BRCGS | Packaging Materials

ISSUE 6 PACKAGING MATERIALS

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[1] BRCGS is a trading name of BRC Trading Ltd.

Contents

Part I
Outline of the Standard

Welcome to Issue 6

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Outline of the Standard

Welcome to Issue 6

Originally developed and published in 2001, the Global Standard for Packaging Materials (referred to hereafter as the Standard) was designed to protect the consumer by providing a common basis for the certification of companies supplying packaging to food producers. The Standard has been updated at regular intervals since, to reflect the latest thinking in product safety, and has now attained usage worldwide, not only by food packaging producers, but by producers of packaging for all applications at all levels of the supply chain.

The Standard now provides a robust framework for all types of packaging manufacturer to assist them in the production of safe packaging materials and to manage product quality to meet customers' requirements, while maintaining legal compliance. Certification against the Standard is recognised by many brand owners, retailers, food service companies and manufacturers around the world when assessing the capabilities of their suppliers. In response to demand, the Standard has been translated into many languages to facilitate implementation by packaging materials companies across the world.

The Standard has been developed to specify the product safety, quality and operational criteria that must be in place within a packaging manufacturing organisation in order for it to fulfil its obligations with regard to legal compliance and protection of the consumer. The format is designed to allow a company's premises, operational systems and procedures to be assessed against the requirements of the Standard by a competent third party – the certification body.

What's new for Issue 6?

The development of Issue 6 followed a wide consultation to understand stakeholders' requirements. A review of emerging issues was also carried out in the packaging industry and the industries it supplies. The information has been developed and reviewed by a working group composed of international stakeholders representing different sectors of the packaging materials manufacturing industry, retailers, brand owners, food service companies, certification bodies and independent technical experts.

Key features remain integral to the Standard, such as:

- meeting the needs of retailers and brand owners to reduce the audit burden
- better recognition of the diversity of the packaging industry and its customers' demands
- encouraging greater transparency and traceability in the supply chain
- encouraging adoption of the Standard as a means of improving product safety at small sites and facilities where processes are still in development.

The focus for this issue has been on:

- enhancing the processes used by quality management systems in printed packaging controls and through a hazard and risk analysis approach
- continuing to ensure consistency of the audit process across the world
- the importance of a product safety and quality culture in the drive to improve transparency and coherence across the supply chains of food and non-food products
- simplifying the hygiene requirements based solely on risk
- introducing a new fundamental clause, corrective and preventive actions, to address issues and minimise the risk of their occurring
- based on risk, putting a microbiological environmental monitoring programme in place
- simplifying the unannounced audit programme.

The requirements of Issue 6 have evolved from those of previous issues. There continues to be an emphasis on management commitment, a hazard and risk analysis-based product safety programme and a supporting quality management system. The objective has been to direct the focus of the audit towards the implementation of good manufacturing practices within the production areas while recognising the diversity and breadth of the packaging industry, and the skills required to audit it.

Unannounced audit programme

The number of unannounced audits requested by specifiers of food and non-food manufacturers has increased. Such audits provide a greater confidence to specifiers that the site is operating to the requirements of the Standard, underpinned by a product safety culture that ensures the production of safe packaging materials. To echo this in the supply chain, the optional unannounced audit programme has been maintained in the Standard but reflects the change in Issue 8 of the Food Safety Standard by becoming a single unannounced option. The option remains voluntary, but it provides added confidence in certification to customers and creates marketing benefits where sites achieve the top BRCGS grade of AA+.

Manufacturing categories

The packaging industry is incredibly diverse, with a wide range of material types, processing technologies and applications. Issue 5 of the Standard took the opportunity to align the manufacturing categories (previously called 'fields of audit') with the processing and manufacturing activities that typically take place in packaging material manufacturers. The intention was to simplify both the number of categories by which each site is labelled and the process of auditor allocation.

Additional modules

Issue 6 has kept the ability to incorporate additional modules which sites can elect to include with the audit to meet particular customer or scheme needs (such as addressing the potential wastage of pre-production materials that can impact the environment).

BRCGS will continue to develop such modules and make these available on its website in response to market needs. It is expected that this flexibility will enable sites to meet regional or specific customer expectations and reduce the number of site audits.

The scope of the Standard

The Standard sets out the requirements for the manufacture of packaging materials that are used in the production of, and filling operations for, food, hygiene-sensitive consumer products (including cosmetics), raw materials, and other consumer products. The requirements are also intended to apply to:

- prior operations (e.g. production of packaging materials for conversion or printing)
- operations that are supplying packaging material from stock where additional product processing or repacking occurs; this has been demonstrated to require the same level of control as a final/integrated conversion operation
- the manufacture and supply of other materials that are unconverted or semi-converted and used or incorporated (e.g. coatings and adhesives), where this is based on a risk analysis and mutually agreed between those involved.

The Standard shall not apply to packaging or materials that do not undergo any process at the site audited, or to activities relating to wholesale, importation, distribution or storage outside the direct control of the company. Where the primary operation of the factory is the production of consumer products and not the manufacture of packaging materials, the products are audited under the Global Standard for Consumer Products.

BRCGS has developed a series of Global Standards setting out the requirements for the wide range of activities undertaken in the production, packaging, storage and distribution of food or consumer products. Appendix 6 provides further details of the scopes of, and relationships between, the current Global Standards.

Companies that meet the requirements of a satisfactory quality management system – for example, one conforming to that specified in ISO 9001 – may already meet many of the requirements of the Standard. It is in the interest of the company to bring these points to the attention of the certification body. The auditor will verify that the procedures are adequate for the purpose of compliance with this Standard.

Packaging legislation

The Standard has always been intended to assist sites and their customers to comply with legislative requirements for product safety.

Legislation covering packaging differs in detail worldwide and commonly focuses on packaging materials in contact with food. It generally requires packaging manufacturers to:

- produce packaging that does not pose a hazard to human health
- provide a processing environment which ensures that the risks of product contamination are minimised
- use raw materials or ingredients that are not injurious to human health
- preserve, protect and contain products adequately throughout the supply chain and the life of the product
- ensure information about the product is presented to the consumer.

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

Benefits of the Standard

Adoption of the Standard leads to a number of benefits for the manufacturers of packaging materials. The Standard:

- is internationally recognised, GFSI-benchmarked and provides a report and certification that can be accepted by customers in place of their own audits, thereby reducing time and cost
- provides a single standard and protocol that governs an accredited audit by third-party certification bodies, allowing a credible independent assessment of a company's product safety and quality systems
- enables certificated companies to appear in the publicly available part of the BRCGS Directory, allowing recognition of their achievements and use of a globally recognised logo for marketing purposes
- is comprehensive in scope, covering areas of quality, legality and product safety
- addresses part of the legislative requirements of the packaging manufacturer/supplier, packer/filler and retailer. Packaging manufacturers may also use this Standard to ensure their suppliers are following good manufacturing practices and are fulfilling legal requirements
- demonstrates a commitment to the prevention of loss of raw materials that may contaminate the environment
- enables companies to ensure their suppliers are following good practice in product safety
- provides a framework for the development of quality and hygiene management systems in companies, encouraging continual improvement, effective environmental monitoring, reduction in waste, and increased efficiency
- provides two audit options, namely announced and unannounced audit programmes. These will not only satisfy customer demands, but also enable companies to demonstrate compliance through a process which best suits their operation and the maturity of their product safety and quality management systems
- is part of a scheme offering an array of training, education and technical support.

The certification process

The Standard is a process and product certification scheme. In this scheme, packaging manufacturers 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 packaging materials manufacturing business to receive a valid certificate on completion of a satisfactory audit, the organisation must select an approved certification body. 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 certification bodies approved by BRCGS is available on the BRCGS Directory website:
www.brcgsdirectory.com

Principles of the Standard

A business must have a full understanding of the processes and products it manufactures. It must also have systems in place to ensure that products are produced within a suitably hygienic environment and consistently meet the quality and product safety expectations of its customers. The Standard is based on the key components of: senior management commitment; risk assessment of the product and manufacturing process; and a systematic approach to managing product quality and safety.

Senior management commitment

Within a business, the safety, legality and quality of the products produced must be seen as a cross-functional responsibility, involving and using different skills and expertise in the organisation. Effective adoption of the principles of this Standard extends beyond the responsibility of a single individual or technical departments and must involve commitment from production operations, engineering, distribution management, procurement of raw materials and those concerned with customer feedback and human resource activity such as training. The starting point for effective implementation of the Standard is the commitment of senior management to the development of an all-encompassing policy as a means to guide the activities that collectively assure the production of safe and legal packaging materials.

A risk-based system

The Standard requires an evaluation of the risks to product safety and quality associated with the manufacture of packaging materials. The hazard and risk analysis process defined in the Standard should enable potential risks to be identified and controlled, either through existing prerequisite programmes, such as cleaning, pest control and maintenance, or by the introduction of specific controls. An effective hazard and risk analysis provides a basis for the management system. The development of the system requires the input of all relevant departments and must be supported by senior management.

Quality management system and suitable operating conditions

The Standard requires the organisation to document the framework of management policies and procedures by which it will achieve the main requirements of this Standard. It also expects the business to maintain the basic environmental and operational conditions that are necessary for the production of safe, legal products under suitable hygienic conditions.

The expectation of the Standard

The Standard requires the development of and compliance with the following:

- **Senior management commitment** The resources required for demonstration of commitment to achieving the requirements of the Standard are detailed in Part II, section 1.
- **A hazard analysis and risk assessment plan** This provides a focus on the significant product and process safety hazards that require specific control to assure the safety of individual packaging materials, products or lines, as detailed 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 the organisation will achieve the requirements in this Standard as given in Part II, section 3.
- **Prerequisite programmes** The basic environmental and operational conditions in a packaging business that are necessary for the production of safe and hygienic packaging materials. These control generic hazards, covering good manufacturing and good hygienic practice, as detailed in Part II, sections 4–6.

Preparation for the audit and planning for success

In order for everyone to gain the most value from certification to the Standard, retailers and other specifiers should have a clear understanding of both the demands it places on their suppliers and the benefits that ensue. Equally, manufacturers need to plan carefully to achieve certification. Both specifiers and companies seeking certification should understand that considerable effort may be needed to work towards certification, especially for companies that have no previous experience of third-party certification schemes or quality management system certification.

It is important to set realistic timescales in which to gain certification and have a clear project plan to ensure that all the necessary actions are completed before the certification audit visit. After the audit visit, 28 calendar days are allowed in which to correct any failures to meet the requirements of the Standard, identified by the audit report as non-conformities. This period is extended to 90 calendar days for non-conformities at initial audits. There is a limit to the number of non-conformities that are allowed before certification is refused (see Part III, section 2.5 for details). If the number of non-conformities exceeds that allowed, or if the non-conformities are not corrected within the allowed timeframe, a complete re-audit will be needed before certification can be obtained. It is therefore not advisable to attempt an audit without adequate preparation.

For specifiers

Retailers, brand owners, food service companies and others contemplating specifying the use of the Standard by their suppliers are advised to inform their suppliers and the certification bodies well in advance of the implementation requirement. This will ensure that the companies have time for adequate planning and that the certification bodies have suitable infrastructure, such as auditor capacity, in place in the countries of demand and for the correct packaging categories. Specifiers (including retailers) may want to organise internal training to ensure that the staff have a good understanding of the Standard. It may be helpful to arrange supplier briefings or other training events to explain the requirements of the scheme and other steps to implementation. Assistance with such matters is available from the BRCGS team.

For packaging material manufacturers

A detailed explanation of the audit process is given in Part III. Companies already certificated to previous versions of this Standard should work through the steps to certification but may find that many aspects have already been addressed.

The packaging industry produces a wide variety of packaging materials, involving an extensive range of materials for use in many diverse industries. Given the scope of this activity, it is essential that the audit against the Standard is appropriate for the nature of the material produced and its intended use. Customers expect that all of the packaging materials they purchase are safe for their intended use and produced to the quality agreed in the specification. It is recognised, however, that the production of packaging for some particular uses (e.g. for direct food contact or hygiene-sensitive products) places more stringent and demanding hygiene requirements on the manufacturer. The Standard directs manufacturers of packaging materials to determine the levels of hygiene required for the production of safe packaging materials in the hazard analysis and risk assessment.

If the requirement says 'on the basis of risk' or 'the site shall use risk assessment', this indicates that the first step is to carry out a risk assessment, document it, then use it to determine the company's policy/procedure/process in order to meet that requirement.

Effective date of Issue 6

As with all revisions of the Global Standards, there must be recognition that a transition period is in place between publication and full implementation. This allows time for the retraining of all auditors and allows manufacturers to prepare for the new issue of the Standard. Therefore, certification against Issue 6 will commence from 1 February 2020. All certificates issued against audits carried out prior to this date will be against Issue 5 and will be valid for the period specified on the certificate.

Acknowledgements: a 'thank you' from BRCGS
BRCGS wishes to acknowledge all those packaging, food, consumer products and audit industry experts who have contributed to the preparation of the Global Standard for Packaging Materials Issue 6. Appendix 7 lists those who participated in the working groups.

Part II
Requirements

How the requirements are set out

1 Senior management commitment

2 Hazard and risk management

3 Product safety and quality management

4 Site standards

5 Product and process control

6 Personnel

7 Requirements for traded products

Part II
Requirements

How the requirements are set out

Each clause of the Standard begins with a statement of intent. This sets out the expected outcome of compliance with the requirements of that section. It forms part of the audit and all sites must comply with the statements of intent in order to gain certification.

Below each statement of intent is a list of requirements. These identify, in greater detail, the particular points that must be met as part of achieving compliance with the statement of intent. The audit will assess compliance against both the statement of intent and the individual requirements.

Colour-coding of requirements

Production processes represent the key activities on site. The audit process therefore gives specific emphasis to the practical implementation of product 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 those that are subject to site security procedures.

As an aid to this process, the requirements within the Standard have been colour-coded. 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.

Key to colour-coding of requirements

Requirements assessed as part of the audit of good manufacturing practice (GMP)	
Requirements assessed as part of the audit of records, systems and documentation ('desk-top' audit)	
Requirements assessed as part of the GMP and 'desk-top' audits	

Fundamental requirements

Within the Standard, certain statements of intent have been designated as 'fundamental'. These are marked with the word 'FUNDAMENTAL' and denoted with the following symbol ✪. The requirements that accompany these fundamental statements relate to the systems which are crucial to the establishment of an effective product quality and safety operation. They can be found in the following sections:

- Senior management commitment and continual improvement (1.1)
- Hazard analysis and risk assessment (2.2)
- Specifications (3.4)
- Internal audits (3.5)
- Corrective and preventive actions (3.6)
- Traceability (3.11)
- Housekeeping and cleaning (4.8)

- Process control (5.4)
- Training and competence (6.1).

Failure to comply with any requirements of a fundamental statement of intent (i.e. a major non-conformity) may lead to non-certification. This will require a further full audit to demonstrate evidence of compliance.

Non-applicable clauses

The majority of the requirements of the Standard will apply to all packaging material manufacturers. There are, however, some requirements that would not apply to some industry sectors or operations; for example, the requirements of clause 5.3 (packaging print control) are not applicable where printing of materials is not carried out. Any such specific requirements may be omitted and will be marked as not applicable (N/A) in the final audit report. The auditor will assess and decide on the applicability of any requirements that the site believes are not applicable.

Risk-based deviations

The requirements have been written to reflect expectations typical of the particular product and process technology across a range of packaging formats (e.g. paperboard, glass, metals). There may be occasions where a requirement may not be appropriate in a particular operation. On the basis of risk, deviations from some of the requirements may be permitted; however, in each case a documented risk assessment must be provided for the auditor to evaluate.

The final audit report will include comments on any clauses deemed as not applicable or which permit risk-based deviations.

Position statements

During the lifetime of a published Global Standard, the BRCGS technical advisory committees may be asked to either review the wording of a clause in the Standard or provide an interpretation of a requirement or rule.

The decision made by the technical advisory committee is known as a position statement. Position statements are binding on the way the audit and certification process is carried out and are seen as an extension to the Standard.

Position statements are notified to sites and certification bodies through regular newsletters and are posted on the BRCGS website.

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 requirements of the Global Standard for Packaging Materials.

Clause	Requirements
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe and legally compliant products to the specified quality and confirms its responsibility to its customers. This shall be: • signed by the person with overall responsibility for the site • communicated to all staff.
1.1.2	The site's senior management shall define and maintain a clear and effective plan for the development and continual improvement of a product safety and quality culture. This shall include: • defined activities involving all sections of the site that have an impact on product safety and quality • a description of how the activities will be undertaken and measured, and the intended timescales • a review of the effectiveness of completed and ongoing activities. Clause effective from 1 February 2021.
1.1.3	The site's senior management shall establish clear objectives to maintain and improve the quality, safety and legality of products manufactured, in accordance with the site's product safety and quality policy and this Standard. These objectives shall be: • documented and include targets or clear measures of success • clearly communicated to relevant staff • monitored, and the results reported at a suitable predetermined frequency to the site's senior management.
1.1.4	The company's senior management shall provide the human and financial resources required for the production of safe packaging material, to the required quality, and in compliance with the requirements of this Standard.
1.1.5	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 • all relevant legislation applicable in the country of manufacture and, where known, the country where the product will be used. Products shall meet the minimum legal requirements in the country of manufacture and of use where known.

Clause	Requirements
1.1.6	The site shall have a genuine, original hard copy or electronic version of the current Standard and be aware of any changes to the Standard or protocol that are published on the BRCGS website.
1.1.7	Where the site is certificated to the Standard, it shall ensure that recertification audits occur on or before the audit due date indicated on the certificate.
1.1.8	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.
1.1.9	The site's senior management shall ensure that the root causes of any non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.
1.1.10	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 5.6).

1.2 Management review

The site's senior management shall ensure that a management review is undertaken to ensure that the product safety and quality management system is both fully implemented and effective, and that opportunities for improvement are identified.

Clause	Requirements
1.2.1	Management review meetings attended by the site's senior management shall be undertaken at appropriate scheduled intervals (at a minimum annually) to review the site's performance against the Standard and the objectives set out in clause 1.1.3.
1.2.2	The review process shall include the evaluation of: • previous management review documents, action plans and timeframes • the results of internal, second-party and third-party audits • any customer performance indicators, complaints and feedback • the effectiveness of the hazard and risk management (HARM) system • the impact of any applicable legislative and certification scheme changes • any incidents, corrective actions, out-of-specification results and non-conforming materials • resource requirements • 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 • the effectiveness of the product defence and product fraud prevention plans.

Clause	Requirements
1.2.3	The meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.
1.2.4	The site shall have a demonstrable system in place which enables product safety, legality, integrity and quality issues to be brought to the attention of a designated manager. The system shall allow for the resolution of issues requiring immediate action.

1.3 Organisational structure, responsibilities and management authority

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

Clause	Requirements
1.3.1	The site shall have a current organisation chart demonstrating the management structure and reporting channels of the company. The responsibilities for the management of activities which ensure product safety, quality and legality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.
1.3.2	The site's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instructions.

2 Hazard and risk management

2.1 Hazard and risk management team

A multidisciplinary hazard and risk management team shall be in place to develop and manage the hazard and risk management system and to ensure that the system is fully implemented and evaluated for its effectiveness.

Clause	Requirements
2.1.1	The hazard analysis and risk assessment shall be developed, reviewed and managed by a multidisciplinary team that includes those responsible for quality, technical, engineering/ maintenance, production operations and other relevant functions. In the event that the site does not have the appropriate expertise in-house, external expertise may be used to analyse any hazards and the risk of them occurring, and/or develop and review the hazard and risk management system. However, the day-to-day management of the system shall remain the responsibility of the site.
2.1.2	The multidisciplinary team shall have a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard and risk analysis.
2.1.3	The team shall be able to demonstrate competence in hazard and risk analysis principles and be kept up to date with factory changes and customer requirements as they occur.

2.2 Hazard analysis and risk assessment

Fundamental
A documented hazard analysis and risk assessment (HARA) shall be in place to ensure that all hazards to product safety and legality are identified and appropriate controls established.

Clause	Requirements
2.2.1	The scope of the hazard analysis and risk assessment shall be clearly defined and documented and shall cover all products and processes included within the intended scope of certification.
2.2.2	The HARA team shall maintain awareness of and take into account: • historical, known and foreseeable product safety hazards associated with specific processes and raw materials • intended use of the product (where known) • known likely product defects that affect safety • relevant codes of practice or recognised guidelines • legislative requirements.

Clause	Requirements
2.2.3	A full description of the product, product group and process shall be developed, which includes all relevant information on product safety and integrity. As a guide this shall include: • composition (e.g. raw materials, inks, varnishes, coatings and other print chemicals) • origin of raw materials, including use of recycled materials • intended use of the packaging materials and defined restrictions on use; for example, direct contact with food or other hygiene-sensitive products, or the physical or chemical conditions.
2.2.4	The process flow diagram prepared for each product, product group and process shall set out each process step from the receipt of raw materials, through manufacture and storage, to dispatch to the customer. As a guide this shall include, where applicable: • receipt and approval of artwork and specification • receipt and preparation of raw materials such as additives, inks and adhesives • each manufacturing process step • in-line testing or measuring equipment • the use of rework and post-consumer recycled materials • any subcontracted processes • customer returns.
2.2.5	The accuracy of the process flow diagram shall be verified by the HARA team at least once per year and following any significant incidents or process changes.
2.2.6	The HARA team shall identify and record all potential product safety hazards that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where relevant: • microbiological hazards • chemical contamination (e.g. taint, odour, allergen, component transfer from inks, varnishes and glues) • potential for unintended migration of substances from the packaging material into food or other hygiene-sensitive products • foreign objects • potential problems arising from the use of recycled materials • foreseeable misuse by the consumer • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use • potential for malicious intervention • potential for raw material fraud.
2.2.7	The HARA team shall identify control measures necessary to prevent, eliminate or reduce each product safety hazard to acceptable levels. Where control is through prerequisite programmes as set out in sections 3, 4 and 6, these shall be reviewed to ensure they adequately control the risk identified and, where necessary, improvements implemented.

Clause	Requirements
2.2.8	For each hazard that requires control, other than by an existing prerequisite programme, the control points shall be reviewed to identify those that are critical. This process shall include an assessment of the risk level for each hazard based on the likelihood of the occurrence and the severity of the outcome. Critical control points (CCPs) shall be those control points that are required to prevent, eliminate or reduce a product safety hazard to acceptable levels. Where a control point is not classified as critical and control may be achieved through a prerequisite programme, a programme shall be developed that is sufficiently specified to effectively control the identified hazard(s).
2.2.9	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, where possible, and the rationale for their establishment clearly documented. Relevant legislation and codes of practice shall be taken into account when establishing the limits.
2.2.10	For each CCP, a monitoring system shall be defined in order to ensure compliance with critical limits. Records of the monitoring shall be maintained. Documented procedures relating to the monitoring of critical controls shall be included in internal audits against the Standard (see clause 3.5).
2.2.11	The corrective action that shall be taken when monitored results indicate a failure to meet the control limit for CCPs shall be established and documented. This shall include the procedures for quarantining and evaluating potentially out-of-specification products to ensure they are not released until their safety, quality and legality can be established.
2.2.12	A review of the hazard and risk management system and prerequisite programmes shall be carried out at least once per year and following any significant incidents or when any process changes. The review shall include a verification that the hazard analysis and risk assessment plan is effective. It shall also include any: • process changes • product composition changes • complaints • product failures and finished product recalls from consumers (including system tests) • product withdrawals • results of internal audits of prerequisite programmes • results from external and third-party audits • new developments in the industry associated with materials, process or product.

3 Product safety and quality management

3.1 Product safety and quality management system

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

Clause	Requirements
3.1.1	The site's documented policies, procedures, working methods and practices shall be collated in a navigable and readily accessible system, with consideration being given to translation into appropriate languages. Where the site is part of a company governed by a head office, the interaction between the site's system and that of other sites and the head office should be documented. All policies and procedures necessary for the operation of the site being assessed must be available at the site.
3.1.2	The system shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.

3.2 Document control

An effective document control system shall 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 documented procedure to manage documents which form part of the product safety and quality management 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 the documents • the system for the replacement of existing documents when these are updated.
3.2.2	Where documents and records are in electronic form these shall be: • stored securely (e.g. with authorised access, control of amendments, or password-protected) • backed up to prevent loss or malicious intervention.

3.3 Record-keeping

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, appropriately authorised, retained in good condition, and retrievable.
3.3.2	Any alterations to records shall be authorised and justification for the alteration shall be recorded.
3.3.3	The company's senior management shall ensure that documented procedures are established and implemented for the organisation, review, maintenance, storage and retrieval of all records relating to product safety, legality, regulatory compliance and quality.
3.3.4	The site shall document its period of retention for records which relate to the usable life of the packaging and the products it is designed to contain, and shall respect any customer requirements.

3.4 Specifications

Fundamental
Appropriate specifications shall exist for raw materials, intermediate and finished products, and for any product or service which could affect the safety, quality or legality of the finished product and customer requirements.

Clause	Requirements
3.4.1	Specifications shall be suitably detailed, accurate and compliant with relevant product safety and legislative requirements. They may be in the form of a printed or electronic document, or part of an online specification system.
3.4.2	The company shall seek formal agreement of specifications with relevant parties where required by the customer. Where specifications are not formally agreed, then the company shall be able to demonstrate that it has taken steps to put an agreement in place.

Clause	Requirements
3.4.3	Where packaging for food or other hygiene-sensitive products is produced, a statement of compliance shall be maintained which enables users of the packaging to ensure compatibility between the packaging and the product with which it may be in contact. The statement of compliance shall be compiled and authorised by a suitably competent person. It shall contain as a minimum: • the nature of the materials used in the manufacture of the packaging • confirmation that the packaging meets relevant legal requirements • the inclusion of any post-consumer recycled materials. The statement shall identify: • its date of issue and, where appropriate, its expiry date • any limitations of use of the product, and • the usable life of the packaging (where relevant). The site shall review the statement of compliance at a risk-based frequency.
3.4.4	The presence of a manufacturer's trademarks or logo on packaging materials shall, where appropriate, be formally agreed between the relevant parties.
3.4.5	A specification review process shall be operated where the product composition or characteristics change or at an appropriate predetermined interval. Reviews and changes shall be documented and communicated to the customer, where required. Any changes to existing agreements or contracts shall be agreed, documented and communicated to appropriate departments.

3.5 Internal audits

Fundamental
The company shall be able to demonstrate that it verifies the effective application of the requirements of the Standard and any applicable module through internal audits.

Clause	Requirements
3.5.1	There shall be a scheduled programme of internal audits. 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 processes shall be audited at least annually. The internal audit programme shall be fully implemented and effective.

Clause	Requirements
3.5.2	As a minimum, the scope of the internal audit programme shall include the: • HARA or product safety and quality plan, including the activities to implement it (e.g. supplier approval, corrective actions and verification) • prerequisite programmes (e.g. hygiene, pest control) • product defence and product fraud prevention plans • procedures implemented to achieve the Standard and modules. Each internal audit within the programme shall have a defined scope and consider a specific activity or section of the HARA or product safety plan.
3.5.3	Internal audits shall be carried out by appropriately trained and competent auditors. Auditors shall be independent from the process or activity being audited to ensure impartiality (i.e. they must not audit their own work).
3.5.4	Internal audit reports shall identify conformity as well as non-conformity. Results shall be notified to the personnel responsible for the process/activity audited. Root cause analysis shall be used to determine appropriate corrective actions and a designated manager shall be responsible for the implementation.
3.5.5	For sites manufacturing materials intended to be in contact with food or other hygiene-sensitive products, 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. At a minimum, these inspections shall include: • hygiene inspections to assess cleaning and housekeeping performance • inspections to identify risks to the product from the building or equipment. The frequency of these inspections shall be based on risk.

3.6 Corrective and preventive action

Fundamental
The site shall be able to demonstrate that it uses the information from failures in its systems and processes to take any necessary corrective and preventive actions.

Clause	Requirements
3.6.1	The site shall have a procedure for the completion of root cause analysis and corrective actions and to determine preventive actions. As a minimum, root cause analysis shall be used to implement ongoing improvements and to prevent recurrence of non-conformities in the event of: • an analysis of non-conformities for trends which shows that there has been a significant increase in a type of non-conformity • a non-conformity which places the safety, legality, integrity or quality of a product at risk (including withdrawals) • the results of internal, second- or third-party audits • customer complaints • failure of in-line testing equipment • any incidents.
3.6.2	The site shall evaluate the effectiveness of root cause analyses, and of any corrective and preventive actions.

3.7 Supplier approval and performance monitoring

The company shall operate effective procedures for the approval and monitoring of its suppliers.

Clause	Requirements
3.7.1	The site shall have a documented supplier approval procedure and continual assessment programme in place, based upon risk analysis and defined performance criteria. These shall apply to the suppliers of: • materials • outsourced (subcontracted) production. The procedure shall ensure that the materials and services procured conform to defined requirements where there is a potential impact to product safety, quality or legality.

Clause	Requirements

3.7.2	The approval procedure shall be based on risk and include either one or a combination of:
	• a valid certification to the applicable Global Standard or GFSI-benchmarked standard. The scope of the certification shall include the raw materials purchased, and the site shall validate any BRCGS certificates using the BRCGS Directory.
	• supplier audits, with a scope to include product safety, traceability, HARA review and good manufacturing practices, 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, traceability, HARA review and good manufacturing practices
	  • obtain and review a copy of the full audit report
	or
	• where a valid risk-based justification is provided, a satisfactorily completed supplier questionnaire may be used for initial approval. The questionnaire shall have a scope that includes product safety, traceability, HARA review and good manufacturing practices, and it shall have been reviewed and verified by a demonstrably competent person.

3.7.3	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 agreed intervals based on risk, and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status. Records of ongoing supplier assessment and any necessary actions shall be maintained and reviewed.
3.7.4	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.
3.7.5	The company shall ensure that its suppliers of raw materials have an effective traceability system. Where a supplier has been approved based on a questionnaire instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least every 3 years. This may be achieved by a traceability test.
3.7.6	Where raw materials are purchased from companies that are not the manufacturer or packer (e.g. purchased from an agent, broker or wholesaler), the site shall know the identity of the last manufacturer or packer. Information to enable the approval of the manufacturer or packer shall be obtained from the agent/broker or directly from the supplier, unless the agent/broker is certificated to the relevant Global Standard (e.g. Global Standard for Agents and Brokers) or a relevant standard benchmarked by GFSI.

Clause	Requirements
3.7.7	The procedures shall define how exceptions are handled; for example, the use of products or services where an audit or monitoring has not been undertaken. Assessment (on a batch or delivery basis) may take the form of: • certificate of analysis • statement of compliance.

3.8 Product authenticity, claims and chain of custody

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

Clause	Requirements
3.8.1	The company shall have processes in place to access information on historical and developing threats to the supply chain which may present a risk of substitution of raw materials (i.e. fraudulent raw materials). Such information may, for example, come from: • trade associations • government sources • private resource centres.
3.8.2	A documented vulnerability assessment shall be carried out on all raw materials or groups of raw materials to assess the potential risk of substitution. This shall take into account: • historical evidence of substitution • economic factors which may make substitution more attractive • ease of access to raw materials through the supply chain • sophistication of routine and upstream testing to identify substitution • nature of the raw material. The output from this assessment shall be a documented vulnerability assessment plan. This plan shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risks. It shall be formally reviewed annually.
3.8.3	Where raw materials are identified as being at particular risk of substitution, the vulnerability assessment plan shall include appropriate assurance and/or testing processes to mitigate the identified risk(s).

3.9 Management of subcontracted activities and outsourced processes

Where any process steps in the manufacture of the packaging material are outsourced to a third party, or the process is wholly subcontracted to another site, this shall be managed to ensure it does not compromise the quality, safety or legality of the product.

Clause	Requirements
3.9.1	The company shall be able to demonstrate that, where any part of the production is outsourced and undertaken off-site, this has been declared to the customer or brand owner and, where required, approval has been granted.
3.9.2	Where any processes are subcontracted or outsourced, including artwork or pre-press activity, the risks to the quality and safety of the product shall form part of the hazard and risk analysis and the company's evaluation of the system shall be held on record.
3.9.3	Clear specifications shall be agreed for all work outsourced or subcontracted.
3.9.4	Where any process steps in the manufacture of the packaging materials are subcontracted or outsourced, final release of the product shall remain the responsibility of the site. Controls shall be in place for checks on finished work to ensure product safety and quality meets specification prior to dispatch to the final customer.
3.9.5	The company shall ensure that any subcontracted or outsourced processors 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 once every 3 years. This may be achieved by a traceability test.

3.10 Management of suppliers of services

The company shall be able to demonstrate that, where services are outsourced, any risks presented to product safety, quality or legality have been evaluated to ensure effective controls are in place.

Clause	Requirements
3.10.1	There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services shall include, but are not limited to: • pest control • laundry services • transport and distribution • storage and dispatch • sorting or rework • laboratory services • calibration services • waste management • product safety and quality consultants to the site. Providers of utilities such as water, electricity or gas may be excluded on the basis of risk. 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 product defence assessments).
3.10.2	Contracts or formal agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential risks associated with the service have been addressed.

3.11 Traceability

Fundamental
The site shall be able to trace and follow all raw materials through processing (including subcontracted processes) to the distribution of the finished product (packaging material) to the customer and vice versa.

Clause	Requirements
3.11.1	The site shall have a documented traceability procedure and system that can trace and follow all raw materials from the supplier through all stages of processing (including subcontracted processes) and distribution of the finished product, and vice versa. Where continuous processes are used, or raw materials are in bulk silos, traceability shall be achieved to the best practical level of accuracy.
3.11.2	Identification of raw materials, intermediate products, finished products, non-conforming products and quarantined goods shall be adequate to ensure traceability.

Clause	Requirements
3.11.3	For traceability, an appropriate system shall be in place to ensure that the customer can identify a product or production lot number for the product. Where coding is applied, this shall be checked for legibility and accuracy against production records.
3.11.4	The traceability procedure and system shall be tested at a predetermined frequency, at least annually, and the results shall be retained and easily retrieved for inspection. Traceability of all materials shall be achievable in a timely manner.
3.11.5	Where rework or any reworking operation is performed or outsourced or subcontracted activities are carried out, traceability shall be maintained.
3.11.6	Traceability of test data and samples to production lots shall be maintained.

3.12 Complaint-handling

Customer complaints relating to product hygiene, safety or quality shall be handled effectively and the information used to reduce complaint levels.

Clause	Requirements
3.12.1	All complaints shall be recorded and investigated (including root cause analysis) and the results of the investigation documented. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.
3.12.2	Complaint data shall be analysed to identify significant trends. Where there has been an increase or repetition of a complaint type, 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.

3.13 Management of product withdrawals, incidents and product recalls

The site shall have a documented procedure and systems in place to effectively manage any product withdrawals, returns from customers, incidents or product recalls in order to ensure that all potential risks to the hygiene, quality, safety or legality of products and the final consumer are controlled.

Clause	Requirements
3.13.1	A product withdrawal procedure shall be documented and include as a minimum: • identification of the key personnel involved in assessing potential product withdrawals or returns, with their responsibilities clearly defined • a communications plan including methods of informing customers • root cause analysis and corrective action to implement appropriate improvements as required.
3.13.2	The withdrawal procedure shall be capable of being operated at any time and will take into account notification to the supply chain, stock return, logistics for recovery, storage of recovered product, and disposal.
3.13.3	The company shall provide written guidance and training for relevant staff regarding the type of event that would constitute an incident. Incidents may include: • disruption to normal production processes • disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications • events such as fire, flood or natural disaster • malicious contamination or sabotage • failure of, or attacks against, digital cyber-security. Where products which have been released from the site could be affected by an incident, the need to withdraw products and, where appropriate, advise customers to withdraw and/or recall products shall be considered. A documented incident reporting procedure shall be in place.
3.13.4	The company shall determine and document the activity required to effectively manage an incident to prevent release of product where hygiene, safety or quality may have been affected.
3.13.5	A procedure to manage product recalls initiated by the brand owner or specifier shall be documented and include as a minimum: • identification of the key personnel involved in assessing potential recalls, together with clearly defined responsibilities • a communications plan that includes methods of informing customers and (where necessary) regulatory bodies in a timely manner.
3.13.6	Where a site's products are involved in a product recall, the site shall assist with provision of information (such as traceability) as required.

Clause	Requirements
3.13.7	The product withdrawal procedure shall be tested, at least annually, in a way that ensures its 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 withdrawals, shall be used to review the procedure and implement improvements as necessary.

4 Site standards

4.1 External standards

The site shall be of suitable size and construction, in a suitable location, and maintained to an appropriate standard to reduce the risk of contamination and facilitate the production of safe and legal products.

Clause	Requirements
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on the safety or quality of the finished product or raw materials, and measures shall be taken to prevent contamination. Where measures have been put in place to protect the site, they shall be regularly reviewed to ensure they continue to be effective (e.g. flood controls).
4.1.2	The external areas shall be maintained in good order. Any grassed or planted areas surrounding buildings shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced to avoid contamination of the product.
4.1.3	The building fabric shall be maintained to minimise potential for pest entry, ingress of water and other contaminants. External silos, pipework or other access points for the product and/or raw materials shall be appropriately sealed and secured. Where possible, a clean and unobstructed area shall be provided along the external walls of the buildings used for production and/or storage.
4.1.4	Where natural external drainage is inadequate, additional drainage shall be installed. Drains shall be properly protected to prevent entry of pests.
4.1.5	Where external storage of raw materials is necessary, these shall be protected in order to minimise the risk of contamination.

4.2 Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas

The internal site, buildings and facilities shall be suitable for the intended purpose and shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.

Clause	Requirements
4.2.1	Walls, floors, ceilings and pipework shall be maintained in good condition and shall facilitate cleaning.
4.2.2	Where suspended ceilings exist, they shall be constructed, finished and maintained to prevent the risk of product contamination, and accessible for cleaning and inspection for pests unless the void is fully sealed.
4.2.3	All internal drain openings shall be suitably protected against the entry of pests and designed to minimise odour.

Clause	Requirements
4.2.4	Where they constitute a risk to product, and based on the likelihood and risk of contamination, windows and roof glazing shall be protected against breakage.
4.2.5	Where they constitute a risk to product, and based on the likelihood and risk of non-production glass contamination, all bulbs and strip lights, including those on flying-insect control devices, shall be adequately protected.
4.2.6	Where elevated walkways are adjacent to or pass over production lines, based on risk they shall be: • designed to prevent contamination of products and production lines • easy to clean • correctly maintained.
4.2.7	Suitable and sufficient lighting shall be provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning.
4.2.8	Suitable and sufficient ventilation shall be provided.

4.3 Utilities

All utilities to and within the production and storage areas shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.

Clause	Requirements
4.3.1	All water used in the processing of the products or equipment cleaning shall be potable or suitably treated to prevent contamination.
4.3.2	Based on risk assessment, the microbiological and chemical quality of water, steam, ice, air, compressed air or other gases which come into direct contact with packaging shall be regularly monitored. These shall present no risk to product safety or quality and shall comply with relevant legal regulations.

4.4 Site security and product defence

A product defence plan shall be in place to ensure that there are systems to protect products, premises and brands from malicious actions while under the control of the site.

Clause	Requirements
4.4.1	The company shall undertake a documented risk assessment (threat assessment) of the security arrangements and potential risks to the 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 product defence plan. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. This plan shall be kept under review to reflect changing circumstances and external influences. It shall be formally reviewed at least annually.
4.4.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.
4.4.3	External storage tanks, silos and any intake pipes with an external opening shall be sufficiently secure to prevent unauthorised access.

4.5 Layout, product flow and segregation

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

Clause	Requirements
4.5.1	There shall be a current map or plan of the site which defines: • access points for personnel • travel routes for personnel, raw materials and intermediate or finished products • staff facilities • routes for the removal of waste • production and process flows • storage areas.
4.5.2	The process flow from intake to dispatch shall be arranged to minimise the risk of contamination or damage to the product.
4.5.3	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe and hygienic conditions.

Clause	Requirements
4.5.4	Sorting or other activities involving the direct handling of the product shall take place in areas that have, as a minimum, the same standards as production areas.
4.5.5	Activities that could produce a contamination risk, such as the removal of outer packaging, shall be carried out in a designated, segregated area.
4.5.6	If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials.
4.5.7	Where possible, all facilities shall be designed and positioned so that movement of personnel is by simple, logical routes.

4.6 Equipment

Equipment shall be suitably designed for the intended purpose and shall be maintained and used so as to minimise the risk to product safety, legality and quality.

Clause	Requirements
4.6.1	Production, storage and warehousing equipment shall be designed for the intended purpose and shall minimise the risk of contamination to the product. Lubrication points and application methods of any lubricant shall not be able to contaminate the product. Equipment shall be constructed of suitable materials and be designed to ensure it can be effectively cleaned and maintained.
4.6.2	Newly installed equipment shall be properly specified before purchase. New equipment shall be tested and commissioned prior to use and a maintenance and cleaning programme established.
4.6.3	Wooden equipment including desks, chairs, tables, etc. shall be properly sealed to enable effective cleaning. This equipment shall be kept clean, in good condition and free from splinters or other sources of physical contamination.
4.6.4	Notices on equipment shall be cleanable and secure.

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	A documented programme of maintenance shall be operated, covering all items of production equipment and plant critical to product safety, legality and quality, to prevent contamination and reduce the risk of breakdown.

Clause	Requirements
4.7.2	Maintenance logs shall be maintained for all off-line testing equipment. This shall include, as a minimum: • any adjustments • the re-calibration date of any interventions.
4.7.3	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment failure or damage, the equipment shall be inspected at predetermined intervals, inspection results documented, and appropriate action taken.
4.7.4	Maintenance work shall not place product safety, quality or legality at risk. Maintenance work shall be followed by a documented clearance procedure which records that contamination hazards have been removed and equipment cleared to resume production.
4.7.5	Tools and other maintenance equipment shall be cleared away after use and appropriately stored.
4.7.6	Temporary repairs/modifications using tape, cardboard, etc. shall only be permitted in emergencies and where product contamination is not at risk. Such modifications shall be subject to a time limit and shall be recorded and scheduled for correction.
4.7.7	Engineering workshops shall be controlled to prevent transfer of engineering debris to production or storage areas (e.g. by provision of swarf mats).
4.7.8	Contractors involved in maintenance or repair shall be suitably monitored by a staff member who shall be responsible for their activities.

4.8 Housekeeping and cleaning

Fundamental
Housekeeping and cleaning systems shall be in place which ensure that appropriate standards of hygiene are maintained and that the risk of product contamination is minimised.

Clause	Requirements
4.8.1	Good standards of housekeeping shall be maintained, which shall include a condition-based cleaning or 'clean as you go' policy.

Clause	Requirements
4.8.2	Documented cleaning procedures shall be in place and maintained for buildings, equipment and vehicles. Cleaning schedules and procedures shall include the following information: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning • cleaning materials to be used • cleaning record and responsibility for verification. The frequency and methods of cleaning shall be based on risk. The procedures shall be implemented to ensure that appropriate standards of cleaning are achieved.
4.8.3	Cleaning chemicals shall be fit for purpose, suitably labelled, and used in accordance with manufacturers' instructions. They shall be stored in a secured, designated location, in closed containers. Chemicals that are strongly scented or could give rise to taint and odour contamination shall not be used. Cleaning equipment shall be kept in a suitable designated location.
4.8.4	Materials and equipment used for cleaning toilets shall be differentiated from those used elsewhere, and physically segregated where necessary.
4.8.5	Where appropriate, based on risk, a microbiological environmental monitoring programme shall be in place to ensure that the cleaning operations are effective in minimising the risk of contamination by microorganisms that would be detrimental to the products. The programme shall consider the likelihood of the microorganisms' survival on packaging materials and their use. Where a programme is in place, this shall include: • sampling protocol • identification of sample locations • frequency of tests • target organisms (e.g. pathogens, spoilage organisms and/or indicator organisms) • test methods • recording and evaluation of results. The programme and its associated procedures shall be documented.

4.9 Product contamination control

All practicable steps shall be taken to identify, eliminate, avoid or minimise the risk of foreign-body or chemical contamination.

4.9.1 Glass, brittle plastics, ceramics and similar materials control

Clause	Requirements
4.9.1.1	There shall be no unnecessary non-production glass, ceramics or brittle plastic present, which may pose a foreseeable risk of contamination. Where non-production glass, ceramics or brittle plastics are required in production, packing or storage areas, and where there is a risk of product contamination, procedures for their handling shall be in place.
4.9.1.2	Glass or brittle plastics (other than the product) that pose a potential product contamination hazard shall be controlled and recorded on a register that includes, as a minimum: • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise the potential for product contamination. Glass or brittle plastics not in the production or storage areas shall be included in the register on the basis of risk.
4.9.1.3	Where non-production glass or brittle plastic breakage occurs, a responsible person shall be placed in charge of the clean-up operation and shall ensure that no other area is allowed to become contaminated due to the breakage. Any product that has become contaminated shall be segregated and disposed of. All breakages shall be recorded in an incident report.

4.9.2 Sharps and metal control

Clause	Requirements
4.9.2.1	There shall be a documented policy for the controlled use and storage of sharp implements, including knives, needles and wires, to prevent contamination. The policy shall include control of these items into and out of the site.
4.9.2.2	Production equipment that incorporates blades or sharps shall be monitored. Blades or other sharp implements shall not be allowed to contaminate the product.
4.9.2.3	Snap-off blade knives shall not be used.
4.9.2.4	Where open noticeboards are present in production, packing and storage areas, loose fastenings, such as drawing pins and staples, shall not be used.

4.9.3 Chemical and biological control

Clause	Requirements
4.9.3.1	Processes shall be in place to manage the use, storage and handling of non-production chemicals, to prevent chemical contamination. These shall include, as a minimum: • a list of approved chemicals for purchase • availability of material safety data sheets and specifications • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • designated storage area with access restricted to authorised personnel • use by trained personnel only.
4.9.3.2	Hazard and risk analysis shall be used to identify, control and manage any potential risks from microbiological contamination and any potential allergens.

4.10 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
4.10.1	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.
4.10.2	Process waste shall be managed to minimise release to the environment. This shall include, but is not limited to, pellet, flake, powder, dust and offcuts.
4.10.3	Suitable and sufficient refuse and waste containers shall be provided, which shall be emptied at appropriate frequencies and maintained in an adequately clean condition.
4.10.4	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal (such as recycling), and sorted, segregated and collected in appropriate designated waste containers.
4.10.5	Substandard trademarked materials shall be rendered unusable through a destructive process. All materials disposed of shall be recorded.
4.10.6	If substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in appropriate waste disposal and shall provide records of material destruction.
4.10.7	External storage of refuse shall be in designated areas and designed or maintained to minimise the risk of pest harbourage.

4.11 Pest management

In order to minimise the risk of infestation and risk to products, the whole site shall have an effective preventive pest management programme in place and the resources available to respond immediately to any issues which occur.

Clause	Requirements
4.11.1	A preventive pest management programme shall be maintained, covering all areas of the site under the site's control. The site shall assess the suitability of its pest management programme to address variation in pest activity through different seasons, and consider any additional preventive activity required. The site shall document and implement any required additional activity.
4.11.2	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 in order to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and 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 contract shall be clearly defined and reflect the activities of the site.
4.11.3	Where a site undertakes its own pest management, it shall be able to 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.
4.11.4	Equipment such as bait stations, traps or electric fly-killing devices shall be appropriately located and operational.
4.11.5	Effective precautions shall be in place to prevent pests entering the premises. The building shall be suitably proofed against the entry of all pests via doors, windows, ducts and cable entry points. This shall include measures to prevent birds and flying mammals from entering buildings or roosting above loading or unloading areas.

Clause	Requirements
4.11.6	In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to identify, evaluate the potential for contamination or damage, and authorise the release of any product potentially affected.
4.11.7	In the event of an infestation, and at appropriate intervals, the site shall request a catch analysis from flying-insect control devices to help identify problem areas. In the event of increase in activity, the site shall use risk assessment to determine the activity required to eliminate the hazard.
4.11.8	Documented procedures and detailed records of pest activity, pest management inspections and recommendations shall be maintained. These shall include, as a minimum: • an up-to-date, signed and authorised site plan identifying numbered 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 and instructions for their effective use • detailed records of inspections, recommendations and of any pest infestation. It shall be the responsibility of the site to ensure that all the relevant recommendations made by the contractor or in-house expert are implemented in a timely manner and monitored for efficacy.
4.11.9	Employees shall understand the signs of pest activity and be aware of the need to report any evidence to a designated manager.

5 Product and process control

5.1 Product development

Documented product development or modification procedures shall be in place to ensure the production of safe and legal products to defined quality parameters.

Clause	Requirements
5.1.1	Customer requirements relating to the design, development, specification, manufacture and distribution of the product shall be documented and agreed with the customer. This shall take into consideration process requirements and end use, where possible. Any critical-use parameters shall be identified and defined; for example, barrier requirements, maximum/minimum use temperature, machine running, use of recycled materials, and testing requirements (including migration, where relevant). Special attention shall be paid to any materials that are required or requested to be manufactured from recycled materials, to ensure that they are both appropriate and legal.
5.1.2	The site shall clearly define and document when a production trial is required. The site shall determine the outputs and success criteria required from a production trial, and any changes and/or additions made to materials, processing characteristics or equipment as a result of the trial. Where appropriate, production trials shall be carried out and testing shall validate that manufacturing processes are capable of producing a safe and legal product to defined quality parameters. New products or product changes shall be subject to suitable evaluation to ensure that required safety and quality parameters can be achieved.
5.1.3	The company shall ensure that production is carried out using defined operating conditions which result in safe and legal products to defined quality parameters.
5.1.4	Where required by the customer, a technical product specification shall be prepared and, where possible, agreed with the customer or brand owner before the production process begins.
5.1.5	Samples as agreed with the specifier shall be retained for future reference.
5.1.6	A documented procedure shall in be in place to address the transfer of customer specifications or requirements to the site's own systems. This shall include (but is not limited to): • validation of accuracy of data transferred • how changes to customer specifications are updated and communicated • how the agreed requirements for customer testing methods are met • evaluation of how changes made to the customer specifications affect the technical product specification (see clause 5.1.1). Settings derived from successfully conducted production trials or equipment installations shall be transferred accurately to process control documentation.

5.2 Graphic design and artwork control

Artwork and all pre-press processes conducted by the site shall be managed to ensure that loss of information and variation from the customer's specifications are eliminated.

Clause	Requirements
5.2.1	The site shall have a documented artwork management procedure covering the activities for which the site has responsibility. This may include, but is not limited to: • collation of information to be included into artwork • receipt of artwork files from the customer • verification of completed artwork and approval by the customer.
5.2.2	A process shall be in place to seek formal acceptance and approval of final product concepts and artworks by the specifier. The outcome shall be documented.
5.2.3	Where appropriate, print trials shall be carried out and testing shall validate that the agreed product quality and print standards can be consistently achieved.
5.2.4	Printing equipment such as plates, silk screens, anilox rollers, cylinders and blankets shall be verified as being correct to specification and artwork version or agreed master prior to use, and fully traceable to the customer's approved origination material.
5.2.5	Customer-approved reference material, including artwork masters and colour standards used during print runs, shall be controlled to ensure minimisation of degradation and shall be returned to appropriate storage after use. The site shall have a policy to address requirements for the renewal of approved masters, as necessary.
5.2.6	The site shall have a documented procedure for managing changes to artwork and print specifications to manage obsolete artwork and printing materials.
5.2.7	Where artwork files and approved masters are in electronic form, these shall be suitably protected to prevent loss or malicious intervention.

5.3 Packaging print control

Where packaging materials are printed or decorated, documented procedures shall be in place to ensure that the information is fully legible and correctly reproduced to customer specification and complies with any legal requirements.

Clause	Requirements
5.3.1	An assessment shall be carried out for the pre-press activity, print process and handling of printed packaging (product) to identify: • risks of loss of essential information • mixing of printed product. Controls shall be established and implemented to reduce the risks identified.
5.3.2	Printing plates, cylinders, cutting dies, print blankets and any other printing equipment shall be appropriately stored to minimise damage.
5.3.3	Each print run shall be approved against the agreed standard (or master sample). This shall be recorded.
5.3.4	A system shall be in place to detect and identify printing errors during the run and to sort these errors from the acceptable printed material.
5.3.5	Where composite print is used (a mixture of different designs printed together), a process shall be in place to ensure effective segregation of differing print variants.
5.3.6	Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.
5.3.7	Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored.
5.3.8	Lighting in print inspection cabinets and other means of print/colour checking shall be agreed with the customer or conform to accepted industry standards.

5.4 Process control

Fundamental
Documented procedures, work instructions and process specifications shall be in place to ensure effective quality assurance of operations throughout the process.

Clause	Requirements
5.4.1	The hazard and risk management team shall identify and record all potential product defects that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where applicable: • product quality defects • defects that may have an impact on the functional integrity and performance of the final product in use • defects which result in the production of products which are outside customer-specified quality parameters.
5.4.2	A review of the manufacturing and, where applicable, printing process shall identify manufacturing process control points that can prevent or limit the risk of producing products with quality defects.
5.4.3	For each manufacturing process control point, machine settings or process limits shall be established and documented – the process specification.
5.4.4	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.
5.4.5	A bill of materials and process specification (including manufacturing process control points) shall be available for each batch or lot during production.
5.4.6	Documented process checks shall be undertaken at start-up, following adjustments to equipment and periodically during production, to ensure products are consistently produced to the agreed quality specification.
5.4.7	A documented clearance procedure shall be in place to ensure that at start-up the line is clear of all previous work and production documents.
5.4.8	In the event of changes to product composition, processing methods or equipment, the site shall, where appropriate, re-establish process characteristics and validate product data to ensure that product safety, legality and quality are achieved.
5.4.9	The documented line clearance procedure shall include: • the roles of persons involved in line clearance • areas where materials can become trapped • validation of the line clearance • sign-off for continuing production. The line clearance procedure shall be fully implemented for each production run.

5.5 Calibration and control of measuring and monitoring devices

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

Clause	Requirements
5.5.1	The site shall identify and control in-line and off-line measuring equipment used to monitor critical control points (where applicable) and product safety, quality and legality. This shall include, as a minimum: • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration and misuse.
5.5.2	All identified measuring equipment shall be checked and adjusted at a predetermined frequency, based on risk analysis. This shall be carried out by trained staff to a defined method to ensure accuracy within defined parameters. All results shall be documented. Where possible, calibration shall be traceable to a recognised national or international standard. Where a traceable calibration is not possible, the site shall demonstrate the basis by which standardisation is carried out.
5.5.3	Corrective action and reporting procedures shall be established and documented in the event of the monitoring and testing procedure identifying any failure of product inspection, testing or measuring equipment. Any such failures shall be subject to an assessment of potential risk; subsequent action may include a combination of isolation, quarantine and re-inspection of products produced since the last acceptance test of the equipment. The site shall conduct a root cause analysis into the equipment failure and implement the appropriate corrective action.

5.6 Product inspection, testing and measuring

The company shall undertake appropriate inspections and analyses that are critical to product safety, legality, integrity and quality.

Clause	Requirements
5.6.1	Quality checks shall be carried out to demonstrate that the finished product is within the tolerances laid down in the agreed product specification and conforms to any critical technical/legal requirements. The frequency of checks and sampling shall be in accordance with industry-accepted practice or customer requirements and based on risk analysis. The site shall define how samples used for checking in-process quality are disposed of. This may be by returning to stock, regrinding/recycling, or segregation and disposal.
5.6.2	Hazard and risk analysis principles shall be used to determine the need for in-line product testing equipment to ensure product safety, quality and legality.

Clause	Requirements
5.6.3	The accuracy of in-line equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.
5.6.4	The company shall establish, document and implement procedures for the operation, routine monitoring and testing of all equipment used in product inspection, testing and measurement. This shall include: • frequency and sensitivity of checks • authorisation of trained personnel to carry out specified tasks • documentation of test results.
5.6.5	Routine off-line quality checks shall be carried out at appropriate stages in production to demonstrate that the product is within the tolerances laid down in the agreed product specification. A system that includes off-line or randomised quality checks shall be in place to identify and remove non-conforming product from the production lot.
5.6.6	In-line testing equipment critical to product quality or safety shall incorporate a system to identify non-conforming product for removal or divert it out of the product flow.
5.6.7	Test methods, analytical methods and customer-approved reference samples (where required) shall be of the most recent version and be available in the laboratory or where off-line testing is conducted. Samples shall be suitably stored to avoid degradation.
5.6.8	The test methods used by the site in both on-line and off-line testing shall be validated to ensure their sensitivity, reproducibility and range, in addition to any other relevant criteria. Where standardised tests are used, the site shall ensure prescribed methodologies are followed. Where testing shows out-of-specification results, a documented procedure for investigating these results shall be established and followed to determine whether the cause is non-conforming product or a testing failure.
5.6.9	Where automated inspection equipment (e.g. vision systems) is used to check print or other material features, the site shall establish and implement procedures for the operation and testing of the equipment to ensure that it is correctly set up and capable of alerting or rejecting the packaging when it is out of specification. As a minimum, testing of the equipment shall be completed at: • the start of the production run • the end of the production 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 production run or when changing batches of raw materials). The site shall establish and implement procedures in the event of a failure in the equipment (e.g. a documented and trained manual checking procedure).

Clause	Requirements
5.6.10	Where the company undertakes or subcontracts an analysis critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025 for the test undertaken (General requirements for the competence of testing and calibration laboratories). Documented justification shall be available where accredited methods are not undertaken. The significance of the laboratory results shall be understood and acted upon accordingly.

5.7 Control of non-conforming product

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

Clause	Requirements
5.7.1	Clear procedures for the control of out-of-specification or non-conforming materials shall be in place, documented and understood by all personnel. These shall include the effective identification and management of materials before a decision has been made on their final disposition.
5.7.2	Non-conforming materials shall be assessed and a decision taken to reject, accept by concession, rework or put to alternative use. The decision and reasons shall be documented.

5.8 Incoming goods

The site shall ensure that incoming goods are appropriately checked for contents, packaging integrity and potential contamination.

Clause	Requirements
5.8.1	The site shall document a raw materials and intermediate product intake procedure to ensure that incoming goods match purchase or product specifications. This may take the form of: • purchase orders • delivery notes.
5.8.2	There shall be a procedure for the inspection of loads on arrival to ensure that products are free from pest infestation, contamination or damage and are in a satisfactory condition. Unloading areas for bulk deliveries shall be clearly identified and designed to prevent product mix-ups. Regarding raw materials, all complaints or defects identified by the site shall be recorded and investigated (including root cause analysis) and the results of the investigation documented.

Clause	Requirements
5.8.3	The site shall have a procedure for the acceptance of raw materials. This may include a valid certificate of analysis (CoA) or testing. All raw materials awaiting the results of in-house testing or verification of data shall be held until released for use.
5.8.4	Receipt documents and/or product identification shall facilitate correct stock rotation of goods in storage and, where appropriate, ensure materials are used in the correct order and within the prescribed shelf life.
5.8.5	The site shall have a system in place to validate all raw materials and intermediate products prior to their introduction to the process.

5.9 Storage of all materials and intermediate and finished products

The handling, management and storage of all materials and products shall minimise the risk of contamination or malicious intervention, and protect product safety, quality and legality.

Clause	Requirements
5.9.1	Procedures to maintain product safety and quality during storage shall be risk-based, understood by the relevant staff, and implemented accordingly. They shall include, as appropriate: • instructions for the packing of finished product • segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergenic), mixing of sorts, or taint • storage of product/materials off the floor and away from walls • specific handling or stacking requirements to prevent product damage.
5.9.2	All materials, work in progress and finished product shall be properly identified and protected during storage by appropriate packaging to protect them from contamination.
5.9.3	Storage, including off-site storage, shall be controlled to protect the product from contamination, including taint or odour and malicious intervention. Where off-site storage is used, the same site standards apply as for on-site storage.
5.9.4	Finished or intermediate product storage shall meet customer requirements (with regard to first in, first out (FIFO), where applicable), with dispatch after positive release. Where external storage of finished product is required, the product shall be suitably protected.
5.9.5	Packaging used for storage or dispatch of intermediate or finished products, such as pallets, shall be appropriately protected if stored outside and inspected for signs of damage or contamination prior to use.
5.9.6	In order to prevent contamination, documented procedures shall be in place to appropriately segregate raw materials, intermediate products and finished products.

Clause	Requirements
5.9.7	The site shall ensure that hazardous chemicals are handled in such a way that risk to product safety, quality and legality is minimised.
5.9.8	Material intended for recycling shall be appropriately protected against contamination hazards.

5.10 Dispatch and transport

The dispatch and transport of raw materials and finished products shall be undertaken in a manner that minimises the risk of contamination or malicious intervention and maintains product safety, legality and quality.

Clause	Requirements
5.10.1	The company shall have procedures for the dispatch and transport of products, which shall include: • any restrictions on the use of combined loads (e.g. where materials from other companies are in the same transport) • requirements for the security of products during transit, particularly when vehicles are parked and unattended away from a designated storage depot.
5.10.2	All products and materials shall be identified and either protected during distribution by appropriate external packaging or transported under conditions to protect the product from contamination. This shall include the risk of taint or odour and of malicious intervention.
5.10.3	All pallets shall be checked. Damaged, contaminated or unacceptable pallets shall be discarded. Wooden pallets that come into direct contact with finished products or raw materials shall not be allowed to contaminate the product. Wooden pallets, if used, shall be sound, dry, clean and free from damage and contamination.
5.10.4	All company-owned or leased vehicles used for deliveries shall be included in the documented cleaning schedules and kept clean and in a condition that minimises the risk of product contamination.
5.10.5	All delivery vehicles and shipping containers shall be subject to a documented hygiene and odour checking procedure before loading.
5.10.6	Where the company employs third-party contractors, there shall be a contract or agreed terms and conditions. All the requirements specified in this section shall be clearly defined in the contract or the company shall be certificated to the Global Standard for Storage and Distribution. Where this is not possible, with general carriers, the packaging shall be adequate to protect the product against damage, contamination hazards, taint and odour.
5.10.7	Vehicle drivers shall comply with the site rules relevant to this Standard. Access to the site for third-party transport personnel shall be controlled and, where possible, facilities provided to negate the need to enter storage or production areas.

6 Personnel

6.1 Training and competence: raw materials 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 adequately trained, instructed and supervised commensurate with their activity and that they are competent to undertake their job role.

Clause	Requirements
6.1.1	All personnel, including temporary personnel and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. Induction training shall include the company hygiene rules.
6.1.2	Where personnel are engaged in activities relating to product safety, quality and legality, relevant training and competency assessment shall be in place. This may include, but is not limited to: • product inspection, testing and measuring • calibration • printed packaging controls • operatives at manufacturing process control points • laboratory testing • product defence.
6.1.3	The site shall define and document how new or changed procedures, working methods and practices related to product safety or quality are communicated to relevant personnel.
6.1.4	The company shall routinely review and document the competencies of all staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.
6.1.5	Records of training shall be available. These shall include: • 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 (external or internal provider). Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
6.1.6	The site shall put in place documented programmes covering the training needs of relevant personnel. These shall include, as a minimum: • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training and trainers • the delivery of training in the appropriate language of trainees.

6.2 Personal hygiene: raw materials 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. These standards shall 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
6.2.1	The requirements for personal hygiene at sites producing materials for direct contact with food or other hygiene-sensitive products shall be documented and communicated to all personnel. These shall include, as a minimum, the following instructions: • wrist bands, wrist-worn devices or watches shall not be worn • jewellery including piercings shall not be worn on exposed parts of the body, with the exception of a plain wedding ring, wedding wristband or medical alert jewellery • fingernails shall be kept short and clean and free from nail varnish • false fingernails and nail art shall not be worn • excessive perfume or aftershave shall not be worn. Requirements at sites producing materials not for contact with food shall be based on risk assessment. Compliance with the site's requirements shall be checked routinely.
6.2.2	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.
6.2.3	Personal items and belongings, including personal mobile phones, shall not be taken into production areas without the permission of the management.
6.2.4	The site shall use risk assessment to determine the procedures and written instructions necessary to control the use and storage of personal medicines in production and storage areas, to minimise the risk of product contamination.
6.2.5	Where visitors cannot comply with site hygiene rules, suitable control procedures shall be in place (e.g. non-handling of product, use of gloves).
6.2.6	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue). These shall be site-issued and monitored when people are involved in work with materials intended to come into direct contact with food or other hygiene-sensitive products. Where appropriate, in addition to the plaster, a finger stall or glove shall be worn.

6.3 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. Such facilities shall be kept in a good and clean condition.

Clause	Requirements
6.3.1	Locker rooms shall be accessed without the need to enter production areas unless appropriately segregated walkways are in place.
6.3.2	Lockers shall be provided for all personnel who work in raw material handling, processing, preparation, packing and storage areas. Lockers shall be of sufficient size to accommodate all reasonable personal items and any protective clothing required.
6.3.3	Site-issued protective clothing and personal clothing shall not be stored in the same locker or shall be appropriately segregated based on risk within the locker.
6.3.4	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in locker and changing rooms.
6.3.5	Suitable and sufficient hand-washing facilities shall be available to enable cleaning of hands before commencing work, after breaks, and as necessary during the course of work. Such hand-washing facilities shall provide, as a minimum: • sufficient quantity of water at a suitable temperature to encourage hand-washing • unscented liquid soap or foam • adequate hand-drying facilities • advisory signs to prompt use (including signs in appropriate languages). Where materials are handled that will be in direct contact with food or other hygiene-sensitive products, hand-washing facilities shall be sited at the entrance to the production area.
6.3.6	Toilets shall not open directly into storage, processing or production areas in order to prevent the risk of contamination to product. Toilets shall be provided with suitable and sufficient hand-washing facilities.
6.3.7	Facilities for visitors and contractors shall enable compliance with the site's hygiene policy.
6.3.8	All food brought into manufacturing premises shall be stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas.
6.3.9	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in the production or storage areas. If it is impractical for personnel to leave their work area, local controlled facilities (such as a fully walled area with hand-washing facilities) shall be provided.
6.3.10	Drinking of water from purpose-made dispensers and/or by using disposable conical cups or spill-proof lidded containers may be allowed, provided it is confined to a designated area away from equipment.

Clause	Requirements
6.3.11	Where smoking is allowed under national law, it shall only be permitted in designated controlled smoking areas which shall be isolated from production and storage areas and fitted with extraction equipment to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall also be provided at smoking facilities, both inside buildings and at external locations. The use of electronic cigarettes and associated materials shall not be permitted in locker rooms, nor in production or storage areas, and shall only be permitted in designated smoking areas.

6.4 Medical screening

Sites that manufacture packaging for direct contact with food or other hygiene-sensitive products shall ensure that documented procedures are in place to ensure that health conditions likely to adversely affect product safety are monitored and controlled.

Clause	Requirements
6.4.1	Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the site shall make employees aware of the symptoms of infection, disease or condition which would prevent a person working. The site shall have a procedure for the notification by personnel, including temporary personnel, of any relevant infections, diseases or conditions with which they may have been in contact or be suffering from. Employees, contractors and visitors suffering from any of the above shall be excluded from work involving the handling of direct food contact or other hygiene-sensitive product packaging for as long as the symptoms persist.
6.4.2	Where permitted by law, visitors and contractors shall be required to fill in a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to being allowed into production, packing or storage areas.
6.4.3	Medical screening for sites producing materials that will not come into direct contact with food or other hygiene-sensitive products shall be implemented on the basis of risk.

6.5 Protective clothing

Appropriate protective clothing shall be worn in production and storage areas to minimise the risk of product contamination.

Clause	Requirements
6.5.1	Hair coverings and/or beard snoods, where appropriate, shall be worn in production areas at sites manufacturing materials for direct contact with food or other hygiene-sensitive products. Hazard and risk principles shall be used to determine the need for any other protective clothing, including garments and footwear in areas handling raw materials, and in preparation, production and storage areas. Where risk assessment has determined that protective clothing is not required in a particular area, it shall be fully justified and not pose a contamination risk to the product.
6.5.2	The company shall use risk assessment to determine, document and communicate to all employees, including temporary personnel and contractors, the rules regarding the wearing of protective clothing in all situations, including: • during the journey to work • in raw materials handling, preparation, production and storage areas • when away from the production environment (e.g. removal before entering toilets, canteen or smoking areas).
6.5.3	Where protective clothing is required, appropriate clean protective clothing that cannot contaminate the product shall be worn. Sufficient sets of clothing appropriate to the activities being carried out shall be provided.
6.5.4	Protective clothing worn in production areas shall provide adequate coverage. Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the clothing shall have no external pockets on the upper body garments or sewn-on buttons. Changes of such clothing shall be available at all times as required.
6.5.5	Based on the assessment of risk to the product, suitable footwear shall be worn within the factory environment.
6.5.6	If gloves are used they shall be replaced regularly, be distinctive, intact and not cause a contamination risk to the product.
6.5.7	Protective clothing shall be kept clean and laundered. Laundering shall be carried out by one of the following methods: • professional laundry service • in-house • controlled laundering facilities • home laundry.

Clause	Requirements
6.5.8	Where home laundry is permitted, the site shall ensure that: • employees have received written instructions regarding the laundering process to be used and these shall be reinforced as part of an induction or other in-house training programme • employees shall be provided with a bag or other suitable means to safely transport washed garments from home to the workplace • there shall be a defined process within the site for monitoring the effectiveness of the system • there shall be a procedure and system for dealing with any case where employees are unable to perform home laundry effectively, either through lack of diligence or inadequate facilities.
6.5.9	Clean and dirty clothing shall be segregated and controlled to prevent cross-contamination.
6.5.10	Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.

7 Requirements for traded products

7.1 Approval and performance monitoring of manufacturers/packers of traded packaging products

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

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

7.1.2	The company shall have a procedure for the initial and ongoing approval of the 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 Global Standard or other GFSI-benchmarked standard. The scope of the certification shall include the products purchased
	• supplier audits, with a scope to include product safety, traceability, hazard and risk management systems review and good manufacturing practices, undertaken by an experienced and demonstrably competent product safety and quality management 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, HARA review and good manufacturing practices
	  • obtain and review a copy of the full audit report.
	By exception, and only where a valid risk-based justification is provided, initial and ongoing approval may be based on:
	• a historical trading relationship supported by documented evidence of performance reviews demonstrating satisfactory performance
	• a manufacturing site questionnaire which has been reviewed and verified by a demonstrably competent person
	• a specific customer requirement to supply product from a manufacturer where liability is with the customer.

7.1.3	Records shall be maintained of the manufacturer's or 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 packaging products traded by the company.

Clause	Requirements
7.1.4	There shall be a documented process for the ongoing review of manufacturers or packers, based on risk and using defined performance criteria, which shall include: • complaints • results of any product tests • regulatory warnings/alerts • customer rejections or feedback. The process shall be fully implemented.

7.2 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
7.2.1	Specifications shall be available for all products. These shall either be in the agreed format as supplied by the customer or, where this is not specified, include key data to meet legal requirements and assist the customer in the safe usage of the product. Specifications may be in the form of a printed or electronic document, or part of an online specification system.
7.2.2	The company shall seek formal agreement of the specifications with relevant parties. Where specifications are not formally agreed, the company shall be able to demonstrate that it has taken steps to put an agreement in place.
7.2.3	Companies shall operate demonstrable processes to ensure that any customer-specified requirements are met. This may be by inclusion of customer requirements within buying specifications or by undertaking further work on the purchased product to meet the customer's specification (e.g. sorting or grading of product).
7.2.4	Specifications shall be reviewed whenever products/packaging or suppliers change or at least every 3 years. The date of review and the approval of any changes shall be recorded.

7.3 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
7.3.1	The site shall use risk assessment where product sampling or testing is required 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.
7.3.2	Where verification of conformity is provided by the supplier (e.g. certificates of conformity or analysis), the company shall use risk assessment to determine whether periodic independent product analysis may be required to ensure confidence in the information provided.
7.3.3	Where claims are made about the products being handled, including the provenance, chain of custody or assured status of a product, supporting information shall be available from the supplier or independently to verify the claim.
7.3.4	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025. Documented justification shall be available where non-accredited test methods are used.
7.3.5	Test and inspection results shall be retained and reviewed to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.

7.4 Product legality

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

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

7.5 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
7.5.1	The site shall maintain a traceability system for all batches of product which identify the last manufacturer or packer of the product. Records shall also be maintained to identify the recipient of each batch of product from the company.
7.5.2	The company shall test the traceability system at least annually to ensure that traceability can be determined back to the last manufacturer and forward to the recipient of the product from the company. This shall include identification of the movement of the product through the chain from the manufacturer to receipt by the company (e.g. each movement and intermediate place of storage).
7.5.3	The traceability test shall include the reconciliation of quantities of product received by the company for the chosen batch or product lot.

Part III
Audit protocol

Part III
Audit protocol

Introduction

The Global Standard for Packaging Materials 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 product safety and quality management systems.

The general audit protocol in section 1 of this part (Part III) describes the requirements for auditing and certification which are applicable to both audit programmes (announced and unannounced). This should be read and fully understood. The process is summarised in Figure 1.

Each of the audit options has its own particular characteristics and these are described in detail in sections 2 and 3. Section 4 deals with the audit protocol for any additional modules which are taken, while section 5 sets out the process and marketing opportunities for all sites after certification.

Every effort has been made to ensure that the content of this audit protocol is accurate at the time of publication. However, it may be subject to minor change, and reference should be made to the BRCGS website (**www.brcgs.com**), 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. This part describes the process to be followed by a company seeking certification.

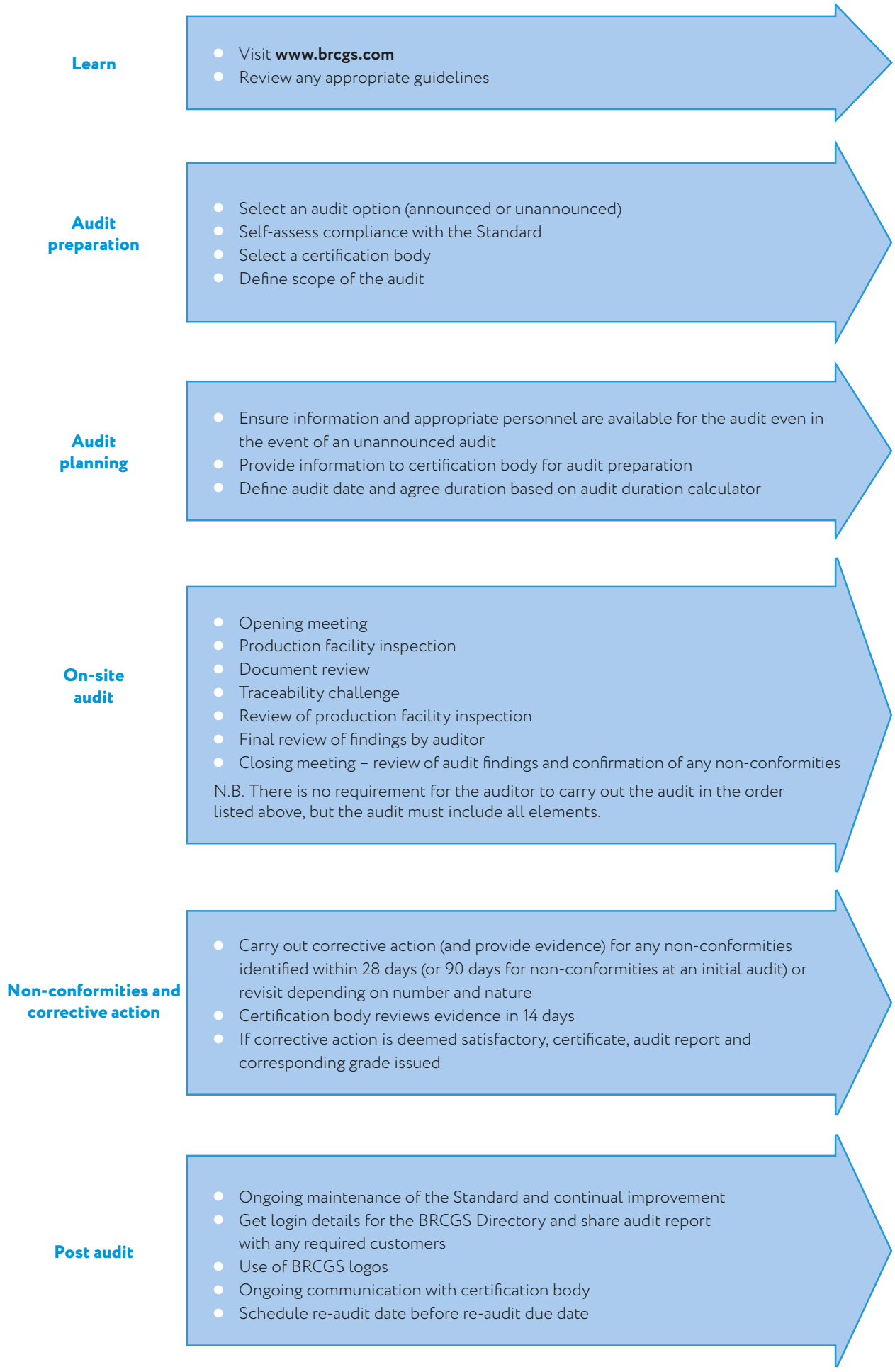

Figure 1 Audit protocol – how to gain certification

1 General protocol – audit preparation

1.1 Selection of an audit option

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

1.1.1 Announced audit programme

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

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

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

1.1.2 Unannounced audit programme

The unannounced audit option is available for existing certificated sites and those new to certification. The unannounced audit option provides sites with the opportunity to demonstrate the maturity of their systems, and successful sites are awarded grades of AA+, A+, B+, C+ or D+ depending upon the type and number of non-conformities identified at the audit.

The conducting of an independent, unannounced review of the production facilities, systems and procedures under this scheme provides a site's customers with added confidence in the site's ability to consistently maintain standards. This may influence the frequency (or even occurrence) 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 Part III, section 3.

1.2 Self-assessment of compliance with the Standard

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

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

Further information, guidance and training to ensure compliance with the Standard, including downloadable self-assessment tools, are available at the Packaging pages on **www.brcgs.com**. BRCGS also has a full range of further guidelines and supporting materials available through the BRCGS website and via BRCGS Participate at **www.brcgsparticipate.com**.

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

Manufacturing units that are newly built or commissioned must ensure that systems and procedures in place are compliant before an initial BRCGS audit is undertaken. It is at the discretion of the company when they wish to invite a certification body to carry out an audit; however, it is unlikely that full compliance can be satisfactorily demonstrated at an audit undertaken less than 3 months from commencement of operation.

Some sites may be able to improve this timescale, such as a small site, a site that has already implemented ISO 9001, or one that is part of a group with established management systems.

With respect to a new production site within an established company, the new site's systems and procedures may reflect those systems already established in other sites within the company, but sufficient documentation must be in place to enable a full audit so that compliance can be assessed against BRCGS requirements for the new site.

1.3 Selection of a certification body

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

1.4 Company/certification body contractual arrangements

A contract shall exist between the company and the certification body in accordance with the requirements of ISO/IEC 17065, detailing the scope of the audit and the reporting requirements. The contract shall also contain clauses which allow the effective management of the scheme by BRCGS and accreditation of the certification body by a BRCGS-approved accreditation body. These are essential to ensure confidence in the way in which the scheme is managed and consistency is 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 Global Standard used. As a GFSI-benchmarked standard record may be viewed in conjunction with any GFSI compliance audit, other documents relating to the audit shall be made available to BRCGS upon request. All documents submitted to BRCGS shall be copies of original documents. Documents provided to BRCGS will be treated as confidential.
- The auditor(s) may be accompanied by other personnel for training, assessment or calibration purposes. This activity may include:
  - training of new auditors by the certification body
  - routine certification body shadow audit programmes
  - witness audits by accreditation bodies
  - witness audits by 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 BRCGS 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 or for feedback on certification body performance, or investigation into reported issues.

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

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

1.5 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, allowing the company access to BRCGS support services including BRCGS Participate, BRCGS Professional and the BRCGS Directory. The certificate and audit report 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.

1.6 Scope of audit

1.6.1 Defining the audit scope

The scope of the audit – products produced and the manufacturing processes – shall be agreed between the site and the certification body in advance of the audit to ensure the allocation of auditor(s) with the correct product and process knowledge and qualifications, as listed in Appendix 1.

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

The audit scope and any permitted exclusions shall be clearly defined both on the audit report and on any certificate issued. The wording of the scope will be verified by the auditor during the site audit. The wording of the scope, description of the product and, where applicable, the application of the packaging material, shall enable a recipient of the report or certificate to clearly identify whether the products supplied have been included within the scope. This shall include a description of the processing activities undertaken at the site that fall within the scope of the Standard where this adds clarity for the user of the report or certificate (e.g. the flexographic printing and slitting of form-fill-seal (FFS) laminate film for fresh produce).

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

The auditor retains the right to refuse the exclusion request where the criteria are not adequately met.

Products purchased for resale by a site (i.e. traded products) can form an agreed exclusion and therefore the requirements of section 7 (Part II) will not be applicable. It should be noted that the BRCGS logo cannot be used for promoting traded products even when they form part of the certificated scope.

1.6.3 Additional manufacturing locations and head office assessments

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

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

The detailed requirements for acceptance and management of such circumstances within the audit protocol are provided in Appendix 3.

1.6.4 Storage facilities – off-site

While the storage facilities on the same site as the production facility shall always be included within the audit of the site, it is not uncommon for sites to own additional off-site storage facilities. Where the company owns or manages additional storage facilities in the vicinity of the production site (i.e. within a radius of 50 km), these shall be identified on the audit report and audited as part of the site audit or against a GFSI-recognised storage and distribution standard.

1.6.5 Additional modules

In addition to the core Standard, BRCGS will develop a range of additional modules which may apply only to particular types of operation or may look in greater depth at a particular market concern. Where such additional modules are undertaken these will be listed on the scope of the report and certificate. If an additional module that is applicable to a site is not selected, this shall be identified as an exclusion to ensure this is clear to the reader of the report or certificate.

A list of additional modules for the Packaging Standard is available on the BRCGS website (**www.brcgs.com**).

1.7 Auditor(s) selection

It is the responsibility of the site to ensure that adequate and accurate information is given to the certification body, detailing the products it manufactures and the process technologies it uses, to enable the certification body to select an appropriate audit team with the required skills to undertake the audit. Auditors must be skilled to audit in the relevant products and manufacturing categories, as listed in Appendix 2.

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

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

2 Announced audit protocol

2.1 Audit planning

2.1.1 Preparation by the company

For initial audits the site shall agree a mutually convenient date, with due consideration given to the amount of work required to meet the requirements of the Standard. There is a requirement on the site to be prepared for the audit, to have appropriate documentation for the auditor(s) to assess, and to have appropriate staff available at all times during the on-site audit.

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

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 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):

- background and structure of the company
- a summary of the site's hazard analysis and risk assessment and any critical control points (CCPs)
- the process flow diagram
- a simple site plan
- the management organisational chart
- the list of products or product groups included within the audit scope
- typical shift patterns
- production schedules, to allow audits to cover relevant processes
- recent significant quality issues, recalls, withdrawals or customer complaints and any other relevant performance data
- any requested exclusions from the scope of the audit.

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

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 report; therefore, the sites are encouraged to fulfil such requests in a timely manner.

2.1.3 Audit duration

Before the audit takes place, the certification body shall indicate the approximate duration of the audit. The typical duration of an audit is 1–3 days (8–9 hours per day) at the site. 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 (**www.brcgs.com**).

The calculation for the audit duration is based on:

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

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

- whether it is an initial certification audit
- whether it is an unannounced audit

- a lack of 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 its impact on material flow
- the labour-intensity of processes
- the audit not being carried out in the first language of the auditor or the company
- the number of non-conformities recorded in the previous audit
- difficulties experienced during the audit requiring further investigation
- the quality of site preparation (e.g. documentation, hazard analysis, safety and quality management systems).

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

In the event that the audit against the Standard includes additional BRCGS 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 expected amount of time needed to undertake the audit at the site. Additional time will be required for the review of any documentary evidence provided and completion of the final audit report.

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

2.2 The on-site audit

The on-site audit consists of the following stages:

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

There is no requirement for the auditor to carry out the audit in the order listed, apart from the opening and closing meetings, but the audit must include all elements.

The site shall fully assist the auditor(s) at all times. It is expected that at the opening and closing meetings, those attending on behalf of the site will be senior managers who have the appropriate authority to ensure that corrective action can be progressed if non-conformities are found. The most senior operations manager on site at the time of the audit, or their nominated deputy, shall be available at the audit and attend the opening and closing meetings (see clause 1.1.8).

The audit process gives emphasis to the practical implementation of product safety and quality management procedures and general good manufacturing practices. It is expected that approximately 30–50% of the audit duration 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 by the auditor 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 shall discuss this with the accompanying site representative at the time.

At the closing meeting, the auditor(s) shall present their findings and reconfirm all non-conformities that have been identified during the audit but shall not make comment on the likely outcome of the certification process. Information on the process and timescales for the site to provide evidence to the auditor of the corrective action to close non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor either at the closing meeting or within 1 working day after completion of the audit.

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

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

The company will be informed of the certification decision following this review.

2.3 Non-conformities and corrective action

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

2.3.1 Non-conformities

There are three levels of non-conformity:

- **Critical** Where there is a critical failure to comply with a product safety or legal requirement.
- **Major** Where there is a substantial failure to comply with the statement of intent of a clause or any requirement of the Standard, or where a situation is identified which would, on the basis of available objective evidence, raise significant doubt as to the conformity of the product being manufactured.
- **Minor** Where a requirement 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 no more than one major non-conformity is given. This shall be detailed on the audit report.

Any non-conformities from the previous audit shall be checked during the current audit to confirm that corrective action has been taken and is operating effectively. Any repetition of these same non-conformities in the current audit shall be noted and raising the status of repeated minor non-conformities to a major non-conformity shall be considered.

2.3.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities during the audit, the site must undertake corrective action to remedy the immediate issue (correction) and undertake an analysis of the underlying cause of the non-conformity (root cause) to develop a preventive action plan addressing the root cause and preventing 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 per Table 1.

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

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

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

It is a requirement of some customers that they shall be informed when their suppliers have a critical non-conformity identified or when they 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 root cause of the non-conformity. The root cause shall be identified and an action plan to correct this, including timescale, provided to the certification body. The proposed preventive action shall be included in the audit report.

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

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

For initial audits only, if there is no temporary solution or if there is a justifiable delay to implementing a permanent solution (e.g. lead time on capital expenditure) for a major non-conformity, then provided that an acceptable statement of explanation is received by the certification body within 28 calendar days, the company may remain in the certification programme for up to 90 calendar days. It will, however, remain uncertificated and will only be certificated following verification of the corrective action being implemented.

For all minor non-conformities and major non-conformities raised at recertification audits, if satisfactory evidence is not provided within the 28 calendar-day period allowed for submission following the audit, certification will not be granted.

In both instances, if the site cannot close out the non-conformity within the time period, the site will require a further full audit in order to be considered for certification.

Non-conformities from the audit shall also be checked during the next site audit to verify effective close-out of the non-conformities and their root cause. Where the correction has been ineffective then a non-conformity shall be raised against clause 1.1.9.

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

2.4 Audit confirmation

Following each audit, confirmation of completion shall be available on the BRCGS Directory within 10 calendar days. Details shall include the date of the audit, the audit scope and the non-conformity found. No audit grade will be included since the certification details, including the details of the non-conformity, will be under independent technical review prior to confirmation.

2.5 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.

2.6 Audit reporting

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

The audit report shall provide the company and users of the report, such as 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 product safety and quality 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.

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

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

Table 1 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 (90 days at initial audits)	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 (90 days at initial audits)	6 months
C	C+		1	11–16		
C	C+		2	10 or fewer		
D	D+			25–30	Revisit required within 28 calendar days	6 months
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.

2.7 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 4.

Logos used on certificates (e.g. BRCGS and accreditation body logos) shall comply with their respective usage rules.

The certificate will detail:

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

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

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

2.8 Ongoing audit frequency and recertification

2.8.1 Scheduling re-audit dates

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

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

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

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

2.8.2 Certificate expiry – justifiable circumstances

There will be some circumstances where the certificate cannot be renewed on the 6-month or 12-month basis due to the inability of the certification body to conduct an audit. These justifiable circumstances, which would not result in the assigning of a major non-conformity (clause 1.1.7), can include when the site is:

- situated in a specific country or an area within a specific country where there is government advice to not visit and there is no suitable local auditor
- within a statutory exclusion zone
- 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).

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 there are products being manufactured. There may be periods in the year where a manufacturing site has an operational 'shutdown' (i.e. the site is not producing any products and a small staff may be on site for maintenance, installation of new equipment and other activities). Where a re-audit due date falls within this period, the audit may only be brought forward, and the site shall ensure that all requirements are complied with during the shutdown and upon restarting production.

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

2.8.3 Audits undertaken prior to due dates

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

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

- The audit report will detail the reasons why an audit has been brought forward.
- The audit due date will be 'reset' to be 12 or 6 months, depending on grade, from this audit date.
- The certificate should be issued with an expiry date of 12 months (or 6 months, depending on grade) + 42 calendar days from the 'new' audit date.
- Under no circumstances should a certificate have a validity of more than 12 months.

3 Unannounced audit protocol

The protocol of an unannounced audit generally follows that of an announced audit (see above); where it differs is outlined as follows. This option requires that the date of the audit shall not be notified to the site in advance of the audit. Although the audit may occur at any point from 9 months before the audit due date, it shall typically be within the last 4 months of the certification cycle.

3.1 Audit planning

3.1.1 Selection of the unannounced audit programme

Where the site is currently certificated, it 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 and enough time for the certification body to choose when to conduct the audit. Non-certificated sites may opt into the unannounced audit programme on the understanding that the audit may not occur for up to 12 months from the request.

3.1.2 Preparation by the company

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

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

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

The site shall supply the certification body with background information when it opts into the unannounced audit programme to ensure the auditor is fully prepared and to provide the best opportunity for the audit to be completed efficiently. Where any changes occur on site (as those listed in sections 5.1 and 5.2 below), the site shall inform the certification body of these immediately once it has opted into the unannounced audit programme. The information will be requested by the certification body and may include (but is not limited to):

- a summary of the site's hazard analysis and risk assessment and any 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
- any requested exclusions from the audit scope
- typical shift patterns
- production schedules, to allow audits to cover relevant processes
- recent significant quality issues, withdrawals or customer complaints and any other relevant performance data.

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

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

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

3.1.4 Nominating non-audit days

The unannounced audit programme allows sites the opportunity to nominate 15 days when the site is not available for an audit.

The dates must be provided at least 4 weeks in advance and the reason must be provided (e.g. a planned customer visit). The certification body may challenge the reason where this does not appear appropriate and at its discretion accept these nominated dates.

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

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

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

3.1.5 Audit duration

The typical duration of an audit does not differ from that of an announced audit, subject to the variance described in section 2.1.3 (Part III).

3.2 The on-site audit

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

3.3 Non-conformities and corrective action

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

3.4 Audit confirmation

Confirmation of completion of the audit shall be available on the BRCGS Directory within 10 calendar days, as required for announced audits (see Part III, section 2.4)

3.5 Grading of the audit

The process for grading is the same as for the announced audit scheme (see Part III, section 2.5). The grade awarded following certification shall be based on the number and level of non-conformities, as outlined in Table 1. Note that the grade will have the addition of a plus symbol after the grade (i.e. AA+, A+, B+, C+ or D+).

3.6 Audit reporting

The audit reporting requirements are the same as for the announced audit scheme (see Part III, section 2.6). However, the report shall state 'unannounced option'.

3.7 Certification

The certification requirements are the same as for the announced audit scheme (see Part III, section 2.7). However, the certificate shall state 'unannounced option'.

This certificate will supersede the existing certificate. The certificate shall be issued within 42 calendar days of the 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), providing the site remains within the unannounced audit scheme. This ensures that where the audit occurs before the expiry of the current certificate and the site remains within the unannounced scheme, it is not disadvantaged by a shorter certificate life and increased frequency of audits.

If the site decides to return to the announced audit programme, the certificate expiry date will be based 6 or 12 months from the date of the unannounced audit.

3.8 Ongoing audit frequency and recertification

3.8.1 Scheduling re-audit dates

The site can choose whether to:

- remain within the unannounced programme
- revert to the announced audit programme.

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

It is the responsibility of the certification body to ensure that the audit is undertaken within the certification window and the late audit non-conformity clause (1.1.7) shall not apply.

If the site wishes to withdraw from the 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.

4 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 issues for a module will be available on the BRCGS website (**www.brcgs.com**) and on BRCGS Participate (**www.brcgsparticipate.com**).

The additional modules can be included with either of the full certification audit options.

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 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.

5 General protocol – post audit

5.1 Communication with certification bodies

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

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

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

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

The certification body may, as appropriate:

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

Changes to certification status of a site shall be recorded in the BRCGS Directory.

5.2 Extension to scope

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

A revisit is required before granting a scope extension when the following are included:

- manufacturing facilities not taken into account in the original audit
- any new processing technology (e.g. printing by lithographic technology where formerly only flexographic printing was within scope)
- any new products which introduce a significant new risk to the facility.

A revisit is less likely, for example, where:

- new products are added to the existing ranges produced on existing equipment
- a new polymer is added to the portfolio of a thermoformer but the process does not change
- a simple additional process is included in the activities of the site.

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 scheme.

Identified non-conformities should be documented and actioned within the normal protocol of the Standard; in other words, the company has 28 (or 90) 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 a standard BRCGS 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 shall be superseded by any new certificate issued. The certificate must use the same expiry date as detailed on the original certificate. The due date of the next full audit will therefore remain the same and this should be made clear to the supplier by the certification body when arranging extension-to-scope visits. The grade shall also remain the same.

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

5.3 Certification withdrawal

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

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

5.4 Appeals

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

The certification body shall have a documented procedure for the consideration and resolution of appeals against the certification decision. These investigative procedures shall be independent of the individual auditor and certification manager.

The documented appeals procedures of individual certification bodies will be made available to the site on request. Appeals will be finalised within 30 calendar days of receipt. A full written response will be given after the completion of a full and thorough investigation into the appeal.

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

5.5 Surveillance of certificated companies

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

Any non-conformities identified at a visit must be corrected and closed out within the normal protocol (i.e. within 28 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 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.

5.6 BRCGS logos

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

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

The BRCGS logo is not a product certification mark and shall not be used on products or product packaging. Any certificated site found to be misusing the mark will be subject to the BRCGS complaints/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 within the audit scope.

5.7 The BRCGS Directory

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

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

Certification bodies are responsible for maintaining site names, addresses, audit content and certificate status. All certification bodies are assessed and graded by BRCGS on how quickly and accurately they update audit data.

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

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

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

BRCGS will launch a new directory during the life of this issue of the Standard which will bring enhancements to all users. For further information on the directory or audit-sharing, contact the BRCGS Directory team via **submissions@brcgs.com**.

5.7.1 Site code

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

A site code is created when a site is audited for the first time and remains unchanged regardless of subsequent auditing certification bodies or audit status. Site codes are located on the top right-hand corner of the first page of the audit report and on the corresponding certificate.

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

5.7.2 Audit-sharing

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

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

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

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

5.7.3 Notification emails

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

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

For further information on the directory or audit-sharing, contact the BRCGS Directory services team via **submissions@brcgs.com**.

Part IV
Management and governance

Requirements for certification bodies

Technical governance of the Standard

Achieving consistency – compliance

Part IV
Management and governance

Requirements for certification bodies

The Global Standard for Packaging Materials 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 2.

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

As a minimum, the certification body must be accredited to ISO/IEC 17065 by a national accreditation body affiliated to the International Accreditation Forum and recognised by BRCGS. Further details are available in the document 'Requirements for organisations offering certification against the criteria of BRCGS', which is available from BRCGS on request.

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

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

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

The acceptability of audit reports generated by certification bodies awaiting accreditation but meeting the above criteria is at the discretion of individual specifiers.

Technical governance of the Standard

The Standard and associated scheme is managed by BRCGS with governance and technical advice provided through a number of stakeholder groups (see Figure 3), each of which works to a set of defined terms of reference.

International advisory boards

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

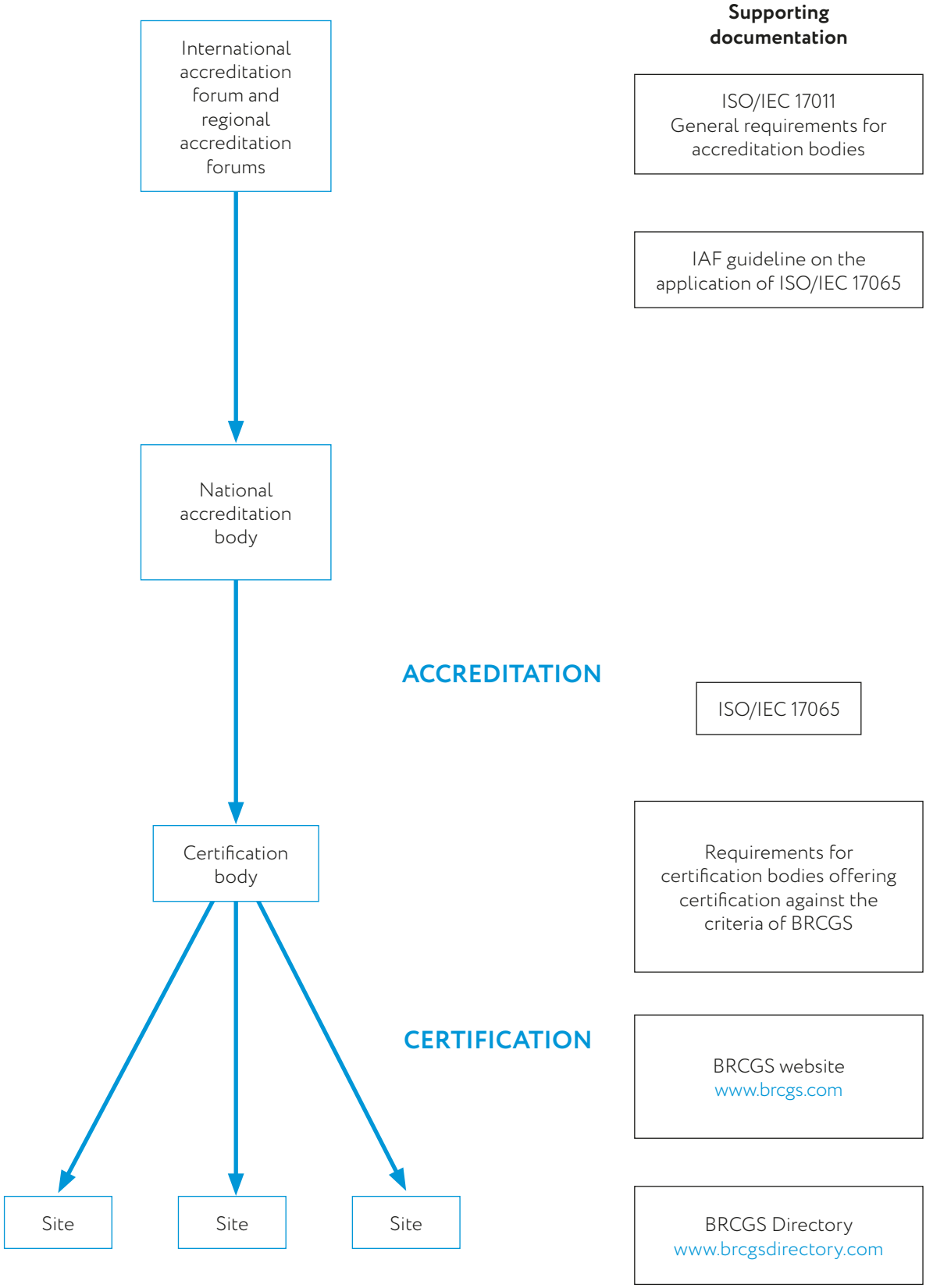

Figure 2 Process for accreditation of certification bodies

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

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 relating to the Standard. BRCGS provides the technical secretariat for these groups.

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

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

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

The certification body co-operation groups

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

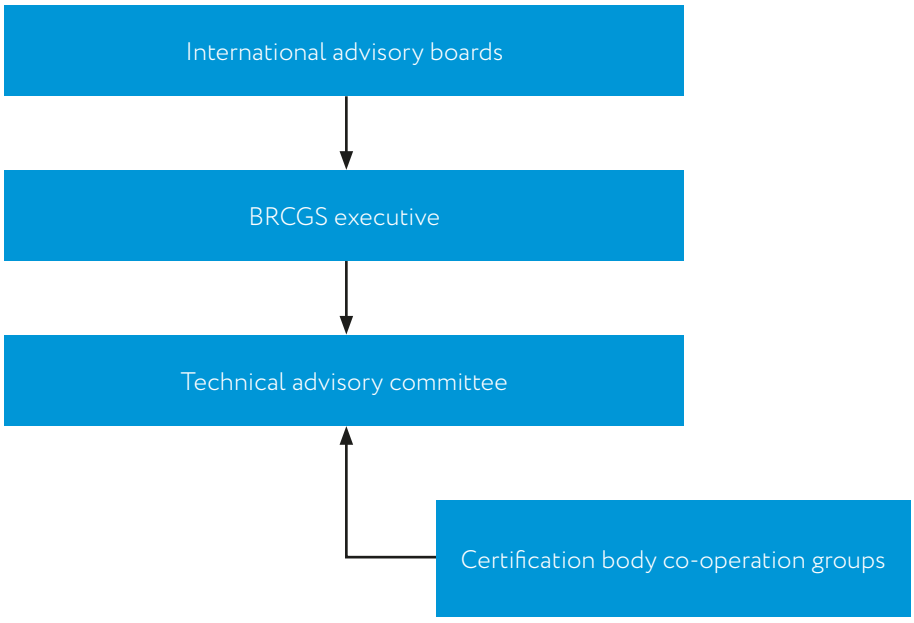

Figure 3 Governance of the BRCGS schemes

Achieving consistency – compliance

The maintenance of a high and consistent standard of audit and certification, and the ability of the certificated sites to maintain the standards achieved at the audit, are essential to 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 BRCGS scheme may only be certificated by certification bodies registered and approved by BRCGS and accredited by a BRCGS-recognised accreditation body. All auditors undertaking audits against the Standard must meet the BRCGS auditor competency requirements and shall be registered with BRCGS. The qualifications, training and experience requirements for auditors who conduct audits against the Global Standard for Packaging Materials are detailed in Appendix 1. 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 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 listed at **www.brcgsdirectory.com**.

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

Calibrating auditors

A key component of the scheme is the calibration of the auditors to ensure a consistent understanding and application of the requirements. All certification bodies are required to have processes to calibrate their own auditors. An essential element of the training and calibration of auditors is the witnessed audit programme. Auditors are observed during an audit and provided with feedback on the performance of the audit. In order to ensure consistency between certification bodies and for the purposes of accreditation, an audit may be witnessed by a 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.

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 BRCGS monitoring programme for certification body performance. All audited sites are invited to complete a feedback survey which is treated confidentially by BRCGS. It can be completed online on the website **www.brcgs.com** at any time.

Complaints

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

From time to time, failure to apply the principles and criteria of the Global Standards 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 as appropriate and may undertake announced or unannounced visits to a certificated site.

Appendices

Appendix 1
Registration, qualifications, training and experience requirements for auditors

All auditors conducting audits against the Global Standard for Packaging Materials are required to be registered with BRCGS. The registration process identifies auditors who have undergone the required training and the categories of packaging in which they have expertise. Evidence of an auditor's qualifications, experience and training has to be submitted to BRCGS prior to their carrying out audits. All registered auditors receive a unique registration number, which is included on the audit report and is automatically cross-checked against their competence before the certification is accepted onto the BRCGS Directory.

The verification of competence to carry out a specific audit shall be carried out by 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.

BRCGS publishes a detailed guide to registered certification bodies on auditor competency requirements, expectations of the initial assessment of auditor competence, ongoing training, and assessment procedures. This is reviewed and updated periodically by the technical advisory committee. The requirements of auditors who may be registered to audit against the Standard are as follows.

Education
Generally, auditors will be drawn from two distinct disciplines: those with expertise and a qualification in food or biosciences, and those with expertise and a qualification in packaging technology. This main qualification will be supported by a minimum secondary qualification in the other disciplines as appropriate. Where equivalence of qualification is unclear, this shall be referred to BRCGS for review.

The auditor shall have:

- a degree or diploma in packaging and have successfully completed a food safety/hygiene qualification at least equivalent to a UK level 3 qualification (see **www.brcgs.com** for information), or
- a degree or diploma in a food or bioscience-related discipline and have successfully completed the PIABC EQIPT or equivalent examination in packaging.

Work experience
The auditor shall have a minimum of 5 years' post-qualification experience related to their main qualification discipline. This shall involve work in quality assurance, technical management or risk management functions within manufacturing, retailing, inspection or enforcement, and the auditor shall be able to demonstrate an understanding and knowledge of specific categories of packaging for which they are approved. The verification to carry out work within specific categories of packaging will be carried out by the certification body.

Professional qualifications

The auditor must have:

- passed a registered management system lead assessor course (e.g. IRCA) or the BRCGS third-party auditor course delivered by a BRCGS-approved trainer
- completed a training course in hazard analysis and critical control points (HACCP), based on the principles of Codex Alimentarius, of at least 2 days' duration, or be able to demonstrate competence in the understanding and application of HACCP principles. It is essential that the HACCP course is recognised by the industry as being appropriate and relevant.

Audit training

Auditors must have successfully completed a period of supervised training in practical assessment, including witnessed assessments of a minimum of three audits against the Standard at a variety of organisations.

Certification bodies must be able to demonstrate that every auditor has appropriate training and experience for the particular categories for which they are considered competent. Auditor competence shall be recorded at the level of each category of audit as indicated in Appendix 2.

Certification bodies must establish a training programme for new auditors, which will incorporate:

- a Global Standard for Packaging Materials awareness course delivered by a BRCGS-approved trainer
- a period of initial training covering product safety, hazard and risk management, and prerequisite programmes that will include access to relevant laws and regulations
- a period of supervised training to cover management systems, audit techniques and specific categories of audit knowledge
- an assessment of knowledge and skills for each packaging category
- documented sign-off on the satisfactory completion of the training programme.

Each auditor's training programme shall be managed and approved by an assessor who can demonstrate that they are technically competent in the packaging categories in which training is given.

Full and detailed training records of the individual must 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.

Appendix 2
Manufacturing categories

Manufacturing categories are used to categorise the sites and ensure that auditors selected to conduct the audit are sufficiently competent to understand the processes carried out at the site.

Manufacturing category	Scope of manufacturing category and typical key processes
Glass manufacture and forming	Key processes include: • raw materials to finished product of glass containers from one furnace through independent section machines to cold end lacquer(s) • further processes for extra furnaces. Any print/decoration is an additional key process Typical manufacturing techniques include: • blow and blow • press and blow • extrusion of ampoules • forming and firing of ceramic bottles, jars or decanters
Paper-making and conversion	Pulp to sheet or web, or conversion of sheet or web-fed paper where **no printing** operations take place (printing activities are additional key processes). Any print/decoration is a further key process. Key processes include: • manufacture of paper from raw materials (e.g. tree/pulp) to sheet or web (e.g. board, liner, cartonboard) • die-cutting, folding and gluing (erecting), and corrugating (from pulp) to corrugated sheet/reel • conversion of paper sheet into bags or sacks (including stitching) • manufacture of self-adhesive label stock (label and carrier/substrate) • die-cutting of sheet or web (including corrugated) to pads or fitments • moulding of pulp (of any source) into trays or fitments • manufacture of spirally wound tubes (including trimming and cutting)

Manufacturing category	Scope of manufacturing category and typical key processes
Metal-forming	Smelting of raw materials into aluminium, steel or tin, and conversion of those materials into packaging containers/materials. Any print/decoration is an additional key process. Key processes include: • smelting with output to sheet or reel • rolling/pressing of aluminium foil • slitting or trimming of aluminium foil • pressing of foil trays or containers • impact extrusion • manufacture of three-piece can bodies • manufacture of two-piece can bodies (steel or aluminium) • manufacture of can-ends • stamping/punching of closures (compounds or wads are a raw material for metal closures and a second manufacturing category is not required)
Rigid plastics forming	Forming of resin into rigid plastic packaging materials. Any print/decoration is an additional key process. Key processes include: • injection moulding • in-mould labelling (additional key process if labels are not applied in other processes on site) • blow-moulding (extrusion/injection/press) • thermoforming
Flexible plastics manufacture	Forming of resin into flexible plastic packaging materials, and laminating of multi-material layers into one layer. Any print/decoration is an additional key process. Key processes include: • extrusion (cast/blown) (addition of shoulder for flexible tubes can be included as part of first key process) • laminating (of any material) • laminating and seaming of flexible tubes, addition of shoulder • construction of plastic bags, pouches and sachets • vacuum metallising • blow-moulding • winding/rewinding films; slitting, scoring, perforating • coating (e.g. wax)

Manufacturing category	Scope of manufacturing category and typical key processes
Other manufacturing	This category will encapsulate the manufacture of those materials not able to be classified into other categories. Key processes include: • construction of pallets, boxes and crates, decorative wooden boxes • processing of wood for food and cosmetic use, wooden utensils (e.g. for lollipops) • processing of natural cork, rubber • construction of hessian sacks, jute products, woven string (plastic or cotton) • processing of strings for tea bags or meat-packing
Print processes	Any packaging material which is printed using any of the following print processes (each constitutes one key process) in addition to any manufacturing process: • flexographic, lithographic, gravure, letterpress (and offset) • screen, tampo or digital print • decoration by hot or cold stamping/blocking Any post-printing conversion, such as cutting/creasing and gluing of folded cartons, is considered part of the print process, as printed packaging materials are typically converted further once printed. Specify printing technologies used at the site.
Chemical processes	Essentially, the manufacture of raw materials used in the printing and conversion of other packaging materials. This includes the manufacture of: • resins • adhesives • inks, varnishes and coatings

The assembly of aerosol valves, actuators and dispensing systems shall be categorised according to the majority material. Where additional materials are used (e.g. metal springs), the next material category shall also be considered.

Appendix 3
Multiple sites audit protocol

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

The audit, report and certificate shall be site-specific. However, in some exceptional circumstances more than one site may be included under a single certification.

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

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

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

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

It must be clearly stated on the report and certificate that the audit has consisted of visits to more than one site address (e.g. the manufacture of PET parisons and preforms at The Total Bottle Company, Bottlehampton, and blow-moulding at The Total Bottle Company, Bottle End, Hampshire).

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

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

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

- Request and review information while at the manufacturing site as part of the site audit (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 (telephone or video conferencing links to allow interview of relevant personnel; fax or email links to allow documents to be requested and viewed) and arrangements can be put in place to ensure availability of relevant personnel
- the amount and type of information can be effectively reviewed and challenged remotely.

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

Reporting

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

Non-conformities

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

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

Subsequent manufacturing site audits

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

Approach 2: 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 remotely.

This 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.

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 only include 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 BRCGS 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 which have not been closed out to the satisfaction of the certification body at the time of the manufacturing site audit shall be counted when calculating the grade for the manufacturing site.

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

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

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

The auditor shall establish that the central system components assessed are the same as those operating at the manufacturing site. The auditor shall verify any corrective 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.

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

It is the responsibility of the site to ensure that evidence of the central system's corrective actions has been provided to the certification body 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-compliance report.

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

The central 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 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.

Appendix 4
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:

Manufacturing categories:

Including additional modules of:

Exclusions from scope:

At COMPANY NAME
SITE CODE
AUDIT SITE ADDRESS

Has achieved grade:

Meets the requirements set out in the

GLOBAL STANDARD for PACKAGING MATERIALS

ISSUE 6: AUGUST 2019

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

Date(s) of audit: [If an extension to scope, include original audit date and visit date]

Certificate issue date:

Re-audit due date: from to

Certificate expiry date:

Accreditation body logo

Authorised by

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 feed back comments on the Global Standards or the audit process directly to BRCGS, please contact enquiries@brcgs.com.

Appendix 5
Other Global Standards produced by BRCGS

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

The **Global Standard for Food Safety** is an auditing standard that sets out the requirements for the manufacture of processed foods and the preparation of primary products supplied as retailer-branded products, branded food products and food or ingredients for use by food service companies, catering companies and food manufacturers.

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

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

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

Appendix 6
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.
agent	A company that facilitates trade between a site or company and its raw material or packaging suppliers or its customers through the provision of services, but does not at any point own or take title to the goods.
allergen	A known component which causes physiological reactions due to an immunological response.
announced audit	An audit where the company agrees the scheduled audit day in advance with the certification body.
artwork	The elements that constitute a mechanical drawing, supplied as type, proofs and illustrations.
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.
batch	A discrete quantity of products made using the same operation and raw materials (alternative term is 'lot').
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.
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.

clause	A specific requirement or statement of intent that a site must comply with in order to achieve certification.
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.
consumer	The end-user of the finished product, commodity or service.
consumer product	Non-food products normally bought or supplied to wholesale and private consumers for personal, business or household use, and included within the scope of the Global Standard for Consumer Products.
contamination	Introduction or occurrence of an unwanted organism, taint or substance to packaging, food or the food environment. Contamination includes physical, chemical, biological and allergen contamination.
contract packer	A company that packages the final product into consumer packaging.
contractor or supplier	A person or organisation providing services or materials.
control	To manage the conditions of an operation to maintain compliance with established criteria, and/or the state wherein correct procedures are being followed and criteria are being met.
control measure	Any action or activity that can be used to prevent or eliminate a product safety hazard or reduce it to an acceptable level.
controlled document	A document which is identifiable and for which revisions and removal from use can be tracked. The document is issued to identified individuals and their receipt of the document is recorded.
correction	Action to eliminate the cause of a detected non-conformity.
critical control point (CCP)	A step at which control can be applied and is essential to prevent or eliminate a food or product safety hazard or reduce it to an acceptable level.
cross-docking	Material is unloaded at distribution premises, and handled, but not formally put away into storage. This may be a staging area where inbound materials are sorted, consolidated and temporarily stored until the outbound shipment is complete and ready to ship.
customer	A business or person to whom a service or product has been provided, either as a finished product or as a component part of the finished product.
customer focus	A structured approach to determining and addressing the needs of an organisation to which the company supplies products and which may be measured by the use of performance indicators.
decoration	An addition, adornment or embellishment applied to a material; may contain legally required text.
dispatch	The point at which the product leaves the factory site or is no longer the responsibility of the company.

distribution	The transportation of goods within any container (goods on the move) by road, rail, air or ship.
exclusion	Not included in the scope of the audit: this can be a physical area of the certificated site or a product category.
flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular item.
food safety	Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
functional barrier	A material that prevents harm to human health by stopping or retarding the passage of atmospheric gases, water vapour or volatile flavours and aromas that can cause unacceptable changes in the composition of food and its organoleptic characteristics. Alternatively, it is a barrier that can prevent shock or compression damage to a consumer product.
fundamental requirement	A requirement of the Standard that relates to a system which must be well established, continually 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.
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 risk assessment (HARA)	A system that identifies, evaluates and controls hazards which are significant for product safety, quality and legality.
hygiene-sensitive product	A product intended for human consumption or that comes into contact with the body; for example, by application to the skin.
importer	A company facilitating the movement of products across an international border. Usually the first recipient of the products in that country.
incident	An event that has occurred that may result in the production or supply of unsafe, illegal or non-conforming products.
initial audit	The BRCGS audit at a company/site which is not in possession of a valid BRCGS certificate. This may be the first audit at a site or a subsequent audit of a site whose certification has lapsed.
integrity (packaging)	Once a packaging container has been filled and sealed, its integrity is based upon its ability to contain, protect and preserve the contained product during its intended use.
internal audit	General process of audit, for all the activities of the company. Conducted by or on behalf of the company for internal purposes.
job description	A list of the responsibilities for a given position at a company.

key staff	Those staff whose activities affect the safety, legality and quality of the finished product.
legality	In compliance with the law in the place of production and in the countries where the product is intended to be sold.
lot	See definition of 'batch'.
manufacturer	A company that produces product from raw materials and/or components and supplies product to a customer.
master sample	See definition of 'reference sample'.
may	Indicates a requirement or text which provides guidance but is not mandatory for compliance with the Standard.
monitoring	A planned sequence of observations or measurements of defined control parameters to assess whether predefined limits are being met.
non-applicable	Any specific requirement that refers to an activity which does not occur on a site.
non-conformity	The non-fulfilment of a specified product safety, legal or quality requirement or a specified system requirement.
outer packaging	Packaging which is visible when the product is released from the site. For example, a cardboard box could be considered as outer packaging even if wrapped in clear film.
outsourced (subcontracted) processing	Where an intermediate production process or step in the manufacture of a product is completed at another company or site.
performance indicators	Summaries of quantified data that provide information on the level of compliance against agreed targets (e.g. customer complaints, product incidents, laboratory data).
positive release	Ensuring a product or material is of an acceptable standard prior to release for use.
potable water	Water being safe to drink, free from pollutants and harmful organisms and conforming to local legal requirements.
premises	A physical building or place owned by the company and audited as part of a site.
prerequisite	The basic environmental and operational conditions in a packaging materials site that are necessary for the production of safe packaging materials. These conditions provide the necessary control of generic hazards required for good manufacturing and hygienic practice and shall be taken into full consideration within the hazard and risk management system.
preventive action	Action to eliminate the fundamental, underlying cause (root cause) of a detected non-conformity and prevent recurrence.
primary packaging	That packaging which constitutes the unit of sale, used and disposed of by the consumer (e.g. bottle, closure and label).
print/printing	Decoration of a pack by any print process, such as litho, flexo, gravure, tampo, screen, digital etc.
procedure	Agreed method of carrying out an activity or process which is implemented and documented in the form of detailed instructions or a process description (e.g. a flowchart).

product recall	Any measures aimed at achieving the return of an unfit product from customers and final consumers.
product safety 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.
product withdrawal	Any measures aimed at achieving the return of out-of-specification or unfit products from customers, but not from final consumers.
protective clothing	Clothing designed to protect the product from potential contamination by the wearer.
provenance	The origin or the source of raw materials.
quality	Meeting the customer's specification and expectation.
quality assurance	A system for ensuring a desired level of quality in the development, production or delivery of products and services.
quality control	A system for establishing and maintaining a desired level of quality in a product through planning, use of proper equipment, continued inspection and corrective action, as required.
quantity check/mass balance	A reconciliation of the amount of incoming raw material against the amount used in the resulting finished products, also taking into account process waste and rework.
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.
recognised laboratory accreditation	Laboratory accreditation schemes that have gained national and international acceptance, awarded by a competent body and recognised by government bodies or users of the Standard (e.g. ISO/IEC 17025 or equivalents).
recycled	Material that has been reprocessed from recovered (reclaimed) material, including post-consumer or post-industrial waste, and made or incorporated into a final product or a component for incorporation into goods or services.
reference sample	Agreed product or components for referral by the manufacturer for production.
regrind	Excess materials or reject containers that are ground into a raw material before being returned to production. Typically this is an in-house process.
regulatory	A law, rule or other order prescribed by an authority that has been designed to regulate conduct or conformity to regulatory requirements.
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 products within a retailer's premises. Retailer-branded products are legally regarded as the responsibility of the retailer.

retained production sample	Representative product or components taken from a production run and securely held for future reference.
risk	The likelihood of occurrence of harm from a hazard.
risk analysis	A process consisting of three components: risk assessment, risk management and risk communication.
risk assessment	The identification, evaluation and estimation of the levels of risk involved in a process to determine an appropriate control process.
root cause	The underlying cause of a problem which, if adequately addressed, will prevent a recurrence of that problem.
sampling plan	A documented plan defining the number of samples to be selected, the acceptance or rejection criteria, and the statistical confidence of the result.
schedule	A tabulated statement giving details of actions and/or timings.
secondary packaging	Packaging that is used to collate and transport sales units to the retail environment (e.g. corrugated case).
senior management	Those with strategic/high-level operational responsibility for the company and the capability to authorise the financial or human resources necessary for the implementation of the Standard.
shall	Signifies a requirement to comply with the contents of the clause.
should	Signifies that compliance with the contents of the clause or requirement is expected or desired.
site	A unit of a company; the entity which is audited and which is the subject of the audit report and certificate.
specification	An explicit or detailed description of a material, product or service.
specifier	A company or person requesting the product or service.
Standard, the	The Global Standard for Packaging Materials Issue 6.
subcontractor	A firm, company or individual carrying out a process step on intermediate products on behalf of the site being certificated to the Standard. *See also* outsourced (subcontracted) processing.
supplier	The person, firm, company or other entity to which a site's purchase order to supply is addressed.
suspension	Where certification is revoked for a given period, pending remedial action on the part of the company.
traceability	Ability to trace and follow raw materials, components and products, through all stages of receipt, production, processing and distribution both forwards and backwards.
traded goods	Goods not manufactured or part-processed on site but bought in and sold on.
trend	An identified pattern of results.
unannounced audit	An audit undertaken on a date unknown to the company in advance.

user	The person or organisation who requests information from the company regarding certification.
utilities	Commodities or services, such as electricity or water, that are provided by a public body.
validation	Obtaining evidence through the provision of objective evidence that a control or measure, if properly implemented, is capable of delivering the specified outcome.
vehicle	Any device used for the conveyance of product that is capable of being moved upon highways, waterways or airways. Vehicles can be motorised (e.g. a lorry) or non-motorised (e.g. container or rail truck).
verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control or measure is or has been operating as intended.
where appropriate	In relation to a requirement of the Standard, it means that the company will assess the need for the requirement and, where applicable, put in place systems, processes, procedures or equipment to meet the requirement. The company shall be mindful of legal requirements, best-practice standards, good manufacturing practice and industry guidance, and any other information relating to the manufacture of safe and legal product.
work in progress/work in process	Partially manufactured products, intermediates or materials waiting for completion of the manufacturing process.
workwear	Company-issued or authorised clothing designed to protect the product from potential contamination by the wearer.

Appendix 7
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