, which provides BRCGS 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, BRCGS operates a compliance programme which reviews the performance of the certification bodies, samples the quality of audit reports, assesses the levels of understanding of the scheme requirements and investigates any issues or complaints. As part of this programme, BRCGS provides feedback on the performance of each certification body through a key performance indicator (KPI) programme. The results are publicly available as a 1–5-star rating of each certification body that is listed in the **BRCGS Directory**.

BRCGS audits the offices of certification bodies and accompanies auditors at site audits to observe their performance. BRCGS also undertakes independent visits to certificated sites to ensure that standards of food safety and quality are being maintained in line with their certification status and that the audit and reporting process are to the expected standard.

3.5 Calibrating auditors

A key component of the scheme is the calibration of 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 BRCGS 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.

3.6 Feedback

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

All audited sites are also invited to complete a feedback survey which is treated confidentially.

3.7 Complaints

BRCGS has implemented a formal complaints process, which is available to organisations involved with the BRCGS Global Standards. Details of the BRCGS complaints process can be found on the **BRCGS website**. Complaints can be reported confidentially on the **Tell BRCGS reporting system**.

From time to time, failure to apply the principles and criteria of the Standard at certificated sites may be reported to BRCGS by, for example, retailers and companies conducting their own audits. In this event, BRCGS will conduct an investigation which may include, as appropriate, a visit to the site by BRCGS, either announced or unannounced, or a request to the certification body to investigate; this may also include a visit to the site. BRCGS will require a full investigation of the issues raised, and a report from the certification body will be submitted to BRCGS within 28 calendar days (or a shorter time in urgent cases).

Appendices

Appendix 1
Other BRCGS standards

BRCGS has developed a range of Global Standards which set out the requirements for the manufacture of food and consumer products; the packaging used; the storage, distribution and procurement of these products; and the retail environment in which they are sold. These Global Standards complement the Global Standard Food Safety and provide precedents, frameworks and resources for the auditing and certification of suppliers.

The **Global Standard Agents and Brokers** is a certification standard applicable to companies that buy and sell products or facilitate the trade of products but do not manufacture, process, pack or store the traded products in their own facilities or on their own sites (although such activities may be offered to their customers via subcontracted service providers). The standard is GFSI-benchmarked.

The **Global Standard Consumer Products** is a certification standard applicable to the manufacture and assembly of consumer products. To reflect the needs of the market, it is composed of two separate standards: personal care and household, and general merchandise. Each standard sets out the requirements for the manufacture of relevant non-food consumer products, including the manufacture of raw materials and components, as well as finished products. There are two levels of certification to this standard: foundation and higher.

Ethical Trade and Responsible Sourcing (ETRS) is a certification standard that is applicable to manufacturers and processors of food and non-food products; it also covers the facilities provided by agents and brokers, storage and distribution, and the provision of services to these companies. It sets out the requirements for the sites to manage ethical trade and responsible sourcing issues. In addition, there is a separate risk assessment module that provides a 'health check' on the way sites manage ethical trade issues. This module can be bolted onto a product safety audit or conducted separately.

The **Gluten-Free Certification Program Global Standard** is a certification standard for the control of gluten in the manufacture, processing and packing of processed foods and ingredients, pet foods, cosmetics, natural health products, and drugs. The standard provides on-pack trademarks for global use.

The **Global Standard Packaging Materials** is a GFSI-benchmarked certification standard that lays down the requirements for the manufacture of packaging materials used for food and consumer products. Food and consumer product businesses may request their packaging suppliers to be certificated against this standard.

The **Plant-Based Global Standard** is a certification standard concerned with the control of materials of animal origin in the manufacture, processing and packing of plant-based processed foods and ingredients, pet foods, and natural health products. It is based on a comprehensive management system approach to ensure the integrity of plant-based products.

The **Global Standard Retail** is a certification standard that sets out the requirements to manage product safety, quality and legality for businesses in the food retail industry. The scope of certification covers applicable operations both at the retailer's head office and at its respective retail stores.

The **Global Standard Storage and Distribution** is a certification standard that sets out the requirements for the storage, distribution, wholesaling and contracted services of packaged 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 are covered by the relevant manufacturing standard (e.g. the Global Standard Food Safety). The standard is GFSI-benchmarked.

Appendix 2
Production risk zones – high risk, high care and ambient high care

The food safety controls operated within 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.

The Standard identifies a number of different production risk zones within the processing and storage facilities which require corresponding levels of hygiene and segregation to reduce the potential for product contamination with pathogenic micro-organisms. Identifying production areas in this way helps to ensure that the appropriate food safety controls are in place and to consider whether the movement of personnel and materials between these areas needs to be restricted.

These production risk zones or areas are classified as:

- open product areas, consisting of:
  - 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).

In addition to the information presented here, BRCGS has published a guideline on production risk zoning, which provides a detailed explanation and interpretation of the requirements for high-risk, high-care and ambient high-care 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 production risk zones, particular consideration shall be given to the risks presented by pathogens. It should be recognised that some products classified as low risk will nevertheless require high standards of microbiological control. For example, those products where the:

- potential for spoilage organisms is a significant issue (e.g. yeasts in yogurt or moulds on hard cheese)
- final product is susceptible to the growth of pathogens but the production process doesn't include a full cook or a process to reduce microbiological contamination to an acceptable level, and therefore the product doesn't fall within the strict definitions of high risk or high care.

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 the environment aim to prevent contamination by pathogenic micro-organisms. Products which require handling in a high-risk area must meet all of the following criteria:

- The finished products require chilling or freezing during storage to preserve food safety.
- All components have received a full cook[7] 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, ready to heat or, on the basis of known consumer use, are likely to be eaten without adequate cooking.

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

It should be noted that where the product has cooking instructions for the consumer that are equivalent to a full cook, then the product may be 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 (see Part 11, clause 5.2.4).

Cooked crustaceans

Cooked crustaceans (i.e. where the crustacean is cooked as part of the production process or where it was cooked at an earlier step in the production process, including at another site) are classified as high risk. Although the Standard recognises that some food products can be effectively managed using consumer cooking instructions, these instructions are not considered a valid justification for a lower-risk production zone for cooked crustaceans, as known consumer use in many countries is to eat the product cold without any heating, and certainly without a full cook. Furthermore, the product appearance could lead consumers to believe that the product is already fully cooked, and that no additional cooking is required.

All fully cooked crustaceans are therefore considered high risk (and will therefore need to meet the relevant high-risk requirements of the Standard). Where a site is partially heating a crustacean (i.e. for less than a log 6 reduction in *Listeria monocytogenes*), then a high-care area will remain appropriate.

Physical segregation in high-risk zones

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 they are 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).

[7] '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.

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 the 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 that require handling in a high-care area must meet all of the following criteria:

- The finished products require chilling or freezing during storage (to preserve food safety).
- All microbiologically susceptible components have received a process to reduce the microbiological contamination to acceptable levels (typically a 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,[8] ready to heat[9] 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.

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 (see Part II, clause 5.2.4).

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 considered 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 by the low-risk zones. This segregation is most effectively achieved by full physical segregation using walls to 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)

[8] 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.

[9] 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.

- 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 above criteria 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 the environment aim to minimise product contamination by pathogenic micro-organisms. Ambient products that are handled in these areas are vulnerable, as pathogens are known to survive on the product. Ambient high-care areas are 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 must meet all of the following criteria:

- A raw material 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. they are not deliberately temperature-controlled).
- The finished products are ready to eat,[8] ready to heat[9] 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 manufactured from ready-made chocolate (that was purchased for incorporation into a biscuit) would not be considered as an ambient high-care product as the risk is associated with the raw cocoa beans that would have been controlled by the chocolate supplier. The biscuit manufacturer would, however, be expected to have a raw material risk assessment process in place which ensured that 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 that these are appropriate must be documented.

It should be noted that the Standard contains only two clauses relating to the specific requirements for ambient high care (clauses 8.1.1 and 8.1.4). 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 will ensure the product is safe to eat.

The hygiene standards in such areas generally require greater emphasis on preventing foreign body and allergen contamination, although they will still need to be based on the risks associated with the specific products. Good manufacturing practices, including good process flow, are still expected.

Products manufactured in this area include the following:

- products that 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 (see Part II, clause 5.2.4)
- 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 and 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 to open product areas, etc.).

Appendix 3
Equivalent processes to achieve 70°C for 2 minutes

Cooking is typically defined as a thermal process which is designed to achieve typically a 6 log reduction in *Listeria monocytogenes*, equivalent to 70°C for 2 minutes (see glossary for full definition).

Where cooking is used to ensure product safety (e.g. as a critical control for pathogenic micro-organisms), the critical process shall be fully validated (see Part 11, clause 2.9.2) to ensure that, when the product is cooked, a safe product is consistently produced. Process specification, work instructions and procedures will reflect these values and ensure consistent application (see Part 11, clause 6.1.1).

Table 5 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 5 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 5 Equivalent processes to achieve 70°C 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

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)
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
Auditing of activities managed by a head office or central function

A food manufacturer may have multiple locations, with a head office or central function managing some of the requirements within the scope of the Standard. Typically, this may apply to activities such as purchasing, supplier approval, product development, product recall and, occasionally, document control and procedures (where there is a group-shared quality management system).

In order to complete the audit process and make a certification decision, all the requirements within the scope of the Standard must be assessed. This means that any centrally managed systems shall be included within the audit process; however, there are two alternative processes for achieving this:

- Request and review information while at each manufacturing site as part of the site audit (one-stage 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 (one-stage audit)

This is recommended only where:

- satisfactory links can be established with the central office (e.g. ICT or video-conferencing links to allow interview of relevant personnel; email or online systems to allow documents to be requested and viewed) and arrangements can be put in place to ensure availability of the relevant personnel
- head office involvement in site operations is limited, or 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, root cause and preventive action plans shall be assessed in the same way as non-conformities raised at the manufacturing site. Non-conformities shall 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 shall be provided at each manufacturing site audit.

Approach 2 – Separate central system and manufacturing site audits (two-stage audit)

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 them remotely.

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

Stage 1 – Central system audit

The audit of the central system shall be completed before undertaking the manufacturing site audit.

For the unannounced audit, the central system audit may be completed as an announced audit, while the production site audits shall be completed as unannounced audits. The date of the central system audit shall ensure that there is sufficient time for the unannounced audits of the participating manufacturing sites to occur before each site's audit due date.

The company can select the blended audit option for its central system and site audits. This will operate in accordance with the blended audit protocol (see Part III, section 3). The clauses that can be audited remotely are in accordance with the normal audit protocol (i.e. based on the certification body risk assessment and the colour-coding of the clauses in Part II). Part III, section 3.1.7 provides further information on the selection of clauses.
In some situations, this may mean that the auditor does not need to visit the head office as all the clauses are appropriate for remote assessment. If the head office audit contains a mixture of clauses (i.e. some that require on-site assessment and others that may be audited remotely), the company may elect to have:

- a blended audit of the central system (i.e. a two-part audit, partially remote and partially on site at the head office)
- a full on-site head office audit
- a remote head office audit with the remaining on-site elements being assessed at each of the site audits.

The audit shall assess both how the central system complies with the relevant requirements of the Standard and how well the central system interacts with 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 include only some of the requirements of the 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 audit report.

The central system report shall not be uploaded to the BRCGS 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 system audit shall be recorded on the audit report of the first manufacturing site audited after that audit, irrespective of whether they have been closed out before the manufacturing site audit. However, only those non-conformities raised at the central system audit that have not been closed out to the satisfaction of the certification body at the time of the first manufacturing site audit shall be counted when calculating the grade for that manufacturing site.

Any non-conformities identified at the central system audit which are still outstanding at the time of further manufacturing site audits (second, third, etc.) shall be included on those manufacturing site reports and be included when calculating the grades for those sites.

Closure of corrective actions, root cause analysis and preventive action plans

Corrective actions, root cause analysis and preventive action plans that are required following the central system audit shall be assessed in the same way as actions raised at the manufacturing site audit, and must be satisfactorily completed before a certificate can be issued to the manufacturing site. This may be documentary evidence, remote assessment or a revisit, as appropriate.

Stage 2 – Manufacturing site audits

Information from the central system audit (including any evidence of corrective action taken) shall be made available to the auditors of the associated manufacturing sites by the certification body.

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

Audit report

The final report shall be applicable to the manufacturing site.

The central system 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 system audit.

The manufacturing site 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, root cause analysis and preventive action

The 28 calendar days allowed for evidence of corrective action, root cause analysis and the development of preventive action plans start from the date of the manufacturing site audit.

It is the responsibility of the site to ensure that evidence of the central system's 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 system's office.

Where the central system's 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-conformity 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 system audit 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 system audit and effectively corrected before the audit of a 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.

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

Scheduling re-audit dates

The head office of the company shall be visited annually.

Re-audits of individual sites under the head office's control are performed at a frequency dependent on the previous audit performance of that particular site.

Appendix 5
Qualifications, training and experience requirements for auditors

Full details of the BRCGS requirements for certification bodies and auditors are published separately from this document. Copies are available on request.

The following summarises the minimum requirements for auditors to conduct audits against the Standard.

Education and work experience

The auditor shall have a degree in a food-related, bioscience or science and engineering discipline.

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, technical management or risk management functions within manufacturing, retailing, inspection or enforcement at a managerial, decision-making level.

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

Lead auditor qualification

The auditor shall have a recognised auditor qualification, including training on quality management systems of 40 hours' duration with an examination. Examples of recognised courses are:

- Management System Lead Assessor course (e.g. IRCA registered course)
- ASQ Certified Quality Auditor or Exemplar Global qualification
- BRCGS Lead Auditor course delivered by a BRCGS-approved trainer.

Other GFSI-benchmarked certification programmes, such as the Safe Quality Food (SQF) and International Featured Standards (IFS) lead auditor training, are also accepted.

HACCP qualification

The auditor shall have completed a training course in HACCP, 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 course is recognised by the industry as being appropriate and relevant.

In exceptional cases, where the auditor can demonstrate practical use and application within the previous 5 years to a high level (e.g. being a recognised trainer of HACCP), a formal training course may not be required.

Global Standard Food Safety (Issue 9) qualification

Auditors shall have successfully completed a Global Standard Food Safety (Issue 9) training course (and the corresponding examinations) delivered by a trainer approved by BRCGS.

Auditor training

Certification bodies shall develop a tailored training programme depending on the auditor's background.

Trainee auditors will have completed a significant number of relevant audits (>10 third-party audits which include HACCP, quality management systems, and good manufacturing practices in the previous 2 years). As a minimum, training shall require auditors to be assessed on their performance during at least three audits (including at least one witnessed audit) against the Food Safety Standard, until they are assessed as competent. Full details of the witnessed audit requirements are available to certification bodies in BRCGS018 – Requirements for Certification Bodies ensuring Auditor Competence through Witness Audits.

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

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

- 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 for which the 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 BRCGS.

Responsibility of the certification body

It is the responsibility of the certification body to ensure that 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 here are given as guidance only and are not an exhaustive list. BRCGS will publish updated examples on its website at **www.brcgs.com**.

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 and primary cutting 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 (including smoked bacon), comminuted meat and fish products (e.g. sausages, fish fingers), ready-to-cook meals, ready prepared meat products, pizzas, plant-based prepared meals, steamer meals	Chilled, frozen	Retail butchery, processing and packing Curing, marinading, vacuum packing, modified atmosphere packaging
	4	Raw fish products	Wet fish, molluscs, crustaceans	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

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, ready-to-eat 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/plastic containers	Canned products (e.g. beans, soups, meals, fruit, tuna). Products packed in glass (e.g. sauces, jams, pickled vegetables) Products packed in plastic pouches (e.g. baby food) Pet food	Ambient	Canning Thermal processing UHT

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 non-dairy coffee creamers	Ambient	Drying, heat treatment
	16	Confectionery	Sugar confectionery, 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 additional modules of:

Exclusions from scope:

Product categories:

At COMPANY NAME
SITE CODE
AUDIT SITE ADDRESS

Has achieved Grade: [Insert grade] [announced, unannounced or blended audit programme]

Meets the requirements set out in the

GLOBAL STANDARD FOOD SAFETY

ISSUE 9: AUGUST 2022

Date(s) of audit: [Include two dates for the blended announced audit. If the audit is an extension to scope, include original audit date]

Certificate issue date:

Re-audit due date: From To

Certificate expiry date:

Accreditation body logo

Authorised by

BRCGS 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 give feedback on the BRCGS Standard or the audit process directly to BRCGS, please contact enquiries@brcgs.com or use the BRCGS reporting system at https://tellusbrcgs.whistleblowernetwork.net

To verify certificate validity, please visit https://directory.brcgs.com

Appendix 8
Corrective action, preventive action and root cause analysis

This appendix includes an example of a completed non-conformity summary sheet.

An important principle of the Standard is the need to ensure that actions are taken to address any failure in the food safety and quality management system. This is highlighted in several places within the Standard, most notably within Part II, section 3.7 and Part III, sections 2.3 and 2.4. There are two types of action recognised within the Standard:

- **Corrective action (sometimes referred to as correction)** Defined as action to eliminate a detected non-conformity or non-conforming product.
- **Preventive action** Defined as action to eliminate the fundamental underlying cause (root cause) of a detected non-conformity and prevent recurrence.

To identify the correct preventive action, it is necessary to complete root cause analysis, which is a problem-solving process for investigating an identified incident, non-conformity or situation. The aim of the root cause analysis is to enable the investigators to look beyond the solution to the immediate problem and understand the causes of the situation, so that the causes can be eliminated and therefore recurrence of the non-conformity or situation is prevented (preventive action).

For example, following a BRCGS audit, a site is required to complete corrective action, root cause analysis and preventive action for each of the non-conformities identified during the audit, and submit information demonstrating completion of these activities to its certification body. The final audit report will include details of each non-conformity, along with a summary of the corrective action taken and the proposed preventive action. (Preventive actions often take longer than 28 calendar days, and sites are therefore not expected to fully complete the preventive action prior to publication of the audit report.) A summary of the root cause analysis will also be included.

Table 6 is an example of a completed summary sheet from the audit report. It is worth noting that this is only a summary of the actions and analysis completed by the site, and does not include the full details that the site shares with the certification body.

Table 6 An example of a completed non-conformity summary sheet from an audit report

MAJOR							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**
1	4.10.3.4	Metal detectors on both production lines failed to reject ferrous and non-ferrous test pieces (synchronisation error) whilst the auditor was observing the test process	Engineer called and adjusted synchronisation immediately and detectors re-tested to confirmed correct operation. Implicated product since last effective test re-checked	1) Metal detection procedure updated to ensure correct rejection is checked. Relevant staff trained on updated procedure 2) Specific review of all metal detectors included in the internal audit schedule 3) As an interim measure, metal detection record sheets updated to include sign-off by a suitable manager (e.g. a shift or line manager) at the end of every production shift	Metal detector tests didn't specifically confirm rejection of the correct test packs. Although metal detector performance is monitored (e.g. use of check pieces), there was no verification or overview of results	1 August 2022	M. Oliver

Root cause analysis is not straightforward and can take time to identify why something occurred. The BRCGS standards are not prescriptive in the methods by which root cause analyses are completed, and a number of tools exist. The simplest of these is the '5 Whys' technique, where the investigator continues to ask why or how something happened until the root cause procedure or process is identified.

It must be noted that root cause analysis never seeks to blame an individual or group, even when human error may seem to be a contributory factor, but aims to consider why the error was made, thereby identifying which process, procedure or way of working failed (resulting in the error). The preventive action will then relate to the process or procedure that can be introduced or amended to prevent recurrence of the non-conformity in future.

Examples of non-conformities, with poor-quality and acceptable root causes, as well as corrective and proposed preventive actions, are shown in Tables 7 and 8.

Table 7 Summary of a root cause analysis (for failure to complete supplier approval audit)

Requirement	Non-conformity	Corrective action	Poor-quality root cause	Acceptable root cause	Proposed preventive action
3.5.1.2	The supplier approval audit for one high-risk supplier had not been completed. This is contrary to the site's supplier approval procedure (SupAp1)	Audit completed 01 July 2022	Travel embargo due to Covid-19 prevented audit from being completed	Travel embargo due to Covid-19 prevented audit from being completed in 2021, and the alternative (temporary) supplier approval was not documented	Ensure emergency procedures are fully documented, including details of minimum records and sign-off required

In Table 7, there are two challenges associated with the poor-quality root cause analysis. Firstly, the pandemic is not a manageable solution; it is outside the site's control, and therefore the conclusion does not help the site to improve food safety. Importantly, the raw material was used by the site; therefore a member of staff approved its use, using an undocumented mechanism, which cannot ensure safe product or compliance with either site processes or the Standard. This is something that the site can fix, by identifying in its procedures and records who is authorised to approve a raw material, and what the emergency process will be in the event of a situation preventing normal supplier approval.

Table 8 Summary of a root cause analysis (for use of snap-off blade in high-risk area)

Requirement	Non-conformity	Corrective action	Poor-quality root cause	Acceptable root cause	Proposed preventive action
4.9.2.1	There was snap-off knife in use in the high-risk area	The snap-off bladed knife was removed during the audit	The engineering tool box is cleaned, checked and updated monthly. Due to the lack of training, a snap-off blade was included during the last restock of the tool box	Company purchasing procedures didn't prevent the purchase of snap-off blades for non-production areas. Snap-off blades were not segregated or labelled to prevent incorrect use	Amend purchasing rules to prevent snap-off blades being purchased

Table 8 is an example of a root cause analysis that has identified staff error as a contributory factor associated with a non-conformity. In these situations, it is important to consider how the error could have occurred and therefore what process could be improved to make the error less likely.

BRCGS has published a full guideline document to help sites understand preventive action and root cause analysis, which includes tools for completing root cause analysis and some pitfalls to be avoided. This guideline is available on BRCGS Participate.

Appendix 9
Position statements

During the lifetime of the Standard, the BRCGS technical advisory committee (TAC; see Part IV) may be asked to:

- review the wording of a requirement in the Standard or protocol
- provide an interpretation for a requirement
- rule on the grading of a non-conformity against a specific clause.

This outcome will be published on the **BRCGS website** as a 'position statement'. Position statements are binding on how the audit and certification process are carried out, and they are considered to be an extension of the Standard.

Companies shall be aware of any published position statements relating to the Standard and, where necessary, ensure that the information is transferred into action. Non-compliance with a relevant position statement may result in a non-conformity against clause 1.1.9 or a specific clause of the Standard relating to the position statement.

Position statements are published on the BRCGS website and on **BRCGS Participate**. They are also communicated electronically to companies and certification bodies (e.g. in bulletins and newsletters).

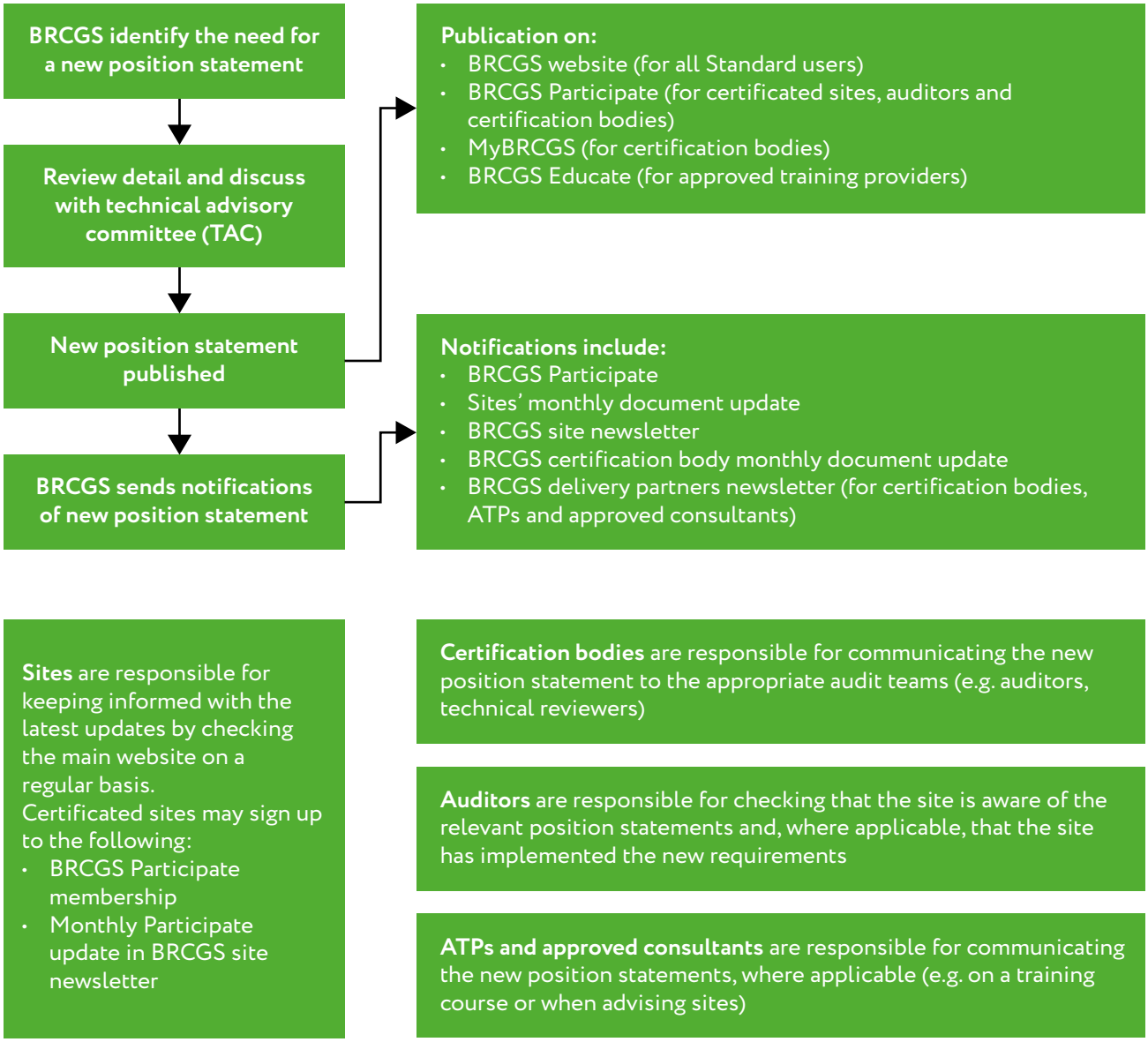

Figure 5 Position statement development and publication process

Appendix 10
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.
Adulterant	An undeclared material added into a food item or raw material for economic gain.
Adulteration	The addition of an undeclared material into a food item or raw material 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).
Allergen cross-contact	Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic substance.
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.
Animal primary conversion	Sites that complete the slaughter and/or evisceration of animals (including red meat, poultry and game) or the slaughter and/or gutting of fish. (Applicable sites will therefore fall within BRCGS product categories 1, 2 and 4.)
Announced audit	An audit where the company agrees the scheduled audit day in advance with the certification body.
Annual/annually	Within 12 months since the action was last conducted.
Assured status	Products produced in accordance with a recognised product certification scheme, the status of which needs to be preserved through the certified production facility (e.g. GLOBALG.A.P.).
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/authentic product	Food authenticity is ensuring that food or raw materials purchased and offered for sale, are of the nature, substance and quality expected.
Batch	The quantity of material prepared or required for one production operation.

Blended audit	An audit that is completed in two parts: • a remote audit of documents and records using ICT • an on-site audit concentrating on production, storage, good manufacturing practices and other on-site activities.
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.
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.
Business continuity	A framework that enables an organisation to plan and respond to incidents of business interruption in order to continue business operations at an acceptable predetermined level.
Calendar days	Calendar days are consecutive days, inclusive of Saturdays and Sundays.
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 BRCGS.
Certification extension	Where a site is operational, but an on-site audit has been prevented by Covid-19 restrictions, a site may apply to its certification body for the validity of the current certificate to be extended by a maximum of 6 months. A certificate extension can only be granted due to Covid-19 restrictions. Full details can be found in BRCGS072, Certification Extension for Audits Impacted by Covid-19, available on the **BRCGS website**.
Checkweigher	A checkweigher is a piece of automated equipment for checking that the weight of products is correct and within the relevant limits (e.g. meets legislative and customer limits).
Clause	A specific requirement or statement of intent that a site must comply with in order to achieve certification.
Cleaning	Cleaning is the process of achieving and maintaining an area to a standard deemed visually free from debris that can include dirt, food, faeces, blood, saliva and other bodily secretions. In other words, it is the removal of soil, food residues, dirt, grease and other objectionable matter.

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 points) is one standard.
Company	The entity with legal ownership of the site which is being audited against a 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.
Consultant	A company, organisation or individual that is subcontracted by the site to provide technical services relating to the product safety and quality management systems (for example, the development, implementation or maintenance of the product safety management system; the development or implementation of the HACCP plan; and the production of manuals or procedures).
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, raw material or the food environment. Contamination includes physical, chemical, radiological, 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 specified individuals and their receipt of the document is recorded.
Cook	'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 when assessing product safety requirements.
Corrective action (correction)	Action to eliminate a detected non-conformity or non-conforming product.
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-contamination (cross-contact)	The transfer of any material from one surface or food to another. The terms 'cross-contact' and 'cross-contamination' are used interchangeably in guidance about allergen management. See allergen cross-contact.
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.
Disinfection	Disinfection is the process or act of destroying pathogenic micro-organisms; it removes most organisms present on surfaces.
Distribution	The transportation of goods within any container (goods on the move) by road, rail, air or ship.
Enclosed product area	An area of the factory where all products are fully enclosed and therefore not vulnerable to environmental contamination.
End-consumer	The ultimate consumer of a foodstuff, who will not use the food as part of any food business operation or activity.
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 ensure 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 integrity	Products that are of the nature, substance and quality expected (e.g. not substituted, diluted, adulterated or misrepresented).
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 safety and quality culture	The attitudes, values and/or beliefs which are prevalent at the site, relating to the importance of product safety and the confidence in the product safety systems, processes and procedures used by the site.

Food safety plan	Often referred to as a HACCP plan. The food safety plan is a set of documents prepared in accordance with the Codex Alimentarius HACCP principles to ensure the control of food-borne hazards. The specific terminology used in the Standard, such as 'prerequisites' and 'critical control points' (CCPs), is intended to reflect the global terminology used to describe expectations. Sites are not required to use the specific terminology in the Standard; alternatives are acceptable providing it is evident that all the requirements have been fully met.
Food security	Procedures adopted to ensure 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	A zone (or 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 zone (or 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 or frozen 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, fraudulent, illegal or non-conforming products.
Initial audit	The audit for certification to a BRCGS standard at a company or site that is not in possession of a valid certificate. This may be the first audit at a site or a subsequent audit of a site whose certification has lapsed.
Inspection	Targeted verification (often a visual check against a 'tick list' for fabrication, environment and equipment) to ensure operation to safe expected levels.
Integrity	See food integrity.
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, authenticity and quality of the finished product.
Label	Any tag, mark, picture or other descriptive matter, whether it is written, printed or otherwise marked, on or attached to the packaging of the product. Where a product is unlabelled, specifications or information to meet legal requirements and to assist customers in the safe usage of the product shall be maintained, and are included in the definition of a label.
Labelling	Any words, picture or symbol relating to the food and placed on any packaging or label accompanying the 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 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.
Malicious contamination	Deliberate contamination of a product or raw material with the intention to cause harm to the consumer or damage to the company or brand owner.
Manufacturer	A company that produces product from raw materials and/or components and packs the product or supplies product in bulk. 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 with the Standard.

Measurement uncertainty (sometimes referred to as uncertainty of measurement)	A parameter that is associated with the result of a quantitative measurement. It characterises the range of values that could reasonably be expected for the attribute being measured (e.g. the micro-organism, allergen or chemical). It is sometimes referred to as the margin of doubt for the result. Measurement uncertainty is important when making conformity decisions (i.e. assessing whether a test result is within legal, safe or acceptable limits) as the uncertainty or range of probable values may cross the limit. A full explanation of measurement uncertainty is given in the Global Standard Food Safety Interpretation Guideline for clause 5.6.2.
Mitigation strategies	Controls to remove, or reduce to an acceptable level, an identified risk, vulnerability or threat. It is often used in food defence where controls are needed to prevent potential threats from occurring.
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.
Online verification equipment	Automated equipment (e.g. bar code scanners) that are used to check the accuracy or quality of product labels and printing.
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.
Outsourced processing (subcontracted processing)	Outsourced processing (also referred to as subcontracted processing) is when intermediate production, processing, storage or a step in the manufacture of a product is completed at another company or site. Outsourced processing is an intermediate step; therefore during outsourced processing, the product or partly processed product leaves the site being audited for the completion of the outsourced processing before returning to the site. The audited site may or may not complete the additional packing or processing steps of the product. Where raw materials receive additional storage or processing prior to their arrival on site, this is not considered to be outsourced processing, but should be managed by the site using supplier approval mechanisms, raw material risk assessments and raw material specifications. When a product leaves the site and does not return, this is not outsourced processing; the activities completed off site are outside the scope of the audit.
Ownership (change of company ownership)	A change of ownership occurs when the title is transferred from one individual or entity to another and results in a change of control of the organisation.
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).
Plant-based product	A product that does not intentionally contain materials of animal origin, and has not intentionally used ingredients (including additives, carriers, flavourings and enzymes), processing aids or any other substances that are of animal origin, at any stage during production and processing.

Position statement	Where clarification of the interpretation of a requirement of a BRCGS Standard or its protocol is necessary, this will be published on the **BRCGS website** as a position statement. Such statements are binding on the way that the audit and certification process are carried out and are considered to be an extension of the Standard. They are applicable from the date specified for implementation (or the date of publication on the BRCGS website, where no date is specified).
Positive release	Ensuring a product or material is of an acceptable standard prior to release for use.
Potable water	Water that is safe to drink, free from pollutants and harmful organisms, and conforms 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 and hygiene practices, and form a foundation for the food safety or HACCP plan. Prerequisites shall be considered as part of that plan.
Preventive action	Action to eliminate the fundamental underlying cause (root cause) of a detected non-conformity and prevent recurrence.
Primary packaging	The packaging that constitutes the unit of sale to the consumer or customer (e.g. bottle, closure, label and tamper-evident seal of a retail pack or a raw material bulk container). When identifying primary packaging, due consideration must be given to the processes that minimise or eliminate any risk which may result in contamination of a food product; for example: • using suitable food contact materials • consideration of anything that is applied onto the surface of a permeable food contact material (e.g. potential for migration of ink components through cardboard is a well-documented risk that has affected a range of packaging). As a general rule, the Standard would not expect transit materials to be classified as primary packaging (e.g. pallets, pallet wrap, shrink wrap, pallet sheets, labels or cable ties applied on the outside of the pallet wrap, recyclable and re-usable travel containers, and plastic crates used to hold glass bottles).
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 removal of an unfit (e.g. unsafe) product from customers and final consumers.
Product security	For the purposes of the Global Standard Food Safety, product security refers to measures to prevent theft or malicious damage to products.
Product withdrawal	Any measures aimed at achieving the removal of out-of-specification or unfit (e.g. unsafe) products from customers, but not from final consumers. A withdrawal is normally used to remove product where there is no risk to consumers; for example, where the product has not reached the point of sale to consumers.
Production risk zones	Zones or areas within the processing and storage facilities that require specified levels of hygiene and segregation to reduce the potential for product contamination with pathogenic micro-organisms. The Standard recognises five production risk zones: • high risk • high care • ambient high care • low risk • enclosed product areas. Sites will also have a range of non-product areas which are separate from the processing and storage areas. Full details of the risk zones appropriate to the Standard are located in Appendix 2.
Protective clothing	Clothing and protective equipment (for example, overalls, hairnets, hats and beard snoods) 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, which also takes into account process waste and rework.
Quantity control	A check on the 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 materials include food ingredients, packaging materials, additives, processing aids etc.
Ready-to-cook food	Food designed by the manufacturer to require cooking or other processing to effectively 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 to be 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, have been awarded by a competent body, and are 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(s)	The underlying cause(s) 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.
Sanitisation	Sanitisation means to adequately treat cleaned surfaces by a process that is effective in destroying the vegetative cells of pathogens, and in substantially reducing the numbers of other undesirable micro-organisms, but without adversely affecting the product or its safety for the consumer.
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 site that is opened for a short duration (typically 12 weeks or less) during a 12-month cycle; for example, to specifically harvest and process a product. Details of the additional considerations for the management of the audit and certification process for seasonal production sites are given in Part III, section 2.7.8.
Secondary packaging	Packaging that is used to collate and transport sales units to the retail environment or customer (e.g. corrugated case).

Senior management	Person or group of people who direct and control an organisation at the highest level. Note that top (senior) management has the power to delegate authority and provide resources within the organisation.
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 Food Safety (Issue 9).
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.
Threat assessment	A risk assessment designed to examine site processes for potential product security and food defence issues.
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/products	Traded products are defined as food products that would normally fall within the scope of the Standard and are stored at the site's facilities, but are not manufactured, processed, reworked, packed or labelled at the site being audited.
Trend	An identified pattern of results.
Unannounced audit	An audit undertaken on a date unknown to the company in advance.
Uncertainty	See measurement uncertainty.
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.
Vulnerability assessment	A risk assessment designed to examine processes and supply chains for potential food fraud.

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.
Working day	A day on which work is usually or routinely done at the site.
Workwear	See protective clothing.

Appendix 11
BRCGS Participate

BRCGS Participate is a document information management system that allows BRCGS to deploy the content from its full range of standards, guidelines and additional modules through digital channels. It is a managed online service that certificated sites can access to view content, download PDFs, watch webinars and have discussions with peers. BRCGS-certificated sites and other Standard users can access the content of the Global Standards and other supporting documents across many devices.

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BRCGS publishes additional guidance on topics covered by requirements within the Standard. Certificated sites can download this guidance for free from BRCGS Participate, and copies can be purchased from the **BRCGS Store**. Topics include:

- air quality
- allergen management
- cleaning of workwear
- environmental monitoring
- fresh produce
- high risk, high care and ambient high care
- internal audit
- lighting
- lubrication
- pest management
- preventive action and root cause analysis
- product changeover
- product recall
- product safety culture
- raw poultry
- raw red meat
- vulnerability assessments.

Appendix 12
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