BRCGS

Global Standard
FOOD SAFETY
ISSUE 9

INTERPRETATION GUIDELINE

brcgs.com

BRCGS | Food Safety

Global Standard FOOD SAFETY ISSUE 9 INTERPRETATION GUIDELINE

August 2022

Copyright and liability

BRCGS[1] publishes information and expresses opinions in good faith, but accepts no liability for any error or omission in any such information or opinion, including any information or opinion contained in this publication.

Whilst BRCGS has endeavoured to ensure that the information in this publication is accurate, it shall not be liable for any damages (including without limitation damages for pure economic loss or loss of business or loss of profits or depletion of goodwill or otherwise in each case, whether direct, indirect or consequential) or any claims for consequential compensation whatsoever (howsoever caused) arising in contract, tort (including negligence or breach of statutory duty), misrepresentation, restitution or otherwise, in connection with this publication or any information contained in it, or from any action or decision taken as a result of reading this publication or any such information.

All warranties, conditions and other terms implied by statute or common law are, to the fullest extent permitted by law, excluded.

Nothing excludes or limits the liability of BRCGS for death or personal injury caused by its negligence, for fraud or fraudulent misrepresentation or for any matter which it would be illegal for it to exclude or attempt to exclude liability for.

The Global Standard Food Safety (Issue 9) Interpretation Guideline and the terms of the disclaimer set out above shall be construed in accordance with English law and shall be subject to the non-exclusive jurisdiction of the English Courts.

Copyright

ISBN for PDF: 978-1-78490-449-4
ISBN for print: 978-1-78490-450-0

Published by: BRCGS, Second Floor, 7 Harp Lane, London EC3R 6DP

Tel: +44 (0) 20 3931 8150
Email: **publishing@brcgs.com**
Website: **brcgs.com**

Edited and typeset by Williams Lea, London.
Printed by Gemini Print Group, Shoreham-by-Sea.

[1] BRCGS is the trading name of BRC Trading Ltd. BRCGS is part of LGC ASSURE.

Contents

Part I – Introduction

Part II – Guidance on the requirements

Appendices

Part I
Introduction

Part I
Introduction

Welcome to the interpretation guideline for the ninth issue of the Global Standard Food Safety (hereafter referred to as the Standard). The interpretation guideline is designed to accompany Issue 9 of the Standard and should be read in conjunction with it. The full details of the certification process and protocol are contained within the Standard.

This document helps in the understanding of each requirement of the Standard and identifies methods of compliance.

Examples are given to explain the type of documents, procedures and level of detail that would be required by a certification auditor.

The contents of the guideline are designed to help interpret the Standard across all food sectors; however, the exact requirements for any particular product, process or site will be specific to that industry and situation. Users of the guideline are therefore cautioned not to rely solely on the information provided here, but also to reconfirm needs on a product-by-product basis. Both legislative and voluntary safety requirements change frequently, highlighting the need for regular checks of precise requirements.

While adherence to the guideline does not specifically form part of the requirement to achieve certification to the Standard (i.e. it does not form part of the audit requirements), companies will need to demonstrate that they have taken account of the topics addressed within this guideline. Examples are given as points to consider but should always be used in the correct context relevant to the business. Practices should be able to withstand challenge by an auditor and be in line with good industry practices.

Achieving a particular requirement is based on evidence collected, observations made during the audit, and on the procedures expected within that industry sector. 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. It is based on the evidence seen during the audit and independently verified by the certification body management.

Certification to the Standard

Why is certification required?

Certification to the Standard was developed to establish a common standard for food safety and product quality management. It allows brand owners to demonstrate control and satisfy legal responsibility for products and consumer safety, as well as reducing audit duplication for manufacturers. The Standard has become a benchmark for best practice and is recognised worldwide by brand owners and manufacturers in the supply chain, with more than 20,000 food companies now certificated to the Standard. The Standard has been developed for manufacturers of food; however, certification throughout the supply chain is available through other BRCGS Standards:

- Global Standard Agents and Brokers
- Global Standard Consumer Products
- Ethical Trade and Responsible Sourcing
- Gluten-Free Certification Program Global Standard
- Global Standard Packaging Materials
- Plant-Based Global Standard

- Global Standard Retail
- Global Standard Storage and Distribution.

First steps to gaining certification

Self-audit or gap analysis

Once the decision has been made by the company to pursue certification to the Standard, the requirements need to be understood. The site needs to be assessed with regard to its current status, and areas that need to be improved must be identified. This may, for example, relate to the structure of buildings, equipment requirements, the design of processes or the documentation and implementation of procedures. The company needs to establish an action plan.

Relevant staff need to understand what is expected. Training courses or further information are available and may be useful.

A gap analysis or self-audit needs to be conducted. This could be undertaken in-house; for example, it could be incorporated into the company's internal audit process. However, it may require external resources in the form of consultancy expertise, or a pre-assessment may be undertaken by the company's chosen certification body.

Once the company has reviewed the gaps between the requirements and its current practices, the company's senior management needs to establish a plan to ensure that work is undertaken to fulfil the requirements. This could include, for example, updating of policies and procedures, training of staff, capital expenditure for equipment and maintenance of the building.

Who undertakes certification audits?

BRCGS does not undertake the audits itself. BRCGS is the Standard owner, documenting the requirements on behalf of stakeholders and controlling the operation of the certification scheme. The Standard is written by a committee of international representatives, coordinated by BRCGS, including retailers, food industry representatives and certification bodies. The BRCGS team then controls how audits are undertaken through the specification of the audit protocol and supporting rules and regulations for certification bodies undertaking the certification audits. Monitoring of certification bodies is undertaken through independent accreditation – for example, by the United Kingdom Accreditation Service (UKAS) or the American National Standards Institute (ANSI), operating to internationally recognised protocols – and by BRCGS.

Therefore, a BRCGS-approved certification body needs to be selected by the company. There is a worldwide choice of such bodies; a list can be found in the **BRCGS Directory**. Certification bodies need to be appropriately qualified to undertake the audit and conform to the company's and its customers' requirements.

Cost of audits

Audit costs vary and are set by the individual certification bodies. They may include the expenses of the auditor (e.g. travel).

Typically, the audit consists of 2 to 3 days on site, depending on factors such as company size (in terms of staff numbers and size of site), the complexity of the manufacturing process, communication difficulties (e.g. language) and difficulties during the audit.

A full list of factors is given in the Standard and an audit duration calculator is available on the BRCGS website. In addition, time is needed to write up the report – typically 0.5–1 day. As with most purchases, the cost should be clearly stated and agreed between the company and the certification body prior to entering into the contract.

Note that certification is a continual process, and it is a feature of the scheme that the certification body has the option to visit a certificated company at any stage of certification to ensure that certification principles are being upheld. This may arise through the receipt of further information, such as a complaint from a customer of the site, and a charge may be made for any subsequent visits or investigations.

A service package fee is payable directly to BRCGS through the certification body for every audit undertaken.

The company also needs to consider investment costs that may be incurred to ensure the company is operating to the level required by the Standard, including site standards, training and procedural costs.

When can the audit be undertaken?

The company and the chosen certification body should agree a mutually convenient date for announced audits and re-audits to ensure that the company retains ongoing certification. (For certificated sites this may be yearly or 6-monthly, depending on the grade attained.) The company may wish to choose a date when:

- products that need to be included within the scope of the certificate are being manufactured
- personnel to be involved in the audit process are available.

Ongoing re-audit dates need to be considered since the announced re-audit date will fall between 11 and 12 months from the original audit date (or 5 to 6 months from the original audit date if a Grade C or D is obtained, where re-audit is required after 6 months).

What to expect on the audit day(s)

The auditor/certification body shall have confirmed to the company the time of arrival on site and may have provided a summary of the audit schedule. The duration of the audit, although planned in advance, will depend on the activities on the day, but it may be shortened if a site is well-organised and information provided in advance as requested by the certification body.

The audit consists of the following activities:

- Opening meeting, to be attended by all relevant company personnel (including the most senior production or operations manager on site), to confirm:
  - the scope and process of the audit
  - highlight any key timings; for example, when specific activities will be completed
  - any staff who will need to be available to discuss specific aspects of the site operations
  - documents that need to be provided
  - any logistics, such as rooms for on-site activities, availability of protective clothing, etc.
- Review of the Hazard Analysis Critical Control Points (HACCP) or product safety plan documentation (where a site has multiple HACCP or product safety plans each will be reviewed).
- Production and storage area audits – it is normal for the auditor to enter production early in the audit, as this provides a clear understanding of the production processes. During the course of the audit, the auditor will need to visit production on multiple occasions; for example, to audit different activities as they occur.
- Document review.
- Vertical audits, traceability exercises and the checks of associated records and documentation.
- Final review of findings by the auditor(s) – preparation for the closing meeting.
- Closing meeting – to review audit findings with the company.

The auditor will need to see the manufacturing process in operation around the site, checking and challenging the operation of the company's procedures. The auditor will check policies, procedures and records for objective evidence that requirements are being met, will ask for specific details and will speak to a variety of staff. After the

audit, the auditor will require some quiet time to write up evidence and collate details of non-conformities, in preparation for the closing meeting with the company, where the audit is summed up and details of the findings, including non-conformities, are given.

Audits – is there anything different?

Issue 9 of the Standard includes three different audit options:

- announced on-site audit
- announced blended audit
- unannounced on-site audit.

Announced audits (with mandatory 1 in 3 unannounced)

Due to the added confidence provided by unannounced audits, the GFSI Benchmark Version 2020 introduced a new requirement for certificated sites to have at least 1 unannounced audit every 3 years, even where they have opted to be part of the announced audit programme. Therefore, this requirement has been added to the announced audit protocol.

For sites that have not previously been certificated to a GFSI Standard, the certification body will agree which year within the first 3 years of certification will be unannounced, thereafter the unannounced audit will normally occur once every 3 years, unless the site opts into the voluntary unannounced programme (see below).

The remaining aspects of the announced audit programme remain unchanged from Issue 8.

The announced, on-site audit programme (including the mandatory unannounced audit every 3 years) remains available to all sites. Full details can be found in the Standard (Part III, section 2).

Blended announced audits

With the evolving role of technology in the supply chain, auditing activity is adapting to incorporate remote assessment elements into the process, with the overall aim of evaluating evidence objectively, to determine the extent to which the audit criteria are being fulfilled. Introduction of the blended audit option provides an opportunity for sites to engage with the auditor using information and communications technology (ICT).

The blended audit has several stages:

- it commences with a risk assessment, completed by the certification body, to confirm the feasibility of an ICT remote audit at the site (i.e. to determine if the audit objectives can be achieved using remote ICT audit techniques)
- a remote audit of documents, such as procedures and records
- an on-site audit of production and storage, including any aspects of documentation which could not be audited remotely.

The blended audit option is only available for the announced audit programme.

It is not available for initial audits (i.e. the first BRCGS audit at the site, which must be completed as a full on-site audit); however, subsequent audits can be completed using the blended audit option.

The significance of this audit option resides in its ability to offer flexibility in achieving the audit outcome by using ICT to conduct the document and record review parts of the audit.

Full details on the blended audit option are provided in the Standard (Part III, section 3).

Unannounced audits

In this audit option all of the certification and recertification audits are unannounced (unlike the announced audit option discussed above, where only one audit every 3 years is unannounced).

The option to undertake the unannounced audit scheme provides companies with an opportunity to demonstrate their confidence in their systems and procedures, to the extent that they are willing to subject these to unannounced scrutiny.

Companies may thereby gain a competitive advantage with their customers, who are given an opportunity to review suppliers' risk ratings. Customers may view suppliers in the unannounced audit scheme more favourably, depending on performance, and they may reduce the frequency of their own customer audits as a result.

The unannounced audit scheme is voluntary and the decision to participate in the scheme rests with the certificated company. To opt into the scheme, companies must notify their certification body of their intention within the first 3 months following a qualifying audit; after this period only the announced scheme will be available.

The grading criteria will be as for the normal audit. Successful completion of the audit will result in the awarding of certification Grade AA+, A+, B+, C+ or D+, where the plus symbol indicates an unannounced audit, and this grade will appear on the certificate. This certificate will supersede the existing certificate.

While it may be accepted that the company would need to ensure that arrangements such as facilities to undertake meetings and review documentation are made available at short notice, an unannounced audit should not affect the logistics of how an audit is undertaken, and should be approached in the same way by both the auditor and the company. The company should consider the requirements for contingency plans in the event of documents, such as personnel records, being kept in locked cupboards and the nominated key holder being off site (e.g. through the provision of spare keys).

Issue 9 of the Standard provides an unannounced audit option, where all aspects of the Standard are audited on an unannounced visit to the site. Full details of the unannounced audit scheme can be found in Part III, section 4 of the Standard.

Explanation of terms

Within the Standard there are some specific terms and language used, and a good starting point for interpreting the Standard is to be familiar with these terms and their context. A full glossary is given in Appendix 1.

Annual frequency

Many requirements in the Standard refer to an annual frequency for the completion of, for example, internal audits or specific tasks. The aim of this specification is to ensure that the tasks are completed within a 12-month period since the last occasion when the activity was completed (e.g. that the test of the system is completed every 12 months).

Please note that there is a difference of 23 months between a test being completed in January of one year, and a subsequent test occurring in December of the following year, which would not meet the requirement for an annual frequency.

Appropriate

A number of clauses within the Standard refer to the need to fulfil requirements 'where appropriate'. 'Appropriate' is defined as suitable for a particular condition or occasion, and requirements shall be met where it is an industry requirement or it is justified to do so.

A number of the requirements specify appropriate timescales, appropriate personnel etc., and thus contain a level of judgement. They are designed to provide a degree of flexibility to ensure the operation of policies or procedures that are right for the organisation and the risks associated with the specific products.

Documented procedures

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

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

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

Fundamental requirements

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

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

A lack of focus on a fundamental requirement may result in certification not being granted.

HACCP, food safety plan, prerequisites and critical control points

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

Risk assessment

Some clauses within the Standard refer to risk assessments being the basis for developing appropriate control procedures, such as establishing a frequency for monitoring a control point. The underlying principle is to demonstrate that potential hazards have been considered by the site, and that relevant controls are applied.

Risk assessment is typically defined as a systematic process of identifying the hazards that may be involved in a proposed product or process, determining their impact on food safety, authenticity, legality or quality, and designing an appropriate control or procedure to minimise the risk of problems occurring.

During the course of the certification audit, the auditor will require evidence of these risk assessments, including how they were completed and evidence that the controls are justified and can stand up to robust challenge. Where risk assessment demonstrates that further action is not required, it is important that this is also documented, with a description of the justification.

Risk assessments do not need to be long, complicated documents; they must, however, demonstrate that all relevant aspects have been assessed. For example, they could be documents that identify the hazard, the risk of its occurrence and, where appropriate, the controls used or introduced to manage the risk; alternatively, this information may be incorporated within established procedures.

The Standard does not prescribe a method for completing risk assessments. Sites are free to use their preferred techniques, which may include relevant electronic or physical tools, and there are many guidelines available (for example, the ISO 31000 Risk Management Guidelines). In many cases, industry best practice, where known and available, will help meet this requirement.

A risk assessment course is available from BRCGS Performance Enhancement and through the global network of approved training providers. More information is available from the **training pages** on the BRCGS website.

'Shall' versus 'may'

The style of the Standard is generally one of guidance, to allow companies to ensure that all aspects of control have been considered, so that thorough and comprehensive policies and procedures may be developed. In some instances the Standard requires that criteria must be included within a policy or procedure, and this is generally covered by the term 'shall'. If any of the points included are not covered adequately, a non-conformity will result.

However, there are also a number of clauses that provide examples or guidelines, generally preceded by the words 'may include' or 'should'. This information is provided as guidance for incorporation in company policies and procedures. It is the responsibility of the company to ensure that the auditor is satisfied that the system in place is appropriate.

Clause 3.11.1 shows an example of both usages:

'The company shall have procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, authenticity, legality or quality. This shall include consideration of contingency plans to maintain product safety, authenticity, legality and quality. Incidents may include …'

Statements of intent

Each main section or subsection of the requirements in the Standard begins with a statement of intent (SOI). This sets out the expected outcome of compliance with the requirements of that section. This forms part of the audit and all companies must comply with the statements of intent. Statements of intent have tinted backgrounds, as shown here.

Below the statements of intent in the tables are more specific and detailed requirements (clauses) that, if applied appropriately, will help to achieve the stated objective of the requirement. All of the requirements and the statements of intent shall form part of the audit and must be complied with in order for a certificate to be issued.

Validation

Validation is defined as obtaining evidence that a control measure (or combination of measures), if properly implemented, is capable of controlling a hazard to a specified outcome. Validation activity is completed before the controls are introduced or when changes are expected (e.g. new products, new processes or new equipment). Validation might include:

- document and data review – previous test results, industry data, codes of practice and legislation may all contain useful information
- experiments/testing – consider tests on the product or factory environment that will demonstrate control (e.g. worst-case-scenario tests, final-product tests)
- challenge studies – for example, microbiological tests to establish whether a micro-organism of concern can grow in the product using the relevant time/conditions
- modelling – a number of predictive tools are available.

Several worked examples of validation can be found in Codex guideline CXG 69-2008, available on the **Codex Alimentarius guidelines** page of the FAO website.

A validation and verification course is available from BRCGS Performance Enhancement and through the global network of approved training providers. More information is available from the BRCGS website.

Verification

Verification is defined as obtaining evidence, on a predetermined and ongoing basis, that a control is operating within the correct parameters. Verification requires the application of methods, procedures, tests or evaluations, in addition to monitoring, to determine whether the control measure is operating as intended. Verification activities may include:

- audits – both internal and third-party
- review of records (e.g. records of the monitoring of temperatures and times, or other records completed during production) to confirm results were within expected limits and consider any trends
- corrective action review
- test results – depending on the control being verified, these might include final products, raw materials, swabs, rapid tests, etc.

A validation and verification course is available from BRCGS Performance Enhancement and through the global network of approved training providers. More information is available from the BRCGS website.

Monitoring

Monitoring is defined as conducting a planned sequence of observations or measurements to assess whether a control measure is within acceptable limits (e.g. temperature checks, metal detector checks, test weights).

Colour-coding the requirements

The audit process gives specific emphasis to the practical implementation of food safety procedures within the factory and general good manufacturing practices. Auditing these areas therefore forms a significant proportion of the audit.

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

The colour-coding also highlights which requirements may be audited remotely, as part of a blended audit, and which must be audited when the auditor is on site.

The colour-coding is as follows:

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

Part II
Guidance on the requirements

Part II
Guidance on the requirements

1 Senior management commitment

1.1 Senior management commitment and continual improvement

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

Interpretation

A fundamental factor in the management of product safety is the product safety and quality culture which prevails at the site; that is, the shared attitudes, values and beliefs relating to the importance of product safety, the confidence in the product safety processes used at the site, and the systems available to report and act on any concerns relating to product safety.

For this culture to flourish and for the importance of product safety to be understood by all members of staff, it is vital that product safety is led from the top of the organisation. This includes not only the official company policies and procedures, the KPIs or targets the company challenges itself to meet, but also the culture which prevails and the direction the company takes. This leadership should also ensure that the necessary commitment, support and resources are available.

Without this culture and management commitment, it is very unlikely that the Standard could be consistently applied or that the customer assurance provided by certification could be honoured. There are requirements within the Standard that need to be understood and applied by most functions within the organisation, from purchasing to personnel and from maintenance to production. Experience has shown that only where the most senior management are committed to the processes can this level of involvement be achieved consistently. Leadership behaviours, tendencies and management practices all influence the culture of safety, increasing the likelihood of the site adhering to good practice.

Senior managers should therefore be fully engaged in the implementation of and ongoing compliance with the Standard.

Continual improvement is also an important principle of the Standard. This is not a question of how many non-conformities the site received in consecutive audits, although if the same non-conformity repeatedly occurred at every audit, that may indicate a wider concern. Continual improvement asks whether the company uses ongoing opportunities to improve relevant aspects of its ways of working. There are many clauses within the Standard that point towards this principle and provide these opportunities. For example:

- Plans to develop and continually improve product safety and quality culture of the organisation (see clause 1.1.2)
- Review processes and meetings – for example, senior leadership management meetings (see clause 1.1.4)
- Data capture and trending – for example, the trending of complaints information, so that significant negative trends can be investigated and improvements made (see clause 3.10.2)
- Processes for remaining up to date with emerging issues, legislation and good practice (see clause 1.1.8)
- The role of preventive action (see clause 1.1.12 and the clauses within section 3.7).

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

Interpretation

Documented policy

The site's policy must clearly state the overall aims to meet customer requirements, including the provision of safe, authentic products of the quality desired by the customer. The policy will also highlight the site's intention to improve product safety and quality culture on a continuous basis, which, as discussed (for example, in the interpretation for the statement of intent and importantly in clause 1.1.2), is fundamental in the consistent application of product safety practices. The policy is designed to show the site's intention, so that all staff can work towards this common goal.

Authenticity of products means ensuring that all products sold or purchased are of the nature, substance and quality expected. This applies not just to product claims, but includes all products and raw materials with the assurance that they meet the specification. Authenticity is defined in the glossary.

The policy must be signed by the person with overall responsibility for the audited site, to demonstrate the commitment at senior management at site level. Where the policy is a group- or company-wide statement, the site management should endorse it; for example, by countersigning it.

The policy statement is only a summary and can usually be expressed in a single page. Although it does not need to be dated, it must be current and should therefore be updated when significant policies or senior management change. The policy forms the foundation for the site's ways of working and the auditor will expect to see how the site management ensure staff understanding and engagement. This may include:

- communication to staff (e.g. through display on noticeboards, inclusion in the induction process, availability on the company intranet, and the use of appropriate languages where the local language is not the first language of all employees. The use of dual languages may improve and speed up understanding and action)
- inclusion of all staff, including temporary and contract staff, in the communication and engagement processes.

Clause	Requirements

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

Interpretation

Food safety and quality culture

Analysis of the root causes of many non-conformities shows that a proactive, positive product safety and quality culture (hereafter referred to as culture) within a company can make all the difference in the effectiveness of the food safety and quality plan and its consistent implementation throughout the site. Culture must be led by senior management and 'felt' throughout the organisation, so that all aspects of the business are informed and involved. It is important to understand that the culture plan is unlikely to be successful if it is viewed as simply a technical function. It will require the input and commitment of the site's senior leadership team and may also align with several teams around the business; for example, with human resources (HR) or personnel management activities.

Culture can be challenging. It relies not just on measurables and specifics but an ethos and values felt by people at all levels of the site. The size and complexity (or simplicity) of the site should not be a barrier to a successful culture.

The site is required to develop, implement and maintain a clear plan or programme for developing and improving its culture. Such a plan should be based on the nature of the organisation, and dependent on its size, seasonality and the overall aims it has identified as important for its own culture. The clause does not prescribe the exact mechanisms that must be used; this is to allow the site flexibility to develop systems that are effective within its specific ways of working, and its current prevailing culture. It does, however, highlight the minimum scope of the plan.

The plan will need to consider the measures needed to achieve the intended positive culture change.

Clause	Requirements
Interpretation *continued*	The plan does not need to be annual. A strategic plan could, for example, cover 5 years, with activities designed to measure current culture, implement changes and assess improvements (or where improvement was not evident, a review of why). Some aspects of the plan may occur more frequently than others. However, for the plan to be effective, the development and improvement of culture will need to be treated as an ongoing and continuous process, and the auditor will expect to see evidence that activities are being completed each year during which the plan is designed to operate. It is not acceptable to design a 5-year plan where all of the activities are completed within the final year. Regardless of the intended length or lifetime of the plan, it is important that it remains relevant and up to date. The site will therefore need to ensure that it is regularly reviewed and updated. At a minimum there must be an annual review. A wide range of activities could be incorporated into a culture development plan, some of which the company may already be conducting. As a minimum the Standard requires: • a clear and open communication on product safety • training • feedback from employees • behaviour changes required to maintain and improve product safety processes • performance measurement on product safety, authenticity, legality and quality related activities. However, note that culture is not simply a matter of introducing another policy, but on developing attitudes and a positive approach to product safety and product safety processes. For example: • Ease of movement of product safety information between different levels and sections of the site can be an indication of a good culture. However, a formal communication policy is not likely to affect company culture, unless the site has considered what is communicated, in what format. For example, if all communication is finance-related and lacks information on product safety, then staff may mistakenly believe that product safety is not important, due to its lack of communication. Instead, regular, open and clear communication, involving all personnel, is needed, including expectations, benefits, product safety successes as well as deviations from what is expected or acceptable. • Training and staff development (e.g. the use of annual staff reviews and one-to-ones) should have a number of aims beyond just training the process or procedure (e.g. awareness of food safety issues, management techniques, and development of positive behaviours and staff development). • Feedback from employees (e.g. staff surveys), focusing on values and culture, can provide useful information on current mindset and culture, impact of recent initiatives and preferred direction of travel. Feedback mechanisms also provide an opportunity to identify and address staff concerns.

Clause	Requirements
Interpretation	• Consideration of the behaviour changes needed to improve culture – the site should choose relevant behaviours that will have a positive impact on product safety. These relevant behaviours may be identified simply by a manager's knowledge of the site, or identified through the results of a site survey (such as the BRCGS Culture Excellence Module), or by considering the many indicators (or artefacts) of the behaviours, beliefs or attitudes that exist at a site. These can provide an indication of the prevailing culture and could be used in this part of the plan. An artefact of culture is described as an existing product safety activity that is not culture itself, but is indicative of the site's prevailing culture (i.e. the site's attitudes towards the value or importance of a specific product safety activity, and its compliance with that activity, is often indicative of the culture of the site). These behaviours or attitudes are often identifiable by the site and useful in the maintenance and improvement of product safety culture and can therefore be built into the culture improvement plan. Many fundamental product safety processes could be considered artefacts of the culture; for example: • food safety policy • objective setting and management review • food safety in management meetings • food safety resources • risk awareness (e.g. for HACCP development) • effectiveness of corrective and preventive actions • internal audits • training. Remember that these activities are not the culture themselves; they are artefacts – indicators of the prevalent product safety behaviours at the site. • Performance measurement – this is different from clause 1.1.3. There, the objectives are used to directly improve food safety, whereas the aim of this clause is to consider the impact of the results and learnings on product safety culture. For example, if an objective is always met, or always missed, or the objective remains unchanged every year, this may indicate a site attitude towards the objectives and provides site leadership with an attitude to focus on. In other words, is the site attitude to develop and continuously improve food safety using the objectives as one of the tools, or are the objectives set only to meet the requirements of the Standard? Along with the activities, the culture plan must also include information indicating how activities will be undertaken, the intended timescales for completion, plans for measurement (including results from previous activities) and a review of the effectiveness of completed activities. This information should be used to review the plan to ensure it remains up to date and relevant for the site. It also has the bonus of creating a history of improvements and impacts. This information can be used, for example, to train new employees, inspire existing staff and further inform the types of activity/implementation that are most effective at the site and those which are more likely to struggle. Culture is often considered to be subjective and therefore difficult to audit. It must be emphasised that auditors are not expected to audit 'food safety culture' of the site, but the evidence of compliance with the requirements of the clause. The auditor will therefore examine evidence of conformity with this requirement during both the audit of the facilities and the documentation audit. This will be achieved using a number of auditing techniques; for example:

Clause	Requirements
Interpretation *continued*	• a review of the documented plan and records – is it complete, does it contain all the relevant information, how were the activities and objectives set, are the monitoring and review processes operating correctly and have they been used to review and update the plan to ensure it remains relevant for the site? • discussion with senior management on the development and implementation of the plan (refer to clause 1.1.11). • discussions may be conducted across all levels of personnel on an informal basis. The auditor would expect to find an awareness of food safety culture, how individuals can impact it, and the company's objectives. • evidence of the site completing the activities in its action plan. • timescales and evidence that they have been met. • monitoring and review processes, and results from previous activities. BRCGS provides a number of services that can support a site's development of its culture plan, including: • an additional voluntary module in product safety culture excellence which helps sites measure the current culture and identify areas for improvement. • a guideline on product safety culture which may be purchased from the BRCGS Store or viewed online at BRCGS Participate. • a training course explaining culture and its implementation.

Non-conformities	To ensure expectations are understood relating to compliance with clause 1.1.2, its consistent application at certificated sites, and assessment during audits, BRCGS has trained auditors and certification bodies to apply the following non-conformities, where sites are non-compliant:
	
	• **Major non-conformity** Where the site does not have a documented plan for food safety and quality culture. In this context a plan is more than a short statement of intent, but is documentation incorporating all of the requirements of the clause.
	• **Minor non-conformity** Where a documented plan exists, but:
	  • is of poor quality (e.g. lacks detail such as timescales for completion or clear action plans)
	  • does not cover all the relevant areas or staff
	  • is not fully implemented (e.g. some activities are not implemented or are not completed to a predefined schedule).
	
	The final bullet point in the clause requires sites to undertake a review of the effectiveness of completed activities. However, it is possible that this review of the success of the programme would not always be implemented in year 1 (since a review cannot be completed until there are activities to review). Therefore non-compliance with this bullet point is not considered a non-conformity at the site's initial audit, but will be assessed from the site's second audit to the Standard onwards.
	
	The site is expected to complete corrective action, root cause analysis and preventive action plans in accordance with section 2.3 of the audit protocol prior to certification, and any non-conformity will be included in the calculation of the site's grade.

Clause	Requirements

Example	**Food safety and quality culture plan**
	
	The company decides to implement a culture plan. Based on the requirements of the Standard it identifies six key areas to include:
	
	• **Enhanced training** Beyond just managing critical control points (CCPs), to an understanding of the reasons for the current product safety processes and involving staff in corrective actions.
	• **Communications** Regular staff updates in addition to the traditional internal message boards. Updates are used to communicate production, incidences of non-conforming product, customer complaints and their corrective actions, and improvements in product quality. They also focus on company strategy and product safety objectives.
	• **A clear feedback process** To initiate communication 'up' to management, so that communication is not seen just as management 'telling staff'.
	• **Recognition** Management instigates 'employee of the month' awards as rewards for successful process improvement ideas.
	• **Behaviours to maintain and improve product safety** The site identifies two areas it would like to focus on:
	  • Previously the site had developed reporting and whistleblowing systems which allow staff to feed back concerns relating to product safety, in accordance with clauses 1.1.6 and 1.2.3 of the Standard. However, staff feedback has identified a lack of use of the systems due to:
	  • a lack of encouragement to report errors and product safety concerns
	  • a lack of trust, and a feeling that it is not safe or comfortable to report problems
	  • a belief that problems will not be taken seriously or that nothing will improve.
	  Senior management therefore decides to include staff reporting and concerns about the current system in the culture improvement plan, and look for ways to build trust and encourage use.
	  • Internal audits are an extremely useful site-based tool for monitoring and improving systems. However, the site notices that many departments undervalue the audit programme, with several reports reflecting a negative attitude towards the programme. Senior management also notes that internal audits require effort and resource to complete robustly and effectively, which have not always been available. In fact, at a previous management meeting the senior leadership had considered the potential to further minimise the internal audit programme (e.g. by resorting to tick-box exercises, reducing the number of audits or auditors, and completing the minimum activity possible, rather than reviewing the actual risks).
	  The culture plan therefore includes activities to build belief in, and use of, the internal audit programme, starting with education about the programme and its importance, training for new internal auditors, communication of audit results (positives as well as non-conformity), using the management review programme to consider learnings from the programme which can further benefit the site.
	• **KPIs** The site's quality KPIs have remained constant for a prolonged period. The site decides to use its annual customer reviews as an opportunity to review the quality KPIs to establish their continuing appropriateness.

Clause	Requirements
Example *continued*	To ensure that the activities proceed according to the plan (and in accordance with the Standard), the site management: • assigns timescales for the start of each activity • nominates leaders for each activity with responsibility to lead the activities identified • makes progress against the product safety culture plan an agenda item at the quarterly senior management team meetings • schedules a follow-up staff survey for 12 months' time which will specifically be used to assess the effectiveness of the planned activities • sets a review date for the complete plan.
1.1.3	The site's senior management shall ensure that clear objectives are defined to maintain and improve the safety, authenticity, legality and quality of products manufactured, in accordance with the food safety and quality policy and this Standard. These objectives shall be: • documented and include targets or clear measures of success • clearly communicated to all staff • monitored and results reported at least quarterly to site senior management and all staff.
Interpretation	**Food safety and quality objectives** Senior management must set objectives concerning food safety, authenticity, legality and quality that help to achieve the stated policy (see clause 1.1.1). The objectives must be communicated so that staff understand what is required from them. The setting of these objectives also helps the allocation of suitable budgets and resources. Auditors will look for evidence that the objectives are in place and have been communicated. Good objectives are usually: • **Specific** Objectives should be clear and directly related to the site's aims or goals for product safety and quality. • **Measurable** Objectives should be measurable so that the site can assess progress. • **Achievable** Targets that stretch the company are acceptable but it is important that they are realistic and that sufficient resources will be available. • **Relevant** Objectives should be designed to maintain and improve product safety and quality. • **Time-bound** Objectives can be long-term (e.g. throughout the period of certification) or shorter-term (e.g. within the next 3 months); however, the timescales or deadlines should be clear to enable the site to review progress and, if necessary, amend activities. There are many examples of objectives that could be included. For example: • reductions in customer complaints, non-conforming products and/or customer rejections or returns • reductions in audit failures or audit non-conformities – include both internal and external audits, but ensure that all audits are still completed to a thorough, rigorous quality • improved product safety training • improvements to the management of product authenticity • increases to product testing.

Clause	Requirements
Interpretation *continued*	In each of these examples it would be necessary for the site to consider how to make the objective specific and measurable (as discussed above); for example, 10% fewer customer complaints to be achieved by year end. Objectives associated with product authenticity are likely to be formed differently; for example, they may be linked to: • improvements to the traceability systems or traceability testing (section 3.9) • evolution of product monitoring processes such as product testing (section 5.6) • outcomes from the vulnerability assessment (section 5.4) • updates to the supplier approval mechanisms and the ongoing monitoring of suppliers (section 3.5). A similar situation exists for objectives associated with legality, as these will also need to be formed differently from those commonly used for product safety. For example, where there is proposed legislation in the region where the company operates, then possible targets may relate to ensuring that relevant staff are trained in a timely manner. Progress against targets must be reviewed and reported to senior management at least quarterly. It may, for example, be included in management meetings (e.g. those scheduled for clause 1.1.4), or it may be the subject of a separate review or included in a report to management. Auditors will look for documented evidence of communication and the quarterly progress review. The Standard also requires communication to staff (including all employees and agency-supplied staff). The Standard is not prescriptive on the methods of communication used to meet this clause. For example, any of the following could be used: meetings, briefings, cascades, huddles, electronic media (e.g. email), and company noticeboards. Independent sites or facilities that are part of a large group with company-wide objectives can adopt the company-wide objectives, but are required to 'own' the objectives and carry out the implementation, monitoring, review etc. at site level.
1.1.4	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually at a minimum, to review the site performance against the Standard and objectives set in clause 1.1.3. The review process shall include the evaluation of: • previous management review action plans and timeframes • the results of internal, second-party and/or third-party audits • any objectives that have not been met, to understand the underlying reasons. This information shall be used when setting future objectives and to facilitate continual improvement • any customer complaints and the results of any customer feedback • any incidents (including both recalls and withdrawals), corrective actions, out-of-specification results and non-conforming materials • the effectiveness of the systems for HACCP, food defence and authenticity, and the food safety and quality culture plan • resource requirements. Records of the meeting shall be documented and used to revise the objectives, thereby encouraging continual improvement. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.

Clause	Requirements

Interpretation	**Senior management review**
	
	The purpose of the management review meeting is to take an overview of the food safety systems. It should therefore be a full and detailed examination of what has happened and what should happen in future. It is not the ongoing management of an issue or concern (although the agenda may include a review of any such concerns) and it is not just incident/non-conforming product management (processes for these activities are covered in the relevant sections of the Standard; for example, in sections 3.8 and 3.11).
	
	The format of the meeting should reflect company size.
	
	The Standard identifies specific agenda items that must be included within the meeting; however, additional relevant subjects should also be included where appropriate. As a minimum the meeting agenda should therefore consider:
	
	• minutes of the previous management reviews and actions agreed. For example, the previous meeting may have set actions and timescales for their completion; however, if actions were not completed on schedule or have failed to be effective, further investigation and actions will be required
	• what has been achieved or not been achieved and progress against objectives (see clause 1.1.3); for example:
	  • if an objective has been met the site can consider future targets based on achievements to date
	  • if an objective has not been met the site can consider why. This can be very informative and allows future objectives (or other actions such as the product safety culture plan) to focus on areas where relevant, achievable actions can take place. This review need not be exhaustive (such as a full root cause analysis) but the site should be able to understand why objectives were not met. The outcome would not be preventive action but continual improvement, allowing the site to refine its future targets
	• internal, second-party and/or third-party audits, and subsequent actions. As a minimum the Standard requires a summary of the results from the internal audit programme to be reviewed at these meetings (see clause 3.4.3). This provides two opportunities for the senior management team:
	  • a review of non-conformities, corrective actions, root causes and preventive actions, with a focus on any outstanding concerns or additional actions required (individual issues should have been identified and acted upon at the time they were identified and where necessary, escalated to the management team during the year)
	  • review of the overall performance and key trends should facilitate continuous improvement (e.g. changes to the frequency of auditing particular areas, training needs or suggestions for improvements or further developments of the internal audit programme)
	  Similarly, second- or third-party activities (including customer audits, regulatory authority visits) could be summarised to facilitate further discussion and identify any actions or improvements that need to be made
	• progress against the product safety and quality culture plan and the effectiveness of completed actions
	• product safety incidents, complaints, out-of-specification results or non-conforming products, to ensure these have been fully actioned, to assess any trends and identify any additional follow-up actions or improvements needed as a result of these incidents and non-conforming situations
	• the management and effectiveness of product safety systems such as HACCP, food defence and product authenticity, along with any existing or emerging issues relating to these topics

Clause	Requirements
Interpretation *continued*	• identification of targets and areas of improvement for the coming year • changes to resource requirements. It is important that sufficient information is presented to the meeting to enable a full and meaningful discussion and, where appropriate, actions to be agreed. Senior management is considered to consist of managers who have the authority to make decisions on food safety objectives and/or the provision of adequate human and financial resources. The management team would usually include the site manager and those managers responsible for production, technical operations, purchasing, engineering and human resources. For large, multi-site organisations the management review meeting may include head office representatives, but this decision should be driven by the senior management on site. It may also include representatives from any departments responsible for specific product safety activities or for specific agenda items. Good practice is to ensure that the meeting is put into all attendees' diaries sufficiently early to maximise attendance and that agendas and papers are circulated in advance. The auditor will be looking for evidence that, for each agenda item, sufficient information has been provided to allow an informed discussion to take place leading to appropriate action plans. This may be demonstrated through a review of the inputs to the meeting, minutes of the discussion of the items and, where necessary, agreed action plans. To demonstrate that, for example, senior management has reviewed the management of the HACCP system, the minutes should contain a general summary of the HACCP review meeting (see section 2.12.3) and a record of its outcomes (these would be inputs into the management review meeting), together with any actions requested during the senior management meeting (i.e. outputs of management review meeting). One of the outputs from the meeting is a review of performance against the objectives (clause 1.1.3) and the establishment of new or amended targets and objectives for the following year. This should be clearly documented within the minutes of the meeting. The outcomes from the review meeting must be communicated to the relevant staff to ensure implementation. It should be evident to the auditor how this has been achieved (e.g. cascaded through staff briefings or posted on noticeboards). It should also be evident that actions are followed up and completed. For example, evidence of completion could be added to meeting records, or assessment of actions could be added to the internal audit programme. The Standard requires an annual review, such as a regular annual management review meeting. However, it is important that meetings are scheduled correctly and of sufficient frequency to maximise the value of the meeting and allow timely actions. Many companies opt to make a review or partial review more frequently (e.g. every 6 months or each quarter), either addressing all the points in summary (after other review meetings) or addressing one or two points in depth in each meeting. The number of meetings and the individual agendas should be based on company need, providing all relevant topics are covered within the 12-month period. Where meetings are scheduled with a large intervening period (e.g. annually) the site needs a process to ensure that any matters needing consideration can be completed in a timely fashion; for example, by incorporating them into management meeting agendas (see clause 1.1.5).

Clause	Requirements
Interpretation *continued*	Special consideration should be given to seasonal and temporary sites to ensure meetings occur at an appropriate point in the season and that actions, targets or objectives can be completed. Some sites therefore opt for two meetings; for example, one at the start of the season, to allow objective setting, and one at the end of the season, when the season's information can be assessed. Alternatively, a management meeting shortly after an external audit allows any non-conformities to be included in the discussion and relevant corrective actions to be agreed. All sites should have a predefined schedule so all participants are aware, in advance, of when the meetings will take place.
1.1.5	The site shall have a demonstrable meeting programme which enables food safety, authenticity, legality and quality issues to be brought to the attention of senior management. These meetings shall occur at least monthly.
Interpretation	**Management meetings** The objective of this clause is to ensure that there is a mechanism that enables the site to learn and react to available information from both internal (within the site and/or company) and external sources (e.g. wider industry, media, etc), allowing food safety, authenticity, legality and quality issues to be raised and discussed at a senior management level within the site. The meeting could include, for example: • review of successes/failures relating to product safety, authenticity, legality and quality and the lessons that can be learnt from these • any ongoing concerns • review of corrective actions, root causes, preventive actions and the effectiveness of these • review of information relating to publications, known recalls of similar products, information from regulatory authorities, media stories and potential implications/learnings for the site. This could include information obtained as a result of activities to comply with clause 1.1.8 • overview of KPIs, complaint levels or other relevant metrics. Meetings will need to include management of a seniority to make decisions, and where appropriate, take actions. Most sites have weekly or monthly management meetings and the inclusion of safety, authenticity, legality and quality as an agenda item within this meeting is one way to meet the requirements of this clause. A schedule for the meetings needs to be in place. Seasonal sites are not expected to have monthly meetings when the site is closed and not operating, but scheduling should consider the length of the season and processes to ensure that food safety, authenticity, legality and quality issues can be discussed in a timely manner. For example, the first meeting could take place shortly before the season begins, with further meetings monthly or even weekly throughout the season, and a final meeting at the end of the season. The audit will confirm whether: • the meetings occur at a defined frequency (e.g. a schedule, diary bookings or agendas) • previous meetings contained relevant discussions (e.g. agenda and minutes for the meetings which clearly state conclusions and any additional actions).

Clause	Requirements
Interpretation *continued*	Good practice is to ensure that any decisions and actions agreed are communicated to appropriate staff, and that there is a system to check that actions are implemented within agreed timescales.
1.1.6	The company shall have a confidential reporting system to enable staff to report concerns relating to product safety, authenticity, legality and quality. The mechanism (e.g. the relevant telephone number) for reporting concerns shall be clearly communicated to staff. The company's senior management shall have a process for assessing any concerns raised. Records of the assessment and, where appropriate, actions taken, shall be documented.
Interpretation	**Confidential reporting system (whistleblowing)** In 2018 a report from the Association of Certified Fraud Examiners found that reports from employees and outside parties are by far the most common method of detecting wrongdoing. It is therefore vital that all sites facilitate effective communication methods allowing staff to report any concerns. Ideally, this will be achievable using procedures developed to meet clause 1.2.3. However, from time to time it may be necessary for individuals to report on hazards or infractions anonymously and confidentially (e.g. if a staff member felt that a genuine concern raised through other mechanisms, such as those covered in clause 1.2.3, had not been adequately addressed), so the site (or company) should have a system in place to manage this. Although the aim of the Standard is to ensure these reporting systems relate to product safety, authenticity, quality and legality, the company may choose to incorporate all staff concerns into the system, and not limit it to concerns related to the scope of the Standard. As a minimum, the system used must ensure that the confidentiality of the employee reporting the concern is maintained (i.e. the employee's identity is not known or released to the site or company management) to protect any staff using it, and the confidential and anonymous nature of the system should be clear to all staff. An email or telephone call to an on-site manager, for example, is unlikely to be anonymous or confidential as the manager is likely to know the employee's email address or recognise their voice. Therefore this would not be considered a confidential system. Many food processors will also have whistleblowing systems established by the brand owners and retailers for which it produces. Where this is the case, the site is still required to have its own system as affected products may not relate to the specific brand owner. Additionally, in some areas, local relevant regulatory authorities will have facilities for confidential reports about a site but this also does not mitigate the need for a site (or company) to have a system. As well as gathering information, the site is required to collate and act on it. The auditor will expect to see a system in place, and transparency about the content of any reports and actions, although not the source of the original concern. Where possible, sites might consider an independent system that receives and processes any concerns raised with appropriate promptness. For example, where quality, safety or conformity of the product is at risk, action should be immediate. This might be by using an independent consultant or a professional organisation that can act as an intermediary.

Clause	Requirements
Interpretation *continued*	Where local legal requirements prohibit certain activities around confidentiality or such reports, the site will need to ensure the system employed meets these legal requirements. This will also be acknowledged by the auditor and compliance with this clause noted within the context of the legal framework. It is not uncommon for larger companies to base the management of their confidential reporting systems at head office, rather than at each individual site. This is acceptable and the audit process is explained in Appendix 4 of the Standard. BRCGS operates the independent 'Tell BRCGS' facility (available **online**). This has been designed so that BRCGS can receive information from any interested party about the status of certificated sites or the certification process. Therefore, when feedback is received, it will be investigated and this may, for example, identify the need for a compliance audit at the implicated site to ensure that it is operating legally and in compliance with the Standard. This is different from the aim of this whistleblowing clause, which is to provide the site/company management with an opportunity to receive and address any concerns raised by employees without the site being subject to an external review. Therefore, a site using the Tell BRCGS system without its own confidential reporting system will not achieve the intended aim of the clause, although it could be used for situations where an employee has tried other site-specific options and is still sufficiently concerned to raise the matter with BRCGS.
1.1.7	The company's senior management shall provide the human and financial resources required to produce safe, authentic, legal products to the specified quality and in compliance with the requirements of this Standard.
Interpretation	**Resources** Sites must have sufficient financial and human resources to be able to maintain the food safety, authenticity, legality and quality systems. Although a review of resources forms part of the management review process (clause 1.1.4), it should not be restricted to a single annual discussion if there is a need to make changes to resource allocation during the course of the year. As well as looking at the minutes of the management review meeting, auditors will also look at the type, number and root causes of non-conformities identified at the audit, as the ability of the site to meet the requirements of the Standard will partly demonstrate that the appropriate resources and skills are available. The auditor will examine this requirement during both the audit of the facilities and documentation. The auditor will expect the site to demonstrate that it is adequately resourcing its product safety, authenticity, legality and quality activities, which may include capital expenditure (e.g. for repairs or new equipment), staff levels and staff training.
1.1.8	The company's senior management shall have a system in place to ensure that the site is kept informed of and reviews: • scientific and technical developments • industry codes of practice • new risks to authenticity of raw materials • all relevant legislation in the country where the product will be sold (where known).

Clause	Requirements
Interpretation	**Technical knowledge and information** Food safety issues and legislative requirements are constantly changing. The objective of this clause is to ensure that sites remain up to date, are able to meet legislation and can adapt their food safety systems to protect against new threats. The company must be able to demonstrate that it maintains up-to-date knowledge of relevant legislation, scientific and technical developments, potential risks to raw materials (e.g. to the authenticity of the raw material) and industry codes of practice, such as Codex Alimentarius. Activities to achieve this may include: • membership of a trade association that provides this service • subscription to a service provider supplying legal updates • help from government officials or local enforcement offices • regular review of identified websites covering legislation and standards. In addition to information relating to food safety, the site must also have a system to obtain and review information relating to the authenticity of raw materials and the potential for substitution or dilution of the ingredients. This information will, for example, be required to demonstrate compliance with clause 5.4.2. The company needs to demonstrate that it can readily access, either directly or through a third party, legislation relating to the product in the country, state or territory where the product is sold to the ultimate consumer (if known, or where it can reasonably be expected to be sold). Good practice is also to consider the country where the product is manufactured. The auditor will therefore look for evidence of systematic checking and of the process for ensuring the information is transferred into action as necessary.
1.1.9	The site shall have a genuine, original hard copy or electronic version of the current Standard available and be aware of any changes to the Standard or protocol that are published on the BRCGS website.
Interpretation	**Availability of a copy of the Standard** The aim of this clause is to ensure the site has easy access to all the relevant requirements for compliance and certification to the Standard. The site must therefore have an official copy of the Standard available in either paper or electronic form. Either a free or paid-for PDF copy of the Standard demonstrates compliance with this requirement. A subscription to BRCGS Participate provides an online version of the Standard (and interpretation and other guidelines) and therefore also meets this requirement. The site will also need copies of any additional voluntary modules to which they are certificated. In addition, during the lifetime of the Standard, the BRCGS technical advisory committee (TAC) may be asked to: • review the wording of a requirement in the Standard or audit protocol • provide an interpretation for a requirement • rule on the grading of a non-conformity against a clause.

Clause	Requirements
Interpretation *continued*	Published TAC opinions are defined as 'position statements'. Position statements are binding on the way that the audit and certification process is carried out and are considered to be an extension to the Standard. Sites must therefore be aware of any published position statements and, where necessary, ensure the information is transferred into action. Position statements are published on the **'Food Safety Help and Guidance'** page of the BRCGS website and available on BRCGS Participate. They are communicated via the BRCGS newsletter. This newsletter is sent to all certificated companies. Position statements are also communicated to certification bodies via the bulletin.
1.1.10	Where the site is certificated to the Standard, it shall ensure that announced or blended announced recertification audits occur on or before the audit due date indicated on the certificate.
Interpretation	**Audit due dates** The audit due date is indicated on both the audit report and the certificate issued to all certificated sites. The responsibility for scheduling the next audit rests with the site. Announced audits may be taken in the 28 calendar days up to and including the audit due date. Blended audits may commence within the 56 calendar days prior to the audit due date. Late audits are likely to result in a gap in certification and a major non-conformity will be awarded unless exceptional circumstances occur as identified in the audit protocol section of the Standard (Part III, section 2.7.2). This includes situations where the site is: • situated in a specific country, or an area within a specific country, where there is government advice not to visit and there is no suitable local auditor • within a statutory exclusion zone that could compromise food safety or animal welfare • in an area that has suffered a natural or unnatural disaster, rendering the site unable to produce or the auditor unable to visit • affected by conditions that do not allow access to the site or restrict travel (e.g. heavy snow) • producing seasonal products where production is delayed by a late start to the seasons (e.g. due to weather or product availability). Lack of personnel is not an acceptable reason for adjusting the audit date. It is expected that the site will appoint adequate deputies and established systems of working to ensure the smooth operation of the site in the absence of individual managers. Nor is the undertaking of building work an acceptable reason for delay unless the site is not in production while the building work is carried out. Where a site has an unannounced audit, either by opting into the voluntary unannounced scheme or due to the requirement for a mandatory unannounced audit, it becomes the responsibility of the certification body to ensure this requirement is met.
1.1.11	The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for certification to the Standard. Relevant departmental managers or their deputies shall be available as required during the audit. A member of the senior management team on site shall be available during the audit for a discussion on effective implementation of the food safety and quality culture plan.

Clause	Requirements
Interpretation	**Senior management attendance at the audit** For a site to successfully complete a BRCGS audit, it will be necessary to involve a range of different site colleagues, including senior managers, section heads and staff responsible for completing specific activities. Involving a range of site colleagues in this way has a number of advantages, including: • It allows the individuals that are responsible for, or who complete, specific activities to explain them and discuss any questions the auditor may have, ensuring that the auditor receives detailed, up-to-date information, and can observe the activity in action. • It allows members of the team who are not currently needed for the audit to complete other duties, either as part of their normal work or preparation for other parts of the audit; for example, compiling the information for the vertical audit. • It indicates a positive product safety culture, where management encourages staff of all levels to be involved in the audit process. As a minimum the most senior production or operations managers on site (i.e. those who are responsible for the hands-on, daily running of the site) must participate in the opening and closing meetings of the audit. The objective is to ensure that non-conformities are effectively understood and agreed; therefore this site representative will need to be sufficiently senior to make decisions regarding any non-conformities and the corrective action to be taken. The auditor will also need to discuss food safety and quality culture and the site's implementation of its plan to improve the culture with this manager or an appropriate member of the senior management team. It may be the case that the most senior operations managers within the company are absent on the day of the audit because of other commitments, especially where an audit is unannounced; however, there must always be a nominated deputy available (clause 1.2.1).
1.1.12	The site's senior management shall ensure that the root causes of any non-conformities against the Standard identified at the previous audit have been effectively addressed to prevent recurrence.
Interpretation	**Recurring non-conformities** An important aspect of the Standard is to encourage continual improvement of product safety processes (e.g. see the statement of intent for section 1.1) and the prevention of non-conforming situations is one aspect of this. Therefore, non-conformities identified in the previous certification audit must have been fully and effectively rectified (i.e. corrective and preventive actions completed) and these will be checked during the current audit. Therefore, for each non-conformity at the last audit, the auditor will expect to see: • **Corrective action** The site will have completed its corrective action within 28 days of the last audit. The auditor will therefore expect to see this action in operation (e.g. that the updated procedure submitted to the certification body as evidence of corrective action is in use, or that repairs have been completed and remain effective).

Clause	Requirements
Interpretation *continued*	• **Preventive action** At the time when the certificate was awarded, the site will have submitted a preventive action plan, but may not have completed all of the preventive action. The auditor will therefore expect to see evidence that the site implemented preventive action and that recurrence of the non-conformity has therefore been effectively prevented. • **Root cause analysis** Root cause analysis is used to identify the fundamental or root cause of a non-conformity, and is therefore a key activity in establishing appropriate preventive action. Although the site submitted the root cause analysis following the previous audit, the auditor may need to review this; for example, if preventive action has been ineffective at preventing the non-conformity. This process is detailed in Part III of the Standard, section 2.3.2. Many sites have found it useful to retain copies of records and documents implicated by non-conformities with the audit records. This allows quick and easy reference to the specific document while reviewing, investigating and correcting the non-conformity. (The original copy of the document, should, of course, be returned to the appropriate place in the site's quality system.) Note that additional information on preventive action and root cause analysis, and non-conforming situations which require their use, is detailed in Part II, section 3.7 of the Standard, and especially clause 3.7.2. A site's attitude towards preventive action may also indicate its product safety culture. For example, minimal follow-up, or preventive action that is just seen as a necessary document to pass an audit, may be a sign of a poor culture. BRCGS has published a guideline to understanding preventive action and root cause analysis which explains some of the techniques available for identifying the cause of non-conformities and preventing them from recurring. The guideline is available from the BRCGS Store or viewed online at BRCGS Participate. If effective corrective or preventive action has not been introduced (e.g. it has been ineffective at preventing recurrence), a non-conformity may be raised against this clause, in addition to a non-conformity against the clause that has the recurring issue.
1.1.13	The BRCGS logo and references to certification status shall be used only in accordance with the conditions of use detailed in the audit protocol section (Part III, section 6.7) of the Standard.
Interpretation	**Use of the BRCGS logo** Sites that have gained certification against any of the BRCGS Standards are entitled to demonstrate their pride in their achievement and use the BRCGS certification logo for marketing purposes. This means the logo can be used on websites, letter headers, business cards, etc. However, the logo is not a product certification mark, so it (or words stating that the product was produced in a BRCGS-certificated site) cannot be used on product packaging. The rules around logo use are highlighted in the protocol of the Standard (Part III, section 6.7) and further guidance is available in the Brand Guidelines on the BRCGS website. Where an auditor finds consumer-facing packaging with any BRCGS logo or wording during an audit, they will raise a non-conformity.

Clause	Requirements
1.1.14	Where required by legislation, the site shall maintain appropriate registrations with the relevant authorities.
Interpretation	**Registration of food production sites** In countries, states or territories where there is a legal requirement to register premises as food production sites, there must be documentary proof that the site has been appropriately registered. The clause is not limited to food defence, but to all requirements for food manufacturing, food safety, authenticity, food defence, etc. However, the clause does not cover other legal registrations related to personnel, health and safety (such as fire regulations) or employment law, as these are outside the scope of the Standard. Examples of registration include: • EU requirements detailed in EC Regulations No. 852/2004 on the Hygiene of Foodstuffs, Article 6(2) and No. 853/2004 for animal products processing • FDA registration requirements in the US • registration with the local authority in the UK.

1.2 Organisational structure, responsibilities and management authority

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

Interpretation

This section has three key objectives, to:

- facilitate clear communication of the roles and responsibilities for food safety, authenticity, legality and quality, and ensure that staff are aware who has these responsibilities
- ensure responsible individuals have the knowledge and ability to fulfil the role
- empower staff to communicate any concerns relating to product safety, authenticity, legality or quality to the relevant individuals, to facilitate a timely response where action is required.

Clause	Requirements
1.2.1	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, authenticity, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.
Interpretation	**Organisational charts and assignment of responsibilities** An organisational chart must be available, clearly indicating reporting lines for all managers on the site and, where applicable, relationships to the company head office roles. The chart would normally be expected to show both a position and the named person occupying that position. Where the chart shows job titles only, other documents must indicate the person occupying each position.

Clause	Requirements
Interpretation *continued*	The chart or associated documentation needs to clearly indicate the responsibilities of each relevant member of staff with responsibility for the management of food safety, authenticity, legality or quality. Examples include technical managers, quality assurance staff, section heads/managers (e.g. those accountable for overseeing production and cleaning activities (i.e. those responsible for ensuring the correct standards are maintained)), any on-site laboratory staff and product development teams. Responsibilities must be defined for key aspects of the food safety and quality management system, including, for example, decisions on corrective actions, non-conforming products, process deviations, finished product release, document control and customer complaints. It is usual for specific responsibilities to be defined within the job descriptions of key staff (especially for management and supervisors); however, they may instead be described within site procedures (e.g. responsibility for decisions on corrective action may be incorporated into the site's corrective action procedure). It must be clearly documented who is expected to deputise in the absence of a manager. Deputies would usually be identified on the organisational chart and/or in job descriptions, but documentation could also be in the form of an additional table. The responsibility may be assigned to either a more senior or more junior person, as long as the deputy has the knowledge and ability to adequately cover for the absent manager. Deputies may be appointed for the whole role or particular responsibilities may be deputised to different people; as long as this is clearly defined. The auditor will be looking for both documented responsibilities and evidence that the responsible person is able to fulfil the role (clause 7.1.7 requires the company to review the competencies of staff and ensure that any necessary training, mentoring or experience is provided).
1.2.2	The site's senior management shall ensure that all staff are aware of their responsibilities and demonstrate that work is carried out in accordance with documented site policies, procedures, work instructions and existing practices for activities undertaken. All staff shall have access to relevant documentation.
Interpretation	**Staff roles and responsibilities** The objective of this clause is to ensure that all staff, including temporary staff and employment agency staff, are able to work effectively and ensure that food safety, authenticity, legality and quality are maintained. Consistent application of these systems relies on the correct and established processes being documented, accessible by relevant staff and used in practice. This will usually be established by the auditor discussing roles with the employees themselves during the audit. There is no requirement for a detailed job description; however, staff should be aware of their particular responsibilities. Where the role or an activity that makes up part of the role covers a food safety, authenticity, legality or quality issue described within a procedure (e.g. a CCP or prerequisite programme), the staff must understand what is expected and be able to access the relevant procedure.
1.2.3	Staff shall be aware of the need to report any risks or any evidence of unsafe or out-of-specification product, equipment, packaging or raw materials, to a designated manager to enable the resolution of issues requiring immediate action.

Clause	Requirements
Interpretation	**Reporting product safety risks and non-conforming product** Where a food safety risk is identified by a staff member, the reporting function and subsequent activity should be sufficiently rapid and effective to mitigate any food safety risks. Identified risks may be associated with, for example, raw materials, work in progress, final product, packaging or equipment. Good practice is to encourage staff to report as wide a range of situations as possible, including out-of-specification results, damage, errors or when the staff member is concerned that something does not look right or as it normally does. The transfer of information from staff to senior management regarding unsafe or out-of-specification situations is an example of a good food safety culture. If staff feel supported and empowered to identify and report issues and make positive changes, this will typically be reflected in the effectiveness of the site's product safety management systems.
1.2.4	If the site does not have the appropriate in-house knowledge of food safety, authenticity, legality or quality, external expertise (e.g. food safety consultants) may be used; however, the day-to-day management of the food safety systems shall remain the responsibility of the company.
Interpretation	**External expertise** Where external food safety consultants have been used as the main source of technical knowledge for a specific activity (e.g. to lead the development of the food safety plan or HACCP plan) it is essential that day-to-day responsibilities are under the control of the site and that it has personnel in place with working knowledge of the product safety systems, who can operate effectively even when the consultant is not available. For example, the requirements of clause 1.2.1, regarding deputies and documented procedures, apply even where a food safety consultant is used. A food safety consultant is seen as a service provider to the site and is therefore subject to the requirements of section 3.5.3.

2 The food safety plan – HACCP

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

Interpretation

The purpose of these requirements is to create a food safety plan to mitigate food safety hazards. The foundation of this food safety plan is a hazard and risk analysis. In order to be effective this analysis must be systematic, science-based, thorough, fully implemented and kept up to date.

In the food industry, the principles for assessing hazard and risk are commonly referred to as HACCP. However, the specific terminology used in the Standard, such as prerequisites and critical control points (CCPs), are drawn from global terminology used to describe expectations. Sites are not required to use the specific terminology used in the Standard; alternative terminology is acceptable, providing it is evident that all the requirements have been fully met. For example, legislative requirements in the US (detailed in the Food Safety Modernization Act) use different terminology but still incorporate all the requirements of the Standard.

Sites are advised to avoid having multiple plans with different terminology as this is administratively complex and unnecessary. (It may, of course, be appropriate to have multiple plans where a site produces different types of products with different product safety hazards, but common terminology should be used throughout.)

Regardless of the terminology used the food safety plan must incorporate all of the Codex Alimentarius HACCP principles. The clauses in Issue 9 have been updated to reflect the latest publication of the Codex Alimentarius HACCP principles, therefore where it is evident that all the requirements in section 2 have been fully met, a site will not be expected to undertake additional activities to meet the Codex Alimentarius principles.

The plan must be specific to the products manufactured, processed or packed on site and the production processes used.

Codex Alimentarius has published background information and extensive guidance on the HACCP principles which can be found in the General Principles of Food Hygiene (CXC1-1969) last updated in 2020. It can be downloaded from the **Codex Alimentarius** page on the FAO's website.

BRCGS offers training on HACCP implementation. **Details are available** from the BRCGS website.

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

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

Clause	Requirements
Interpretation	**The HACCP food safety team (aligned with Codex Alimentarius Step 1)** For a comprehensive HACCP or food safety plan to be established, maintained and kept up to date it needs to be managed by a nominated team with suitable training, relevant skills and experience. The number of HACCP food safety team members needs to be appropriate to the size and structure of the company, as the team will include representatives of each department with responsibility for the operation of the Standard (e.g. technical, quality assurance, purchasing, engineering, new product development, hygiene/sanitation and senior leadership team). There will always be more than one person, since a single person does not constitute a 'team'. The team needs knowledge of the types of operations that are carried out at the site and the hazards these operations may present to the product. It is good practice to document the team members within the study, with a summary of their roles, experience and areas of responsibility within the company. Membership of the HACCP food safety team needs to be reviewed and, when necessary, updated (e.g. when job responsibilities change or personnel leave or join the company). The team leader must be able to demonstrate competency and experience in HACCP/food safety processes. This can be shown by: • the quality of the plan • documented evidence of their qualification (e.g. successful completion of an industry-recognised HACCP training course) • demonstrable, extensive experience in implementing or training HACCP. The team will need sufficient knowledge of HACCP processes, products manufactured on site, production processes and relevant hazards, to facilitate a thorough hazard and risk analysis and the creation of an appropriate food safety plan. This may be demonstrated by, for example, training records (see clause 7.1.6) that show adequate training (e.g. through an industry-recognised training course or good quality internal training) has been given to all HACCP food safety team members. Any format or delivery method of training is permitted; however, the outcome should be a suitably trained individual capable of executing a HACCP or food safety plan as part of their team. Where there is a legal requirement for specific training the site is expected to ensure this has been completed. Where external expertise has been used in developing the HACCP or food safety plan, the site must demonstrate ownership of the identified requirements by ensuring that the day-to-day management of the food safety system remains the responsibility of the site (see clause 1.2.4). At the audit, the competency and understanding of the HACCP/food safety plan team will be assessed, as well as the quality of the resultant HACCP or food safety plan. The site should also be able to establish the training and competence of any external consultant in HACCP/food safety principles (see section 3.5.3). Senior management commitment (clauses 1.1.1 to 1.1.14) is required to support the HACCP food safety team. This may be demonstrated by the presence of senior management within the team, policy statements referring to HACCP or food safety, or evidence within management review meetings that HACCP/food safety issues are discussed and reviewed.

Clause	Requirements
Interpretation *continued*	The existence of a food safety plan does not, in itself, guarantee product safety, and it is vital that the results of the HACCP or food safety plan are implemented, applied correctly and integrated into the food safety and quality management system.
2.1.2	The scope of each HACCP or food safety plan, including the products and processes covered, shall be defined.
Interpretation	**Scope of the HACCP or food safety plan** The scope of the HACCP or food safety plan must be identified. The scope should describe all the products and processes to be included within the study. In sites with a small range of similar products, it may be possible to incorporate all of the products and processes into a single HACCP or food safety plan; however, where there is a wide range of different products or processes with different hazards, it is likely that the site will need to use more than one plan. The format of these plans is not prescribed by the Standard; various formats are acceptable as long as the scope for each plan is clearly defined and all activities and products are covered within the processes. For example, a HACCP or food safety plan may cover each group of products with similar process characteristics, or the plan may be split into 'modules' which cover specific process steps; these modules can then be used in a 'mix and match' structure to create a HACCP or food safety plan for any given product.

2.2 Prerequisite programmes

Clause	Requirements
2.2.1	The site shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list: • cleaning and disinfection (see section 4.11) • pest management (see section 4.14) • maintenance programmes for equipment and buildings (see sections 4.4 and 4.6) • personal hygiene requirements (see section 7.2) • staff training (see section 7.1) • supplier approval and purchasing (see section 3.5.1) • transportation arrangements (see section 4.16) • processes to prevent cross-contamination (see sections 4.9 and 4.10) • allergen management (see section 5.3). The prerequisite programmes for the particular areas of the site shall take into account the production risk zoning (see clause 4.3.1). The control measures and monitoring procedures for the prerequisite programmes shall be clearly documented and shall be included within the development and reviews of the HACCP or food safety plan.

Clause	Requirements
Interpretation	**Prerequisites** The prerequisites are the basic environmental and production conditions necessary for the manufacture of safe food and the control of generic hazards. Note that the list of examples in the Standard is not exhaustive, and others will exist in some sites; for example, utilities, air and general aspects of the production environment. Sites must therefore define the full range of prerequisites applicable to their site and operations. Although the prerequisites are usually covered by day-to-day activities such as good manufacturing or hygiene practices, it is vital that they work effectively and to the correct standards as: • The prerequisite programme needs to provide a solid base on which the rest of the HACCP or food safety plan can be developed. • The company is relying on the prerequisite activities to mitigate the identified hazards and deliver safe product (e.g. if a site identifies cleaning as a prerequisite, then it relies on the cleaning activities to adequately remove food residues and dirt that might otherwise result in hazards such as allergen cross-contamination or microbiological contamination). Therefore there should be a whole work stream behind each identified prerequisite to ensure that the relevant activity, procedures and policies are in place, that they are working correctly and that they continue to deliver the level of control required. Although the prerequisite programme is expected to be effective in achieving the level of control required to ensure food safety, it is not a requirement that a documented validation of every prerequisite is undertaken, as prerequisite programmes typically cover a wide range of general environmental controls, often with results that are not quantifiable. However, where a prerequisite programme is used to manage a specific hazard (e.g. cleaning regimes used to prevent allergen cross-contamination), there needs to be a documented validation that the prerequisite controls the identified hazard (see clause 2.7.4 for further details regarding the validation). Some companies prefer to differentiate prerequisites that manage specific hazards from other prerequisites by referring to them as operational prerequisites (oPRPs). Sites that need to meet the requirements of the US Food Safety Modernization Act (FSMA) should note that they must ensure that preventive controls are subject to validation and verification. Some of these controls may cover activities that have traditionally formed part of the prerequisite programme. The clause contains references to later sections of the Standard which provide detail on the requirements for effective management of some specific prerequisites, including cleaning (section 4.11), pest management (section 4.14) and training (section 7.1). These are not intended to be an exhaustive list of all prerequisites or all the relevant sections of the Standard. The prerequisite programmes are often dependent on the production risk zoning (see clause 4.3.1); for example, cleaning within a high-risk zone. Therefore it may be necessary to place greater attention on some prerequisites that are particularly important for food safety in those specific zones. Good practice is to review the prerequisite programmes and their management. The frequency of this review should be based on risk, but it could be included, for example, in the annual review of the HACCP or food safety plan.

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

Clause	Requirements
2.3.1	A full description for each product or group of products shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list: • composition (e.g. raw materials, ingredients, allergens, recipe) • origin of ingredients • physical or chemical properties that impact food safety (e.g. pH, a_w) • treatment and processing (e.g. cooking, cooling) • packaging system (e.g. modified atmosphere, vacuum) • storage and distribution conditions (e.g. chilled, ambient) • maximum safe shelf life under prescribed storage and usage conditions.
Interpretation	**Product description** A full description of the product is required to ensure that all aspects that could potentially affect food safety are considered. The Standard gives guidance on the factors that may be considered: • composition (e.g. raw materials or ingredients used, allergens, recipes) • origin of the ingredients (e.g. climatic conditions, culture or food safety standards may make some countries a greater risk than others) • physical or chemical properties that impact food safety (e.g. pH, a_w) • treatment and processing conditions (e.g. cooking, chilling) • product packaging system (e.g. modified atmosphere, vacuum packing or canning) • storage and distribution conditions (e.g. chilled, frozen or ambient) • maximum safe shelf life under prescribed storage and usage conditions. Good practice is not to simply describe the product, but to consider the possible implications of what will be needed later in the HACCP study. For example, when considering the origin of ingredients, rather than just stating the material comes from a specific country or region, it may be useful to consider whether the potential climatic conditions, culture or food safety standards in the country change the hazards. Product groups can be used where the products are similar (e.g. different pack sizes). However, where significantly different products (e.g. coated and non-coated meat products) are manufactured, these are to be treated as separate products or groups.

Clause	Requirements
2.3.2	All relevant information needed to conduct the hazard analysis shall be collected, maintained, documented and updated. The company shall ensure that the HACCP or food safety plan is based on comprehensive information sources, which are referenced and available on request. As a guide, this may include the following, although this is not an exhaustive list: • the latest scientific literature • historical and known hazards associated with specific food products • relevant codes of practice • recognised guidelines • food safety legislation relevant for the production and sale of products • customer requirements • a copy of any existing site HACCP plans (e.g. for products already in production at the site) • a map of the premises and equipment layout (see clause 4.3.2) • a water distribution diagram for the site (see clause 4.5.2) • indication of any areas (zones) where high-risk, high-care or ambient high-care production facilities are required (see clause 4.3.1).

Interpretation

Sources of information

Up-to-date background information must be taken into account when preparing the HACCP or food safety plan. Therefore, suitable information must be collated and maintained.

There are many sources of information, particularly on the internet; for example, Codex Alimentarius, European Food Safety Authority, US Food and Drug Administration, or the Rapid Alert System for Food and Feed (RASFF). Sources of information must be referenced in the HACCP or food safety plan and be recoverable or available on request (using an internet search engine to find the information during an audit is not acceptable, as this implies that the information was not collected and maintained for use during the development of the HACCP or food safety plan). A list of legislation and codes of practice referenced may be helpful.

Many membership organisations also provide useful information. Where membership information is referenced, this also needs to be available on site (either electronically or as hard copy).

The Standard gives some guidance on the types of information that may be considered in developing the HACCP or food safety plan. These include:

- the latest scientific literature (good practice is to understand the source of the material; for example, peer-reviewed science may have greater validity and usefulness)
- historical and known hazards associated with specific food products (good practice is to be as specific as possible, giving, for example, the name of the micro-organism(s) that are known hazards to the product, rather than just listing 'bacteria')
- relevant codes of practice
- recognised guidelines – for example:
  - material provided on BRCGS Participate
  - publication by regulatory authorities
  - publications available from industry experts, trade associations, etc.
- food safety legislation relevant for the production and sale of products in destination countries, states or territories

Clause	Requirements

Interpretation
continued
	• customer requirements
	• existing HACCP plans; i.e. plans from products that are already in production. There are two uses for the existing plan:
	  • learnings from previous plans may provide a useful reference
	  • existing products, ingredients or processes within the same manufacturing area may result in additional risks that need to be managed
	• a map of the premises and equipment layout
	• a water distribution diagram
	• indication of any production risk zoning.

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

Clause	Requirements
2.4.1	The intended use of the product by the customer, and expected alternative uses, shall be described, defining the consumer target groups, including the suitability of the product for vulnerable groups of the population (e.g. infants, elderly, allergy sufferers).
Interpretation	**Identify the use** The HACCP food safety team needs to consider and document the intended use of the products by the customer and the ultimate consumer to ensure all the risks have been assessed. For example, the team should consider: • the target population (e.g. does this include high-risk groups such as infants, elderly people or allergy sufferers?) • handling and preparation (e.g. will the product be consumed without further cooking?) • the customer supply chain • storage (e.g. frozen, or the requirement for chilled storage after opening the pack). Where there is an expected alternative food use for a product, including the potential for a customer or consumer to misuse or mistreat the product in a way not intended by the manufacturer, this information should be included in the description in the HACCP assessment so that any implications can be considered as part of the subsequent hazard analysis. This alternative use may occur in the consumer's home (e.g. consumption of a product that looks ready to eat without completing the correct cooking) or elsewhere in the supply chain (e.g. an unintended use of a raw material). A number of product recalls have occurred, for example, with frozen raw vegetables and coated/battered poultry products due to unintended use of the product. Inclusion of intended and expected alternative uses of a product can also provide a useful due diligence reference demonstrating to a customer or regulatory authority the scope of hazards that have been considered.

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

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

Interpretation

Process flow diagram

The process flow diagram provides the site with an important tool, allowing it to evaluate the possible introduction, occurrence or change of hazards at each step of the process. It should therefore be used when identifying hazards (see clause 2.7.1) and conducting hazard analysis (see clause 2.7.2).

Therefore, an accurate flow diagram indicating all the process steps, including all inputs and outputs, needs to be constructed for each HACCP or food safety plan. This may be achieved with a single diagram, or it could be in a modular form with several documents compiled to provide the complete information (in this situation it must clearly identify the interaction between the process steps). The Standard lists guidance on the points to consider and include when developing the flow diagram; for example:

- a plan of the premises and equipment layout to facilitate consideration of cross-contamination risks (e.g. allergen control)
- raw materials – it should be clear where raw materials are stored and the routes they take into the production area; this includes the introduction of utilities and other contact materials (e.g. water or packaging)
- sequence and interaction of all process steps (e.g. method of transportation between each step)
- outsourced processes and subcontracted work, including, for example, off-site processing, storage, packing or transport
- potential for process delay (i.e. how products or ingredients will be handled if a delay occurs)
- rework and recycling
- low-risk/high-risk/high-care segregation (i.e. clearly indicating where the different production zones are located)
- finished products, intermediate/semi-processed products, by-products and waste (e.g. where waste products leave the production process, and the storage of intermediates and finished products).

Clause 3.2.1 of the Standard requires the site to have an effective document control system. Signing and dating the approved process flow diagram is one method of demonstrating that this is occurring.

Clause	Requirements
Examples	There is no set pattern or format for the diagram. However, it is important to show all the steps in the process, from raw materials through to final products, as shown in Figure 1.

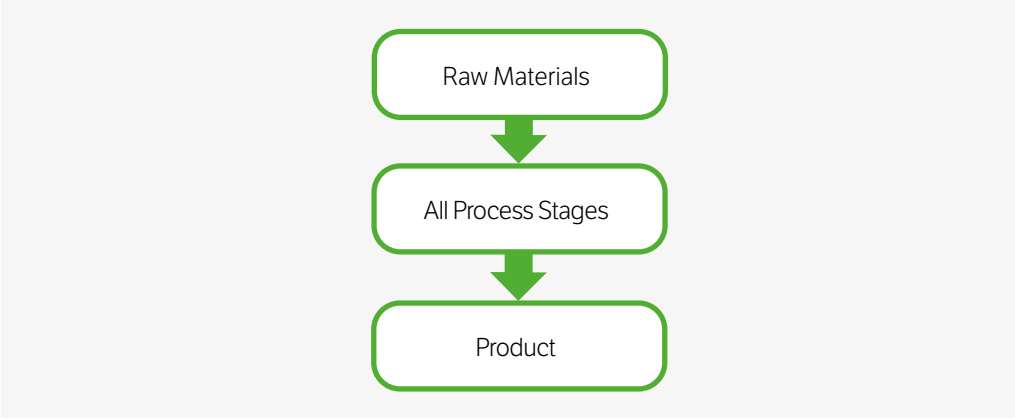

Figure 1 Example of a process flow diagram: linear

All products must be covered in the diagram, so if your site has a wide range of similar products or processes, a modular option may be preferable; Figures 2 and 3 show examples. Otherwise a separate linear diagram is needed for each product; i.e. 20 products would need 20 linear process flow diagrams.

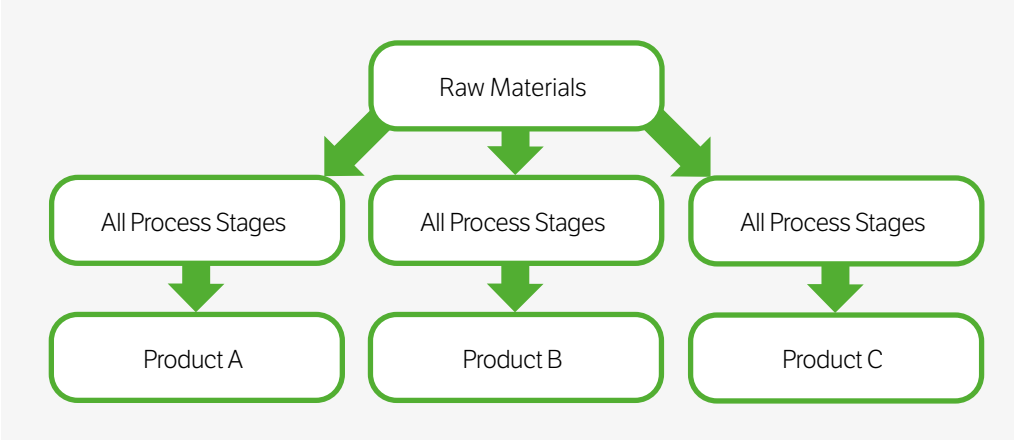

Figure 2 Example of a modular process flow diagram (1)

Clause	Requirements
Examples *continued*	

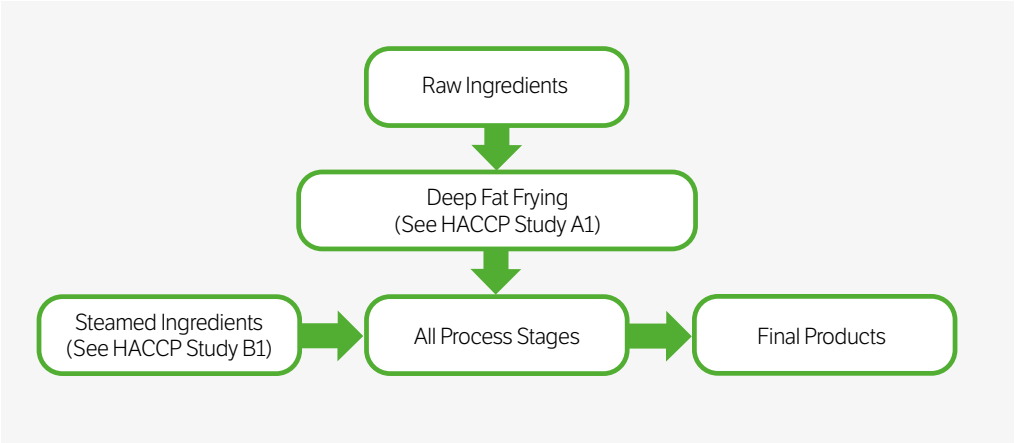

Figure 3 Example of a modular process flow diagram (2)

If you use a modular or generic diagram, take care to ensure that it includes all steps and all products. If your site manufactures multiple products that are considerably different or require different processes, you will need to have several separate diagrams.

In addition to the process steps, the diagram needs to contain:

- all raw materials used in the manufacture of the product(s), including the introduction of utilities and other contact materials (e.g. water or packaging)
- details of any outsourced or subcontracted process (i.e. any activity that is part of the production process but does not occur on site)
- rework or recycling
- low-risk, high-care and high-risk segregation
- routes taken by waste products
- all finished products, intermediates, semi-processed products or by-products.

Examples of completed process flow diagrams are shown in Figures 4 and 5.

Clause	Requirements

Examples
continued

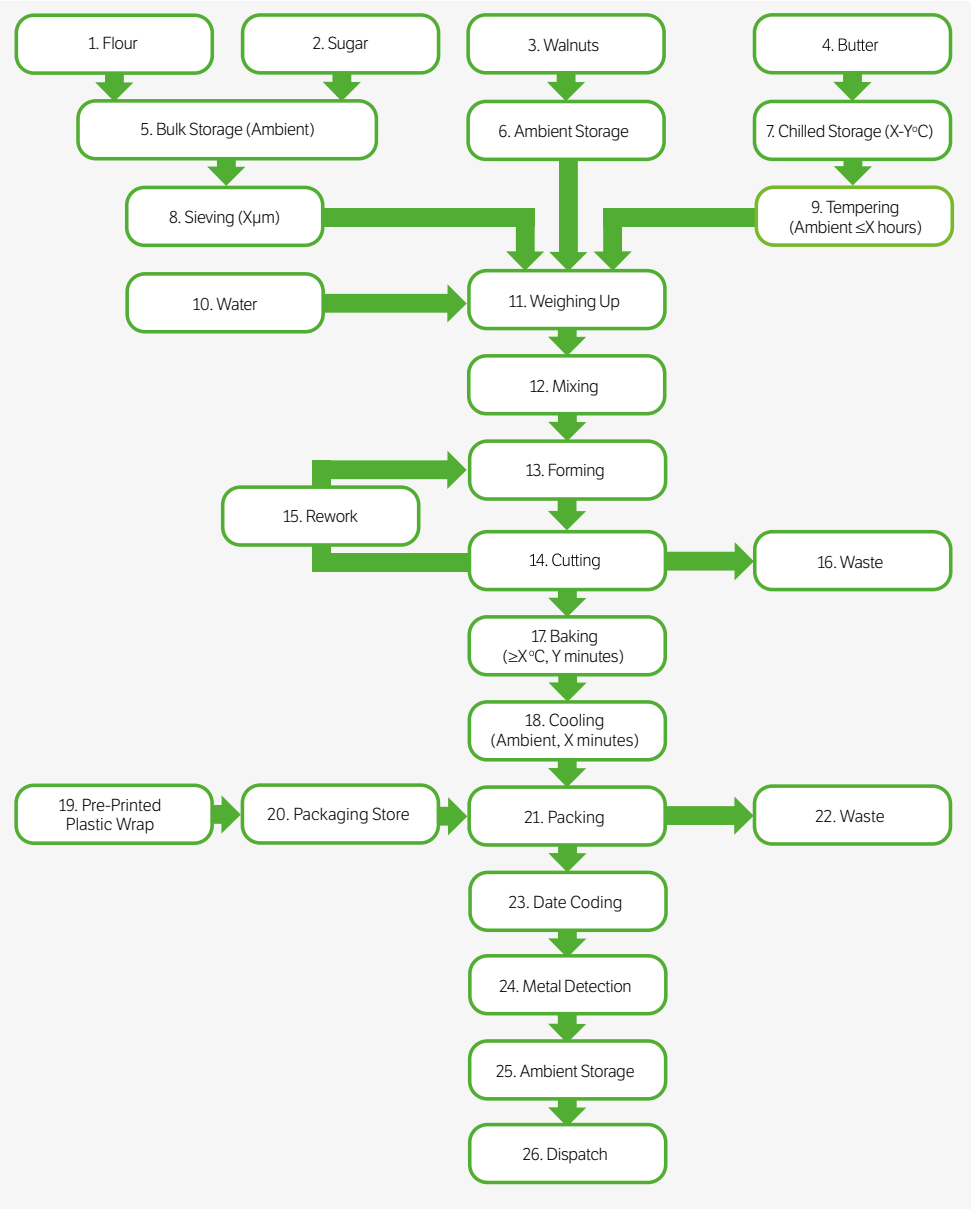

Figure 4 Example of a completed process flow diagram: walnut biscuit

Clause	Requirements
Examples *continued*	

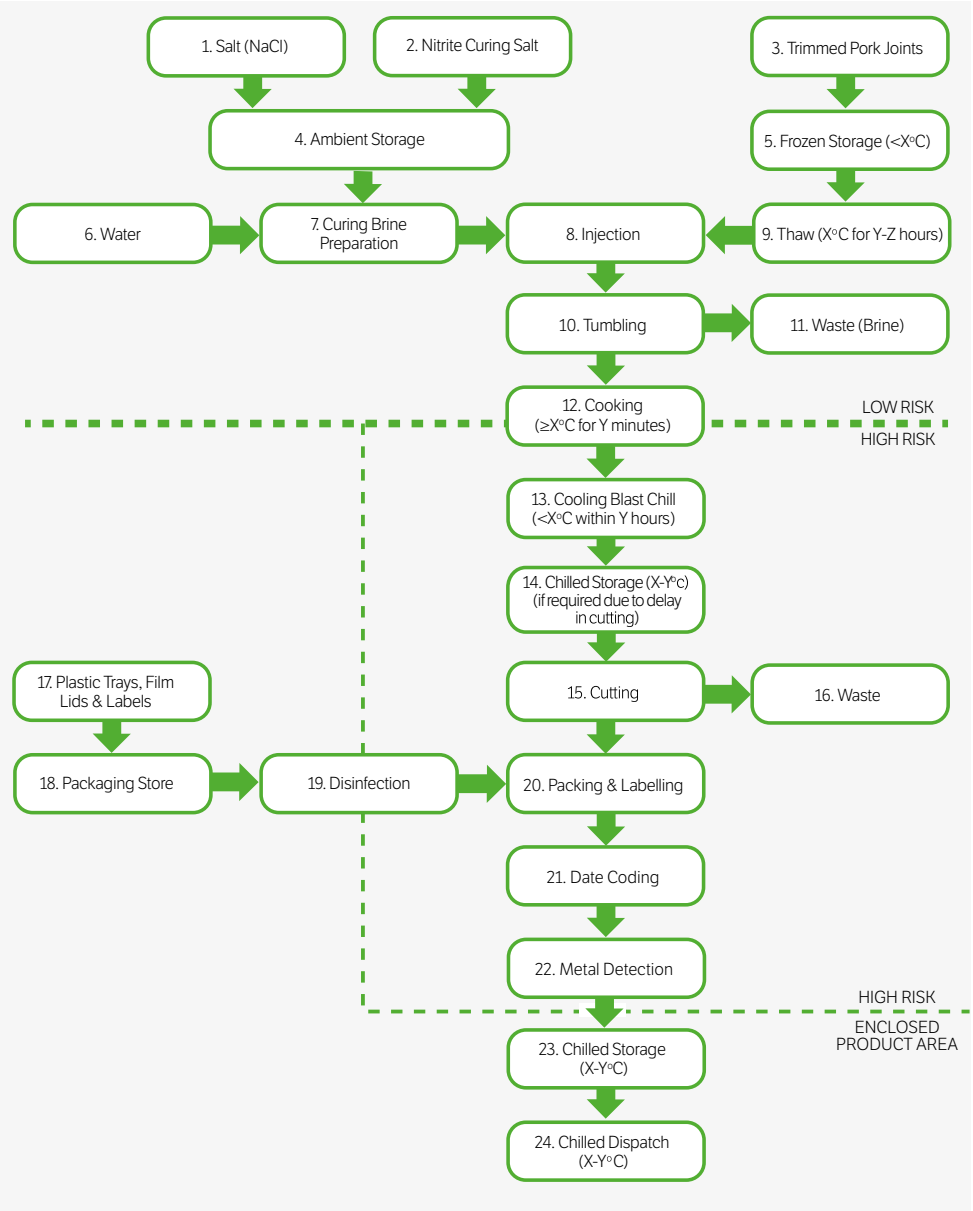

Figure 5 Example of a completed process flow diagram: cooked cured meat

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

Clause	Requirements
2.6.1	The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit at least annually, and whenever there are changes to the process, to ensure any changes have been considered as a part of the HACCP or food safety plan. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.

Clause	Requirements
Interpretation	**Verifying the flow diagram** The flow diagram shall be verified as accurate. A member of the HACCP food safety team who is based at the site, part of the team, or the whole team must check that the flow diagram is accurate by on-site audit. This may be achieved using a physical walk-through of the process within the production area. A report of the activity and any findings will help to demonstrate that this has been completed. During the BRCGS audit, the auditor will confirm the accuracy of the documented process flow diagram by following the process in production. It is vital that the process flow diagram remains up to date; therefore verification should occur whenever there is a review of the HACCP or food safety plan (e.g. whenever there is a change to the plan or operational activity) and at least once per year. For example, the manufacture of a new product (see clause 5.1.2) should result in a HACCP review to confirm that any hazards to existing products have been managed appropriately, as well as ensuring that any hazards affecting the new product are controlled. It is important that any daily (e.g. different shifts, including any night or weekend shifts) or seasonal variations are considered during the verification process (e.g. the production of a Christmas range that uses ingredients or processes not used during the rest of the year or significant changes in production volume). The site must retain records of the diagrams and verification activities. For example, a verification record could include an annotated diagram showing: • the date and time of the verification • the product(s) being manufactured at the time the activity was observed • any amendments or alterations that were noted. Alternatively, a separate report could be produced in the format of an internal audit. The records should also be signed to confirm who completed the verification.

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

Clause	Requirements
2.7.1	The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and consideration of the following types of hazard: • microbiological • physical contamination • chemical and radiological contamination • fraud (e.g. substitution or deliberate/intentional adulteration) (see section 5.4) • malicious contamination of products (see section 4.2) • allergen risks (see section 5.3). It shall also take account of the preceding and following steps in the process chain.

Clause	Requirements
Interpretation	**List of potential hazards** It is expected that the list will include specific hazards. The Standard provides examples of those that should be considered, including: • specific micro-organisms (e.g. *E. coli* or *Salmonella*) • specific chemicals (e.g. veterinary residues, pesticides or radiological contaminants) • cleaning chemicals • machinery lubricants • specific foreign bodies (e.g. glass, metal or plastic) • specific allergens (e.g. peanuts or egg); i.e. those identified by the company, materials that are considered allergens in the country of intended sale and any customer requirements • the potential for fraud and/or adulteration • malicious tampering with the product or processes. It is important that the company considers all relevant potential hazards from all relevant sources. These could include raw materials, processes and the factory environment. The process flow diagram is a useful tool in considering the potential risks at each stage of production. Some sites find it useful to consider each hazard, at each step, in terms of: • whether the hazard is likely to be present in, for example, the raw material or the processing environment • whether there is the potential to introduce or create a specific hazard at the step in the process being considered • if there is the potential for growth of micro-organisms • whether the hazard will survive the processing step; for example, whether a pathogen can survive in the product, or whether the contaminant is stable to the process being completed (e.g. heat stable). There must be a description of each hazard and its sources – one hazard may have several potential sources and occur at more than one point in the process. This is important to ensure that effective controls for each source of hazard are established in the subsequent steps of the process. The Standard has referenced food fraud and malicious contamination (food defence) in the list of hazards in this clause to draw attention to the need to include these within site assessments. However, later sections of the Standard (sections 4.2 and 5.4) provide greater detail on the expected activity in these areas. This clause does not require those assessments to be repeated or duplicated (as part of the HACCP plan, and then in compliance with sections 4.2 and 5.4) – separate assessment processes are acceptable and the site can reference the additional assessment within the HACCP plan. However, the outputs from those separate assessments must be considered as part of this process, to ensure that the correct controls, monitoring, verification, etc. are in place. The aim of including radiological hazards within the clause is to consider potential contamination by radioactive isotopes (a legal requirement in some countries) which may be present in water or soil (either from a naturally occurring source or resulting from contamination caused by humans). A number of authorities produce reports on known radiological hazards; for example:

Clause	Requirements
Interpretation *continued*	In the UK: • FSA: **Radioactivity in Food and the Environment (RIFE)** • UK Health Security Agency: **Three Steps to Manage Radon in Buildings – Check, Measure, Act** • UK government: **Radioactivity in Food and the Environment (RIFE) Reports**. In the US: • FDA: **FDA Response to the Fukushima Daiichi Nuclear Power Facility Incident**. In Ireland: • EPA: **National Radiation Monitoring Network**
2.7.2	The HACCP food safety team shall conduct a hazard analysis to identify the significant hazards (i.e. those hazards that are reasonably likely to occur at an unacceptable level), which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to the following: • likely occurrence of hazard • severity of the effects on consumer safety • vulnerability of those exposed • survival and multiplication of micro-organisms of specific concern to the product • presence or production of toxins, chemicals or foreign bodies • contamination of raw materials, intermediate/semi-processed product, or finished product. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.
Interpretation	**Hazard analysis** Any hazards identified in clause 2.7.1 must be evaluated against the criteria detailed in this clause to identify those which are significant. For the purposes of the Standard a significant hazard is a hazard identified by the hazard analysis, which is reasonably likely to occur in the absence of a control, at an unacceptable level (i.e. a level that would be considered unsafe or illegal), and therefore control is essential for the production of a safe product. The HACCP food safety team must therefore take into account: • the likely occurrence of the hazard, taking into consideration existing prerequisite programmes, the nature of the facility and the equipment used • the severity of the effects on consumer safety • the vulnerability of those exposed • the survival and growth of micro-organisms (i.e. those of concern to the product(s) within the scope of the HACCP or food safety plan) • the presence or production of toxins, chemicals or foreign bodies • contamination of raw materials, intermediates, semi-processed product or finished product. Evidence of the decisions, along with the justification for the decision and the decision-making process, must be kept within the HACCP or food safety plan.

Clause	Requirements
Interpretation *continued*	There are a range of tools that may assist with the evaluation of hazards (e.g. quadrant graphs, scoring systems, logic tables or decision trees). The team may choose to use these tools but should keep a record of any that are deployed. Such tools may also help in establishing CCPs. It is useful to remember that the quality of the output from the assessment depends on the quality of the data or evidence used. The hazard analysis should, wherever possible, be based on demonstrable evidence such as documented validation studies, trend analysis and science-based literature. Where this information is not available at the site, it may be necessary for the site to obtain it from suppliers or reputable external sources to establish the likelihood or severity of the specific hazards. Where elimination of a hazard is not possible, acceptable levels need to be defined. Reference should be made to legal requirements or scientific evidence to justify the acceptable levels (e.g. microbiological standards or presence of mycotoxins).
2.7.3	The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Consideration may be given to using more than one control measure.
Interpretation	**Control measures** Control measures required to reduce or eliminate the specific hazards (i.e. each hazard identified in clause 2.7.1) must be established. Any hazard that cannot be eliminated must have control measures designed to reduce it to an acceptable level of presence. This acceptable level (e.g. setting a target of <100 cfu/g of *Staphylococcus aureus* in finished product) needs to be justified; in other words the site should understand the potential consequences of the hazard and be able to demonstrate that the acceptable level will adequately protect the consumer. Industry guidelines, codes of practice, legislation etc. can help to establish and justify these levels.
2.7.4	Where the control of a specific food safety hazard is achieved through prerequisite programmes (see section 2.2) or control measures other than critical control points (CCPs; see clause 2.8.1), this shall be stated and the adequacy of the programme to control the specific hazard validated.
Interpretation	**Validation of prerequisites** It is important that all controls are effective and consistently prevent identified hazards from occurring. Therefore where specific hazards are controlled by mechanisms other than CCPs (e.g. by prerequisite programmes or other control measures) these also need to be validated. It is not a requirement that a documented validation of every prerequisite is undertaken, as prerequisite programmes typically cover a wide range of general environmental controls, often with results that are not quantifiable. However, where a prerequisite programme is used to manage a specific hazard (e.g. cleaning regimes used to prevent allergen cross-contamination), there needs to be a documented validation that the prerequisite controls

Clause	Requirements
Interpretation *continued*	the identified hazard. Some companies prefer to differentiate these prerequisites that manage specific hazards from other prerequisites, by referring to them as operational prerequisites (oPRPs). Examples of prerequisites that require validation include: • control of allergen cross-contamination by cleaning the production equipment. Evidence is required that the cleaning regime can effectively and consistently remove the allergen (examples of how this might be achieved are given in the guidance to clause 5.3.8). • chilled storage conditions for product safety. The defined storage temperature must be validated by reference to technical literature, confirming the control of growth of relevant spoilage or food poisoning organisms. The storage facility must be validated as being capable of consistently delivering the defined temperature. Prerequisites used to control specific hazards must also be subject to routine verification and monitoring, and records should detail the control measures and monitoring procedures used (see clause 2.12.2 for full details of this requirement).

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

Clause	Requirements
2.8.1	For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. CCPs shall be those control points which are required in order to prevent or eliminate a food safety hazard or reduce it to an acceptable level. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be modified at that step, or at an earlier step, to provide a control measure.
Interpretation	**Determine the critical control points – Codex Alimentarius Step 7, Principle 2** Each control measure must be examined to identify which are critical (i.e. to identify the points at which control can be applied). This is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Records must be available showing how this has been conducted and how decisions have been reached. The Standard is not prescriptive on the tools used to facilitate this process; for example, a two- or four-question decision tree may be useful. The site must, however, be able to demonstrate that it has used a logical approach and, therefore, a copy of any decision-making tools used and the results (e.g. the results of the questions from the decision tree) must be recorded. If a hazard has been identified as critical but there is no control measure at that step or any other, the product or process should be modified so that a suitable control measure can be incorporated either at this step or at an earlier point in the process. Sites working in accordance with the US Food Safety Modernization Act (FSMA) are likely to find that the preventive controls required by that legislation include all of the controls that would normally be identified as CCPs using a HACCP system. For example, CCPs are known

Clause	Requirements
Interpretation *continued*	as process preventive controls (PPCs) in an FSMA-compliant food safety plan. For certification purposes, it does not matter which terms are referenced as their management (for certification purposes) would be the same. Other preventive controls are historically treated as PRPs (prerequisite programmes) in many sites. In some cases, parts of them are elevated to preventive controls; these include food allergen, sanitation, supply chain, based on known or reasonably foreseeable risk of a serious adverse health consequence or death to humans or animals (SAHCODHA) hazard. Where the management components of those preventive controls do not contain all the same elements of the CCPs/PPCs it is expected that the site would combine the most stringent requirements of FSMA and the Standard together. For example, a sanitation preventive control does not require validation for allergen cleaning under FSMA but it is required by the Standard (see clause 2.7.4), therefore the Standard expects additional compliance with this requirement. Auditors shall be looking to confirm that the site has identified the correct points at which control should be exercised by the appropriate control mechanisms.

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

Interpretation

Once the HACCP or food safety team has identified all the relevant CCPs, it must then identify critical limits. The critical limit is the point that separates safe from unsafe or acceptable from unacceptable product.

Some critical limits are defined by legislation; however, many will require experimental results, the advice of appropriate industry specialists or consideration of customer requirements.

Clause	Requirements
2.9.1	For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be: • measurable wherever possible (e.g. time, temperature, pH) • supported by clear guidance or examples where measures are subjective (e.g. photographs).
Interpretation	**Critical limits** All identified CCPs must have defined critical limits – the point that, if properly and consistently implemented, separates safe from unsafe or acceptable from unacceptable product. Wherever possible the criteria used should be objective (i.e. measurable), such as the temperature, time, moisture level, pH and a_w. Where objective criteria are not available, subjective parameters can be used. These may include sensory parameters such as visual appearance and texture, but they must be supported by clear guidance or examples. Photographs of acceptable and unacceptable limits or product samples for comparison could be shown as examples to staff at process control points.

Clause	Requirements
Interpretation *continued*	Good practice is often to identify action limits as well as critical limits with the aim of ensuring the measured parameter remains controlled; i.e. to identify a point at which action can be taken or a review completed, when the product or process is approaching the critical limit, but prior to it actually exceeding the critical limit. Details on how the critical limits have been determined must be documented; these may include industry best practice, legislation or validation studies undertaken by the company.
2.9.2	The HACCP food safety team shall validate each CCP, including critical limits. Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.
Interpretation	**Validation and documentation of critical limits** Documented evidence must be available showing how the control measures for CCPs and critical limits have been validated to ensure they control, reduce or eliminate the hazard to an acceptable level. Validation must be specific and demonstrate that if the control measures are followed as specified and the critical limits are met (at minimum and maximum levels where a range is indicated), a consistently safe product will be produced. Evidence could come from professional bodies, trade associations, historical processing data, scientific and technical literature or legislation. In addition, scientifically valid experimental or pilot plant trial data or exercises, such as challenge testing, may be required to confirm the capability of the process.

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

Interpretation

Monitoring is a planned set of checks or measurements for each CCP to ensure it is consistently meeting the identified critical limit. Monitoring must be recorded in terms of both the procedures to be followed and the results obtained.

Clause	Requirements
2.10.1	A monitoring procedure shall be established for each CCP to ensure compliance with critical limits. The monitoring system shall be able to detect loss of control of CCPs and, wherever possible, provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list: • online measurement • offline measurement • continuous measurement (e.g. thermographs, pH meters). Where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.

Clause	Requirements
Interpretation	**Monitoring systems** Each CCP needs to be monitored to ensure the established limits are not exceeded. This can be achieved by observing or measuring the CCP at scheduled intervals or by the use of automated continuous measurement systems. A monitoring procedure must be established for each CCP. At a minimum, this should include: • the CCP to which the procedure relates • the staff (or staff role) responsible for monitoring the CCP (clause 1.2.1 requires the staff responsible for product safety activities to be documented) • training requirements for responsible staff (see clause 7.1.2) • the frequency at which the monitoring is completed • instructions on how the monitoring is completed • the requirements for record-keeping (clause 2.10.2) • the critical limit(s). It is often useful for the procedure to include the action to be taken if the specified limit is exceeded (e.g. who to inform). Monitoring must be able to detect variation, which may result in limits being broken if no remedial action is taken. Wherever possible, monitoring must be sufficiently frequent to ensure that any necessary remedial action can be taken in adequate time so that there is no risk to the product and that no potentially affected product is released for sale or dispatched to the customer. Methods used may include online or offline measurements and may be continuous or discontinuous.
2.10.2	Records associated with the monitoring of each CCP shall include the date, time and result of measurement, and shall be signed by the person responsible for the monitoring and verified, when appropriate, by a suitably competent and authorised person. Where records are in electronic form, there shall be evidence that records have been checked and verified.
Interpretation	**Monitoring system records** The results of monitoring activities must be recorded. At a minimum, these records must include: • date and time when the measurement was made • the result • the signature of the individual conducting the monitoring • the signature of the individual (e.g. the line manager) checking and verifying the record. Records of the monitoring should be evaluated by a designated person with knowledge to confirm the acceptability (or otherwise) of the results and authority to carry out corrective actions when necessary. It is often valuable for the verification to be completed by a different individual rather than the staff member who completed the monitoring, however, this is not always possible in very small sites. This verification should be completed at appropriate frequencies which, depending on working practices, may be at identified points during the day (e.g. at the end of the shift) rather than every time a measurement is made.

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

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

Interpretation

Establish a corrective action plan

A documented procedure needs to be established, detailing the actions to be taken when monitoring indicates that limits have been exceeded or when trends suggest they may be exceeded if no remedial action is taken.

The site will need to ensure that all CCPs are covered by corrective action plans. This may be achieved by having a single corrective action document or by individual documents for each CCP. However, it is important that the identified actions are specific to each CCP and not simply generic statements.

The procedure must include:

- Authorised personnel – identify who can make decisions about product produced where limits have been exceeded and the corrective actions to be taken.
- Immediate remedial action to be taken – for example, to bring the process back within critical limits.
- Quarantine procedures – instructions on how implicated products (those that have passed through the process and may therefore have exceeded the limits) are identified, handled, isolated and/or stored until their safety status is established (e.g. products that have been metal-detected since the last satisfactory metal detector check). The handling and storage procedure must ensure that implicated product cannot enter production or be distributed to customers unless it has been confirmed as safe and released by the authorised staff.
- Disposal procedures for unsafe products.
- Additional actions that may be required (e.g. alternative processing, increased monitoring, etc.).

Good practice is to use root cause analysis, where possible, to identify and correct the fundamental cause of the out-of-specification result.

All actions should be recorded.

When investigation shows that the implicated product is safe and can be released to customers it may be necessary to review the critical limit, as the 'safe' product implies that the critical limit has not been set at the correct value.

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

Interpretation

Validation is defined as obtaining evidence through the provision of objective evidence that a control or measure, if properly implemented, is capable of delivering the specified outcome. In other words, it is objectively confirming that the plan will perform, effectively, as intended.

Similarly, verification is 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. In other words, verification seeks to answer the question, 'Has it been operating effectively, as intended?' Codex Alimentarius has published guidelines for the validation of food safety control measures (CXG 69-2008) which can be downloaded from the **Codex Alimentarius guidelines** page of the FAO's website.

Clause	Requirements
2.12.1	HACCP or food safety plans shall be validated prior to any changes which may affect product safety, to ensure that the plan will effectively control the identified hazards before implementation. For existing HACCP or food safety plans, this may be achieved using the established processes detailed in clauses 2.12.2 and 2.12.3.
Interpretation	**Validation of the HACCP or food safety plan** It is important that the site validates the food safety plan to confirm it will perform, effectively, as intended, and therefore prevent food safety hazards from occurring. In other words, the site should assess whether what it intends to put in place will actually work in practice. Obviously, to be effective this validation needs to be completed before the plan is implemented and before any changes are made (e.g. in production) that could affect food safety. In some countries (e.g. the US), there is an additional legal requirement for a revalidation after implementation, which must occur within a specified timescale, such as 90 days. This is good practice as it allows sites to consider the effects of upscaling (i.e. moving from trial systems to full production) or any other changes that may have occurred during the first few weeks of production, and therefore ensure that the plan still accurately reflects the actual production. Sites operating in countries where this is not a legal requirement may also find this a useful good-practice addition to their ways of working. There are a number of aspects of the plan that should be validated, including: • production process flow • identification of the correct hazards at the correct steps of the process • identification of the correct CCPs • the establishment of monitoring and verification activities, including what to monitor and how frequently • critical limits and the corrective actions associated with each CCP. Validation in this context could include a range of activities, depending on the relevant hazards, such as: • review of literature • mathematical modelling • validation studies • guidance from authoritative sources (e.g. legislation). It is important that the site has a mechanism to ensure that every subsequent change is captured and reviewed. This might include changes to processes or seasonality. Where a HACCP plan already exists and has been operating effectively for a period of time the validation may be achieved using established verification and review processes developed in accordance with clauses 2.12.2 and 2.12.3.

Clause	Requirements
2.12.2	Procedures of verification shall be established to confirm that the HACCP or food safety plan, including controls managed by prerequisite programmes, continues to be effective. Examples of verification activities include: • internal audits • review of records where acceptable limits have been exceeded • review of complaints by enforcement authorities or customers • review of incidents of product withdrawal or recall. Results of verification shall be recorded and communicated to the HACCP food safety team.
Interpretation	**Establish verification procedures** The HACCP or food safety plan, including controls managed by prerequisites, must be verified to ensure that it remains effective. Verification requires objective evidence that the specified requirements are being met. This may include verification that monitoring has been completed correctly, that results are understood and that appropriate corrective actions have been completed. Examples of activity that can be included in verification studies are: • internal audits (e.g. to ensure the correct procedures and work instructions are in use and that monitoring frequencies are correct) • review and trending of records (e.g. CCP monitoring records) • review of complaints by enforcement authorities or customers • review of incidents (e.g. product withdrawal or recall). The results of this verification must be documented and communicated to the HACCP or food safety team as part of the review process. Verification should be completed to a planned schedule.
2.12.3	The HACCP food safety team shall review the HACCP or food safety plan and prerequisite programmes at least annually and prior to any changes which may affect food safety. As a guide, these may include the following, although this is not an exhaustive list: • change in raw materials or supplier of raw materials • change in ingredients/recipe • change in processing conditions, cleaning and disinfection procedures, process flow or equipment • change in packaging, storage or distribution conditions • change in consumer use • emergence of a new risk (e.g. known adulteration of an ingredient or other relevant, published information, such as the recall of a similar product) • review following a significant product safety incident (e.g. a product recall) • new developments in scientific information associated with ingredients, process, packaging or product. Appropriate changes resulting from the review shall be incorporated into the HACCP or food safety plan and/or prerequisite programmes. Changes shall be fully documented, and the validation shall be recorded. Where appropriate, the changes shall also be reflected in the company's product safety policy and food safety objectives.

Clause	Requirements
Interpretation	**Review of the HACCP plan** The HACCP or food safety plan and associated prerequisite programmes must be reviewed regularly, at a minimum of once a year, even if there have been no changes to the product range or processing methods. Some or all of the plan should be reviewed whenever there is a significant change. Changes that may affect product safety, such as those listed in this clause, need to be evaluated in the context of the plan before they are introduced, and the plan amended as necessary. A procedure could be documented that lists the activities or changes which trigger a HACCP review, but this would have to be backed up by documented evidence that the review has actually been carried out (e.g. by documenting minutes of the meeting or an agreed action plan). In the case of published incidents (e.g. recalls or media stories), it is good practice to consider whether the product involved is similar to those produced at the site, and therefore whether a similar problem could occur with the site's products. Where a genuine risk is identified, the site should complete a review of the existing HACCP controls to establish whether they remain sufficient or whether amendments are required. However, it is not a requirement of the Standard to complete an in-depth analysis of every recall that occurs where no similarity or risk exists.

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

Clause	Requirements
2.13.1	Documentation and record-keeping shall be sufficient to enable the site to verify that the HACCP and food safety controls, including controls managed by prerequisite programmes, are in place and maintained.
Interpretation	**HACCP documentation** Records must be kept to demonstrate that the HACCP or food safety plan, including the prerequisite programmes, is fully implemented. This must include all the steps in creating and reviewing the plan, records of control and monitoring procedures, and training records of staff. Further details on record-keeping are available in the requirements in section 3.3 of the Standard and its interpretation.

3 Food safety and quality management system

3.1 Food safety and quality manual

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

Interpretation

A well-documented, systematic management system forms the basis for the product and process controls necessary to produce safe products, meet the requirements of the Standard, meet customer specifications and enable staff to be trained and informed.

In many instances, the Standard specifically states that requirements shall be satisfied by documented procedures; in others, this is implied as the company needs to ensure consistent application throughout the site and show that systems are in place to demonstrate food safety to external stakeholders (including regulatory authorities, customers and the BRCGS auditor). The Standard therefore requires policies, procedures, records, risk assessments, etc., to be documented in sufficient detail to achieve these aims.

The Standard does not prescribe a review frequency for the food safety and quality manual, or the documents within it; however, good practice is to update the manual, or relevant parts of it, whenever there is a change to processes or procedures.

Clause	Requirements
3.1.1	The site's procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual.
Interpretation	**The food safety and quality manual** Policies, procedures and work instructions must be in place, easily retrievable and available where needed, and must cover the requirements of the Standard. These documents must be collated into one or more quality manuals which form the reference point for all documents included in the food safety and quality system. These documents may exist on paper (i.e. as hard copy) or may be controlled on an electronic system. In either case, they should be easy to follow and kept up to date. In a small, simple operation, the manual may contain the majority of the procedures controlling the processes. In a complex operation it may contain the headline policies and indicate where more detailed operating instructions can be found. The manual should include an overview of how the company's policies and procedures are organised. This organisation should be understood by those using the documents and easily demonstrated. Where the site is part of a company governed by a head office, the interaction between the site's documented system and that of the other sites and the head office should be clear. All policies and procedures necessary for the operation of the site being assessed must be available at that site. There is no requirement for sites to have a quality manual that is numbered in accordance with the Standard's numbering system.

Clause	Requirements
3.1.2	The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to relevant staff.
Interpretation	**Availability of the manual to staff** The objective of this requirement is to ensure that key staff have access to up-to-date policies and procedures at all times and in the most appropriate format. For example, the incident management procedure should be available to the relevant team members via internet link, hard copy or other off-site format. Staff needing such documents as part of their role within the company must always have access to them. During the audit the procedures documented in the manual will be evaluated against the actual practices on the site, with the expectation that they are followed correctly.
3.1.3	All procedures and work instructions shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. This should include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language).
Interpretation	**Clear procedures and work instructions for staff** Procedures and work instructions must be documented in a clear and unambiguous format. Anyone using an authorised document must be able to understand its relevance, what it is for and how to use it. Evidence is required to demonstrate that staff clearly understand the procedures as this will be challenged by the auditor. Consideration may be given to providing procedures in appropriate languages, either written or oral, to ensure staff understand the documents and their role. Where translations are used, a record should be kept of who translated the information into which language(s). Both the translator and the recipient staff should sign the training record to indicate that the translated version has been understood. Documentation should include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient. For example, diagrams added to cleaning instructions can show clearly which pieces of equipment to remove or focus on. Signs and pictures can be particularly useful for communicating personal hygiene and protective clothing requirements.

3.2 Document control

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

Interpretation

Documents must be effectively controlled to ensure that staff are working with the most up-to-date information and to minimise the potential for mistakes. Documents include policies, procedures, work instructions, records, forms, specifications, data lists and any information that is written down and defined. They may be available on paper (i.e. as hard copy) or in electronic format.

Key documents found to be in use during the audit that have not been properly authorised or are not the correct version may lead to a non-conformity.

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

Interpretation

Documented management system

The control of all documents within the food safety and quality system (for both external and internal use) is important for several reasons, including:

- the documents are kept up to date
- staff are working with the correct version
- the potential for mistakes caused by multiple versions of a document is minimised.

Therefore all documents in use need to be properly authorised and must be the correct version.

The Standard requires the site to have a documented procedure that describes the method by which documents are controlled and managed. This procedure needs to include instructions on how the following features of the document management system are controlled:

- responsibilities for the management of the system
- list of all controlled documents, indicating the current version number and the allocation of controlled copies of the document (see below)
- identification of controlled documents (e.g. document ID, issue date, version number)
- records of the reason for any change(s) (see below)
- method of rescinding and replacing documents.

In order to demonstrate the control of document issue, it is necessary to maintain a register of all controlled documents, their allocation and issue status. Where the controlled documents are all contained on an electronic system, it is usual for printed versions to be marked as uncontrolled. Each copy must be authorised (e.g. with a signature or stamp) to show it is for use, and each must be given a version number so that out-of-date documents can be identified and removed. This must be evidenced by the fact that all documents in use are the most up-to-date versions.

Where documents are maintained electronically, the site is required to ensure that they are stored securely and cannot be amended by unauthorised persons; for example, by using individual passwords or security swipe cards. This includes backing them up appropriately to ensure no data is lost. The auditor will ask to see evidence (e.g. a procedure) that the site has an effective backup process, rather than auditing that the backup contains all the relevant files.

Clause	Requirements
Interpretation *continued*	The methodology or type of electronic storage is not specified. The site may choose to use an internal server to store data; or it may use cloud services, which are generally considered to be secure and backed up, providing there is control of authorised/authenticated users. When a document is changed, a record needs to be made of the change and the reason for it. This can be achieved by keeping a copy of the previous version with the reason for the change written on it, or by keeping a history of amendments. Consideration should also be given to the most effective method of communicating the changes to staff; for example, by highlighting the change within the new document or training relevant staff.
Further guidance	**How to put a document control procedure in place** Firstly, ensure there is a single, clear, documented system that operates across all documents within the food safety and quality management system and that it includes the minimum requirements highlighted in the Standard: • identification of the individual(s) responsible for management of the system (i.e. who is authorised to issue or amend documents). This might be someone with the authority to instigate and maintain the system • the list of all controlled documents • methods of identification of controlled documents • records regarding the reasons for any changes • the method of collecting and replacing documents. **List of documents** Your site needs a list of all the documents within the food safety and quality system. Typically this will include: • the document identification or number. The Standard does not set out how you should identify your documents, but an example format would be using sequentially numbered documents or an initial letter (often representing a department or activity) followed by a number (e.g. P0123); Figure 6 shows an example • the document title. Use a concise title that clearly explains the purpose or content of the document (e.g. 'metal detector check procedure') • the current issue or version number. Each time the document is updated, amended or replaced, a new version number should be used • the issue date. Include the date when the current version of the document first came into force • withdrawal date (if applicable) • review date (if applicable). Documents may require periodic review to ensure the information remains applicable and up to date • the allocation of controlled copies (i.e. who has a copy of the document).

Clause	Requirements

Further guidance
continued

REFERENCE NUMBER	TITLE	VERSION NUMBER	ISSUE DATE	WITHDRAWAL	REVIEW DATE	ALLOCATED COPIES
P101	Metal Detection Check Procedure	1	1 June 2019	1 January 2020	N/A	J Jones B Brown S Smith
P101	Metal Detection Check Procedure	2	1 January 2020		N/A	J Jones B Brown S Smith
P102	Product Check Weight Procedure	1	1 January 2019		N/A	S Smith G Green

Figure 6 Example of a document list

Identification and authorisation of your documents

The simplest way to identify your document is to include a footer on each page that contains the relevant information, as shown in Figure 7. This may include the:

- document reference
- issue or version number
- title of the document
- date of issue
- page number and total number of pages.

REFERENCE: P101	TITLE: METAL DETECTOR CHECK PROCEDURE	
Version Number: 2	Page: 1 of 5	Issue Date: 1st January 2020

G001	Acceptance of Raw Materials	Version 1	Page 3 of 4	Issued: 1/1/20

Figure 7 Typical formats for footers

You will need to include a method of authorisation too (e.g. a signature or a stamp that identifies genuine copies of the document). Where these are held electronically, it may be more convenient to label printed copies as uncontrolled copies.

Making changes to your documents

When a document is changed, you will need to make a note of the change and the reason for it. You can do this by:

- keeping a copy of the previous version with the reason for the change written on it, or
- keeping a 'history of amendments' log within each document; Figure 8 shows an example.

Clause	Requirements

Further guidance
continued

DATE	CHANGES
1 Jan 21	New metal detector purchased which needed to be reflected in this procedure
28 Sept 21	Frequency of checks updated to reflect requirements of a new customer

Figure 8 Example of an amendments log

A new issue or revision always replaces an existing document. You must not have two different issues or revisions of the same document at any time.

You will also need to ensure that any policy or procedure changes are communicated to the relevant staff. This can be done by highlighting the change within the new document or by specific training prior to the issue of the new version.

Replacing your documents

You will need to keep a record of all controlled documents and their allocation. This will mean that whenever a document is updated or replaced, the person responsible can ensure each old copy is returned when the new version is issued. The easiest way to do this is by using a sign-off sheet where staff sign to indicate that they have returned the previous version and collected the new one.

3.3 Record completion and maintenance

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

Interpretation

Records are documented information that provide permanent evidence about past events – particularly events concerning product safety, quality and legality. Records must therefore be maintained in an appropriate way to ensure they demonstrate control of systems and operations.

Where records are kept electronically, it is good practice to ensure that the IT management system facilitates good quality, secure, accurate record-keeping. For example, it should:

- include suitable systems for storing and backup of data (it may be useful to check the effectiveness of the system to restore data, e.g. as part of the incident management procedures detailed in section 3.11)
- define access and IT management responsibilities
- set a frequency of backup based on risk
- confirm the security of data storage.

Clause	Requirements
3.3.1	Records shall be legible, maintained in good condition and retrievable. Any alterations to records shall be authorised and justification for the alteration shall be recorded. Where records are in electronic form these shall also be: • stored securely (e.g. with authorised access, control of amendments, or password protection) • suitably backed up to prevent loss.
Interpretation	**Record completion** Records must be legible and genuine; for example, they must be completed at the time of the checks (i.e. not before or after the event) and in an appropriate manner (e.g. using a pen, as pencil could be altered after the event). Records should be appropriately authorised; this may include the initials or signature of the operator or supervisor verifying the records. Any alterations to records need to be justified and authorised. A suitable procedure must be in place to manage any mistakes that are made (e.g. neatly crossing through the 'inaccurate' information, noting the reason for the error and giving the initials of the person making the change). Note that the use of correction fluid is not acceptable as this makes the initial information illegible. Records must be retrievable when required (e.g. during an audit or the investigation of a customer complaint), and must therefore be maintained and stored to allow this (e.g. by being appropriately filed by date or reference number and in such a way that they are still legible within the specified storage timeframe). They must be created in such a manner that they accurately transmit the intended information (e.g. they can be read by others and are traceable to the creator of the record via initials or signature). Where records are stored electronically, this storage must be secure. The site should ensure that passwords or other mechanisms required to access records are known only by the people who need to use them. When using electronic systems, it may also be useful to assign different access levels; for example, for staff who can view records, and for those who can also add or amend existing data. Electronic documents must be suitably backed up to prevent loss. Consideration should be given to testing electronic retrieval systems, and records of these tests should be retained.
3.3.2	Records shall be retained for a defined period with consideration given to: • any legal or customer requirements • the shelf life of the product. This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing). At a minimum, records shall be retained for the shelf life of the product plus 12 months.

Clause	Requirements
Interpretation	**Record storage** The retention time for records must be established by the company, and procedures put in place for appropriate handling, so that records are retained in good condition for this period and are retrievable. Consideration should be given to the potential for degradation during storage (e.g. due to fading ink, degradation of thermal paper or breakdown of electronic media). Records that may be called upon to demonstrate the safety, authenticity or legality of the product must be kept for an appropriate period. Examples of appropriate periods for products or ingredients are as follows: • **Final products** A period not less than the indicated shelf life plus 1 year. • **Ingredients** (i.e. where the site sells an ingredient that will be used in the manufacture of a final product) The shelf life of the final product plus 1 year. Where the final-product shelf life is not reasonably known, records should be kept for 3 years or a period agreed with customers. • **Products of an undefined shelf life** (e.g. some wines and alcoholic drinks) The company should define a reasonable record retention period based on experience of customer usage, time for complaints and any legal precedents. It would be usual for records to be kept for at least 3 years in these situations. Additional retention time may be required by legislation, by customers or because of the nature of the product (e.g. extension beyond the normal shelf life by the inclusion of customer freezing instructions on the product packaging must be observed). As records may be called upon by a customer as part of a legal defence, consideration should be given to the length of time that may pass from production of a product to notification of impending legal action in the country of sale. Some regions have specific legal requirements. FSMA legislation, for example, requires a storage period of a minimum of 2 years for all documents and records relating to the food safety plan, and records must be retrievable within 24 hours, even when stored off site.

3.4 Internal audits

Fundamental

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

Interpretation

An internal audit is any audit completed by or on behalf of the company rather than by a second or third party. In second-party audits, the company carrying out the audit may have a commercial interest (e.g. a customer audit), while a third-party audit is generally conducted by an independent organisation (e.g. a certification body).

Internal audits are one of the most powerful self-assessment tools that a site has available; they are a key factor in ensuring continued compliance with the requirements of the Standard, and the operation of its food safety and quality management systems. They must therefore be regarded by the management of the company as critical to its operation, and this section of the Standard is listed as fundamental to food safety and compliance with the Standard.

The internal audit programme can be used to:

- confirm that the product safety and quality management systems are correct and effective
- verify that product safety, authenticity, legality and quality activities and processes are being completed correctly (i.e. the actual work completed)
- monitor and confirm that products are manufactured correctly
- provide early identification of potential risks or potential non-conformities (sometimes referred to as near-misses), allowing timely correction such that they do not become actual non-conformities
- identify areas for improvement
- undertake verification of systems (a crucial step within the control of the HACCP or food safety plan; e.g. see clause 2.12.2).

The site's attitude towards its internal audit programme is also likely to indicate its food safety and quality culture. For example, a site with a poor food safety culture may be tempted to:

- reduce the number of internal audits and inspections to the minimum, rather than the level indicated by thorough risk assessment
- under-report non-conformity and near-misses (i.e. find less than exist in reality)
- not follow up on non-conformities (e.g. corrective, preventive actions and root cause analysis).

The scope of the internal audit programme must cover all areas of the food safety and quality management system, including all the requirements of the Standard, implementation of the HACCP or food safety plan, prerequisite programmes and procedures, food defence and prevention of food fraud. It must also cover both the systems in place and the work practices.

It is not a requirement of the Standard that all of the internal audits in the programme are completed prior to the site's BRCGS audit. However, the Standard does require the site to have a planned schedule, with audit dates spread throughout the year, and for the site to complete the individual audits according to this schedule (see details below). For sites that are already certificated the auditor may review the internal audits from the previous year, if the BRCGS audit occurs early in the year, and little of the current year's schedule has been completed.

The Standard is not prescriptive on the type of auditing techniques used during internal audits, and the site may therefore choose the most applicable techniques for the activity being audited. For example, there are some areas that may be auditable remotely, while others are likely to require physical, on-site auditing techniques. Whichever techniques the site uses, it is still expected to have an effective audit programme. That means being able to demonstrate that the systems associated with the food safety plan, the Standard and the food safety and quality management system are operating effectively and as intended.

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

Interpretation

Internal audit programme

The scope of internal audits needs to be established and must ensure that all aspects of the food safety and quality management systems (including the HACCP programme, prerequisite programmes, policies, documentation, hygiene and production), the product safety and quality culture plan, and systems associated with authenticity, product legality and quality management are audited at least annually.

All the internal audits should not be conducted on a single day; nor should every internal audit attempt to cover all aspects of the food safety and quality management system or the Standard. A once-a-year check against all the requirements of the Standard may be of value as a gap analysis when preparing for an audit or confirming the contents of the food safety and quality management systems, but is insufficient to cover the full requirements of an internal audit programme as it will not provide the depth of assessment or level of confidence required.

Development of the internal audit schedule should begin with a risk assessment. The aim of this is to identify:

- all the areas or activities that need to be audited
- the frequency with which each part of the product safety and quality management system needs to be audited. This will be dependent on the risk inherent in each activity or section of the food safety and quality management system. For example, the site should be aware of the consequences of not complying with its own systems, which could lead to hazards not being identified in a timely manner. Therefore internal audits of CCPs are likely to be more frequent than those for less critical activities.
  Frequency may also be influenced by known issues within the company or customer requirements. This may result in a site needing to audit an activity multiple times throughout the year, or developing a programme with more than four internal audit dates (see below)

Clause	Requirements
Interpretation *continued*	• the most relevant dates for each internal audit; for example, if activities or processes are seasonal (see below) or if specific activities need to be completed more than once a year. Sites may also find it useful to consider completing internal audits during different shifts, including, for example, nights or weekends. The majority of sites are likely to benefit from a programme of audit dates spread diversely throughout the year, as this maximises the opportunity to identify any non-conforming processes in a timely manner, allowing correction and minimising the potential for standards to fall between audits. The Standard promotes this concept by requiring a minimum of four audit dates spread throughout the year. However, it does not require all audits to be completed quarterly, as there may be genuine situations where risk assessment shows an alternative frequency. Seasonality is an example; if a site is open only for part of the year, then there is little value in completing internal audits while the site is shut. For seasonal production, the site is not expected to complete a series of internal audits when the site is not operating; however, there must be a system for the management of start-up processes, and internal audits are therefore expected to start before the season commences to ensure the site is ready to start production. For example, the HACCP programme should be audited to ensure that it is up to date and appropriate for the forthcoming production; that hygiene and fabrication are correct; and that staff are appropriately trained. The remaining areas of the internal audit programme should be covered throughout the season. Further information is available in the BRCGS Fresh Produce Guideline available from **BRCGS Participate** or the BRCGS Store. Even where a site is open throughout the year, seasonality can affect the internal audit dates; for example, if certain activities, such as the harvest of grapes or bottling of wine, are only completed at certain times, or if there are seasonal changes in production volumes which apply a greater burden on the product safety systems at certain times of year. Where a site is part of a multi-site company, and the company conducts annual corporate food safety audits, it is acceptable for this annual audit to be incorporated into the internal audit schedule. However, additional internal audits that look at specific parts of the food safety and quality system, and compliance with the Standard, should be scheduled throughout the rest of the year. The most common way of completing an internal audit is by taking documented procedures and work instructions and comparing them with the actual working practices and records. Note that a tick-box exercise is not sufficient, as it does not provide the rigour or depth that an effective internal audit programme requires. The use of an external consultant (e.g. by small sites) is acceptable, providing the internal audit programme is scheduled throughout the year and not in a single block of activity. See clause 1.2.4 and section 3.5.3 for details relating to the requirements for product safety consultants. BRCGS has produced a guideline to internal auditing which is available on **BRCGS Participate** or from the BRCGS Store.
3.4.2	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be independent (i.e. not audit their own work).

Clause	Requirements
Interpretation	**Auditor training and independence** Good auditing is a thorough, evidence-based assessment of an activity or system, completed by an independent auditor. It should ultimately contribute towards the site's continuous improvement. Auditing is therefore an acquired skill and auditors need to be trained and competent to ensure they are carrying out this function effectively. Training should include: • auditing skills, such as how to complete an effective audit • relevant technical knowledge of the activity to be audited, such as HACCP or appropriate product technical knowledge. This may be by work experience in the sector or specific training • soft skills associated with auditing. Internal auditors must be able to show via training records (clause 7.1.6) that they have received formal training on internal auditing, via either attendance at an external course or training within the company. Training should also cover the planning and scheduling of the internal audits, preparing audit reports in the company's agreed format, the correct use of audit techniques (e.g. documentation and process auditing, audit trails and discussions with colleagues) and follow-up of audit findings (see clause 3.4.3). Training must be of sufficient duration and depth to ensure that auditors can complete robust, consistent audits. External auditors may be used where internal resources are insufficient, providing the requirements of clause 3.4.1 can be met (for scheduling audits throughout the year). The site should refer to clause 1.2.4 and section 3.5.3 for the requirements for the management of food safety consultants. Internal auditors must be independent of the process being audited. This is to ensure that there is no conflict of interest (i.e. that the audit is rigorous and thorough) and that any work needed to make corrections or improvements can be identified by an auditor who is not biased or influenced by working in the area. Internal auditors may not audit their own work or any programmes for which they are immediately responsible. It is not acceptable, for example, for workers on one shift to audit the work of another shift completing the same work, as they are not independent of the operation. During the BRCGS audit, the auditor may discuss the process with internal auditors to establish their level of competence. Sites may find it useful to calibrate their internal auditor team (e.g. at the beginning of the year, before a new schedule of internal audits begins) to ensure that there is a consistent approach across the company. A number of sources of further guidance and training for internal auditors are available including: • BRCGS guideline on internal auditing (see BRCGS Participate or BRCGS Store) • BRCGS internal auditor training • ISO 19011 Guidelines for auditing management systems.

Clause	Requirements
3.4.3	The internal audit programme shall be fully implemented. Internal audit reports shall identify conformity as well as non-conformity and include objective evidence of the findings. The results shall be reported to the personnel responsible for the activity audited. Corrective and preventive actions, and timescales for their implementation, shall be agreed and their completion verified. All non-conformities shall be handled as detailed in section 3.7. A summary of the results shall be reviewed in the management review meetings (see clause 1.1.4).

Interpretation

Internal audit records and corrective actions

The management review processes (see clause 1.1.4) must ensure that the internal audit programme operates effectively and that necessary corrective or preventive actions are appropriately completed. As a result, the internal audit process will often contain a number of steps. For example:

- internal audit completed
- corrective actions agreed
- corrective actions completed and signed off
- completion verified
- root cause analysis used to identify any necessary preventive actions
- preventive actions completed and reviewed
- overall management review completed.

Each internal audit must examine the process or activity in detail and will usually include a number of activities such as:

- observing how activities are completed
- asking relevant staff how an activity is completed or why it is completed in a specific way
- reviewing procedures and records to confirm whether the activity has been completed and recorded correctly.

In addition to the actual internal audit, it is important that appropriate reports are completed, clearly indicating what was audited, the actions that are agreed and the review of these actions.

Reports must show evidence of conformity as well as non-conformity, with objective supporting evidence (e.g. what documents or actions were observed). Some sites have also found it useful to include recommendations for improvement, where the audit can highlight any that are noted during the audit.

Tick lists showing that items have been assessed will not normally be accepted as the only form of evidence; information showing how the audited items have fulfilled the requirements, or how they are non-compliant, is required. This is important, as recording conformity is documenting evidence that due diligence is taking place; in other words, that required procedures are taking place, and have been observed by auditors who are independent of the process. This may subsequently be useful, for example, in the event of an incident, or for answering questions from regulatory authorities or customers.

Clause	Requirements
Interpretation *continued*	Notes, references or copies of the documents and records should be kept as evidence of aspects that have been examined, to allow an independent reviewer to reach the same conclusion as the internal auditor. For example, the dates and titles of records that were inspected should be noted in sufficient detail to allow them to be traced; if any records are non-compliant, precise details of the non-compliance should be given. The listing of records reviewed also ensures that a wide range of records are considered (e.g. training records of a variety of staff rather than repeated audits of the same records). Records will also confirm whether anything has changed since the last audit. The Standard is not prescriptive regarding the format of the internal audit reports; for example, they may be hand-written, stand-alone electronic documents or uploaded into a company database. Good practice is to retain any auditor notes that are completed during the audit, as well as the final report. Figure 9 shows a typical example of a completed audit report. The results of audits need to be communicated to the relevant staff; i.e. those who are responsible for the area or activity, and corrective actions, root cause and preventive actions and timescales for their completion agreed. This may be achieved via operational or review meetings, or via an update at the end of the audit combined with documentation such as a memo or a copy of the audit report. Responsibility for corrective actions must be documented – for example, by being recorded on the audit record sheet. Full details for handling non-conformities, including corrective and preventive actions, are provided in section 3.7. Note that finding a non-conformity during an internal audit should not necessarily be viewed as a negative, since it allows the site to implement action before the non-conformity becomes a more serious problem. Where non-conformities have been identified, effective completion of corrective and preventive action must be verified. Good practice is to ensure that a nominated member of staff with the appropriate authority checks that the action has been taken within the agreed timescale, and that this has rectified the problem sufficiently to prevent recurrence. The nominated staff member should not be the person responsible for completion of the actions; ideally this should be the original auditor. Good practice is to complete a review of the internal audit programme; for example, looking at the outputs and trends, and any insight these provide. A summary of the programme and results will also be required for the management review meeting (see clause 1.1.4). A non-conformity will be raised against clause 3.4.3 if there is a non-conformity in the operation of the internal audit programme itself. Examples include if the audit schedule is not properly implemented or if corrective and preventive actions are not completed within the agreed timescales. Where the site consistently obtains negative results (i.e. no non-conformities are identified throughout the scheduled programme) good practice is to review the programme to ensure it is operating robustly; for example, to: • consider if all activities are correctly incorporated into the programme • review rigour, robustness and consistency of the internal audits.

Clause	Requirements
Interpretation *continued*	Full records of all internal audits and the results, including conformities and non-conformities and verification of corrective and preventive actions, must be kept for a defined period, typically 2 years.

AREA REQUIREMENT: Control of Non-Conforming Product **DATE:** 14 February 22 **AUDITOR:** A Checker

BRC REQUIREMENT	SITE POLICY	EVIDENCE	COMPLIES
The site shall ensure that any out of specification product is effectively managed to prevent unauthorised release.	Procedure QM11 & form QRec11.	All non-conformities trended for inclusion in management review meetings (log reviewed and management report for 1/9/21)	Y
		Waste disposal records checked (Sept – Dec 21) against records of non-conformities – disposal of outer packaging on 1/1/22 unaccounted for.	N
There shall be documented procedures for managing non-conforming products.	Procedure QM11 – specifies all requirements – non-conforming products are stored in identified area and labelled 'on hold', 'reject' or 'QC pass'. Form to be completed and attached, with copy sent to specified management. Sign off approved staff only. Form QRec11 for recording information.	Procedure QM11 version 3 dated 1/2/22 in use.	Y
		Records for Aug 21 – Dec 21 checked and indicated correct sign off.	Y
		Random staff check on staff numbers 94, 157 & 196 – queried what they should do with incorrectly baked product.	N
Records of the decision on use or disposal and records of destruction where product is destroyed for food safety reasons.	Form QRec11 for recording information.	Records comply with disposals instructions.	Y
		One pallet of product (failed customer quality checks) segregated for disposal, correctly labelled and authorised for disposal.	Y
		Records for 12/1/22 reviewed – correctly completed.	Y

NON-CONFORMITIES IDENTIFIED:

NON-CONFORMITY	ACTION	RESPONSIBILITY	DUE BY	VERIFIED AS COMPLETE
Staff numbers 157 & 196 were unclear of procedure.	Retraining to be completed against QM11.	Production Manager	21/2/22	A Checker 22/2/22
Waste disposal records checked (Sept – Dec 21) against records of non-conformities – disposal of outer packaging on 1/1/22 unaccounted for.	Investigate cause and introduce corrective action. Ensure staff aware of procedure.	Production Manager	24/2/22	A Checker 25/2/22

Figure 9 An example of a completed audit report

BRCGS has produced a guideline to preventive action and root cause analysis which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.

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

Interpretation

Documented inspections

In addition to the internal audit programme the Standard requires a programme of documented inspections to ensure that the factory environment and processing equipment are maintained in a suitable condition. These inspections are different from the internal audit programme specified in clauses 3.4.1 to 3.4.3, which examines practices against documented procedures. Audits are an in-depth challenge to the systems and procedures that a site has put in place to manage hazards, to confirm that the site is effectively mitigating identified risks. A documented inspection, however, is a simpler approach to assessing the conditions present, so an entirely separate inspection plan should be in place.

These hygiene- and fabrication-based inspections assess standards of cleaning, equipment, building fabrication and personal hygiene to ensure that high standards are maintained and that a safe, hygienic production environment is in place. For example, inspections should include:

- appropriateness, status, state of repair and cleaning of doors, walls, floors and other fabrication and facilities (e.g. those detailed in section 4.4)
- hygiene inspection to confirm equipment and facilities have been suitably cleaned
- equipment inspection to identify and control potential foreign bodies (e.g. from worn or damaged equipment) before they have the opportunity to contaminate a product.

The frequency of the inspections should be based on risk. For open product areas, inspections need to be at least monthly, whereas inspections in high-care and high-risk areas are likely to be more frequent (e.g. daily or weekly); seasonal products or activities should be included where appropriate. Line start-up checks, which may occur daily or at shift changes in many operations, can form part of this inspection programme.

It is also good practice to complete inspections after any activities that potentially change the risk to products; for example, after maintenance.

A review of the inspection programme should be completed prior to any changes which may affect food safety; for example:

Clause	Requirements
Interpretation *continued*	• introducing new equipment or facilities • changes to products • changes to processing conditions or process flow • following a non-conformity in an audit (e.g. internal, BRCGS, customer, or regulatory audit) or an independent inspection (e.g. following recommendations for improvement from the pest control in-depth survey). The individuals responsible for completing these inspections should be suitably trained for the systems they are checking. However, staff completing hygiene and fabrication inspections do not need the same level of training as internal auditors. The absolute requirements for independence identified in clause 3.4.2 do not always apply to these inspections; for example, it would be acceptable for line start-up checks to be carried out by line supervisors or managers. External agencies may be used to carry out inspections. It is important that issues identified at the inspections are corrected as soon as possible so that product risk is minimised. The records of inspections and corrective actions must be retained. Inspection records can provide useful information to identify trends and drive improvements (e.g. through the use of scored inspection results). To facilitate this, and to promote discussions about improvements to hygiene and fabrication, a summary of the results will be discussed at the management review meetings (see clause 1.1.4).

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

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

Interpretation

All materials brought onto the site to become part of the final product must be sourced through approved suppliers and monitored. This approval process and programme for monitoring raw materials will consider the potential risk the material represents (in terms of safety, authenticity, legality and quality).

Primary packaging materials are also included in this requirement. Packaging is vital to product integrity in the packing environment, and during storage and distribution within the supply chain. Primary packaging is defined in the Standard as:

'The packaging that constitutes the unit of sale to the consumer or customer (e.g. bottle, closure, label and tamper-evident seal of a retail pack or a raw material bulk container).' (A full explanation is available in the glossary.)

The supplier approval system must consist of an initial approval process and an ongoing monitoring process.

The risk assessment process should help to focus increased attention on the raw materials or suppliers that present a greater risk.

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

Interpretation

Raw material risk assessment

The aim of this clause is to ensure the potential risks to product safety, authenticity, legality and quality that could result from specific raw materials, have been identified, and where necessary mitigation measures put in place, for example, by adding controls into:

- supplier approval and purchasing processes
- goods receipt controls and product testing
- the food safety plan (HACCP) or specific parts of the food safety and quality management systems.

All proposed ingredients and packaging must be subjected to a documented assessment of their inherent risk.

This raw material risk assessment is not intended to be a duplication of other clauses. For example, the reference to authenticity is not intended to duplicate the requirements within section 5.4; the processes are intended to operate together. In other words, section 5.4 should highlight any authenticity risks within the supply and identify suitable controls, whereas this clause is intended to bring those identified risks into the supplier approval, raw material management and raw material receipt processes. Similarly, this may form part of the HACCP or food safety plan; however, as this is an important starting point for the production of safe food, it needs to be detailed and will be specifically assessed by the auditor.

Clause	Requirements
Interpretation *continued*	The assessment may be of individual products or, where a number of raw materials share the same characteristics and likely risks, these may be grouped together. When grouping materials, each should still be considered separately to ensure that it does not have different risk factors from the rest of the group. Risk, and therefore the opportunity to group ingredients or not, may vary between factories and processes because of the different overall effect on quality. For example, in a bakery, all dried fruit may be considered to be of similar risk, but where flour is a critical ingredient, it may be necessary to consider each type of flour separately (e.g. white or wholemeal); however, other non-bakery sites may group all the types of flour together. The Standard lists the minimum types of hazards that the company must consider, including: • allergens – both the intended allergen content and the potential for the raw material to be contaminated should be included • foreign-body risks – these maybe intrinsic or extrinsic (i.e. an inedible part of the raw material, such as bones in animal products; or materials from the growing environment or manufacturing processes) • microbiological contamination • chemical contamination – including contaminants that occur naturally in the environment, those that migrate from packaging materials, or artificial additions in the supply chain (such as pesticides or veterinary medicines) • potential for variety or species cross-contamination (i.e. where the supplier handles multiple varieties of a product and inadvertent contamination could occur during processing • the potential for fraudulent activity in the supply chain – for example, undeclared additions, dilution or substitution of the raw material or a component of it. (As discussed above, the identification of hazards and necessary control measures may be completed as part of the activities for section 5.4.) • the risk of non-compliance with legal requirements specific to the product (e.g. banned substances) – it is important to remember that legislative requirements in the country of raw material production may be different from those of the country where the site is located or where the final product is intended to be sold • any customer requirements. Identification of the actual level of risk often requires the company to consider several factors; for example: • access to reference information and an awareness of emerging food issues are essential to ensure all known risks are assessed (clause 1.1.8) • how the ingredient is used (e.g. an ingredient added following the final microbiological kill step may present a different risk from an ingredient added at the beginning of a process) • nature of the supplier • historical evidence of the supplier and raw material • geographic origins (products from particular origins may carry a greater risk due to environmental conditions, because of more relaxed local legal requirements or a less developed food safety culture)

Clause	Requirements
Interpretation *continued*	• methods of manufacture/processing of the raw material (e.g. if a site is using egg as an ingredient, the microbiological risk will depend on whether fresh or pasteurised egg is used. Similarly, the type or level of processing may change the risks; for example, whole carcass, compared to cuts of meat, compared to cubes or mince or mechanically recovered meat) • significance of the ingredient to the final product (e.g. some 'safe' ingredients, such as flour in breadmaking, may be fundamental to the performance of the product and therefore require higher levels of control to ensure consistent quality) and the spread of the ingredient in the company/final products • customer or legislative requirements (e.g. suppliers may be specified by customers, but this does not negate the need for risk assessment) • additional focus on raw materials where claims are being made about the final product (e.g. 'organic' or 'suitable for allergy sufferers') or where there is a microbiological risk from components added after heat treatment. Sites should also consider the primary packaging materials used as they too are raw materials. There is potential for packaging materials to pose a problem, whether because of contamination, malicious intervention or the use of inappropriate materials. Where different departments are involved in the process (e.g. head office or different sections of the site technical team), there needs to be a linked process to demonstrate the responsibilities of each team and how these work together to operate the system. The outcome of this risk assessment must also be considered when assessing the requirements for supplier approval and for monitoring and acceptance procedures (clause 3.5.1.2 and section 3.5.2). Risk assessments must be up to date and the site must therefore review the assessment whenever there is a significant change (e.g. new suppliers, new raw materials, new countries of origin or an emerging risk) or where an incident (e.g. a product recall or withdrawal) is related to a specific raw material. At a minimum risk assessments must be reviewed every 3 years.

Clause	Requirements

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

Interpretation

Documented supplier approval and monitoring system

All suppliers must be evaluated for their ability to meet the specifications of the materials (ingredients and primary packaging) they are supplying and requirements for safety, quality and legality.

The company must document its procedure for supplier approval and monitoring. This needs to include the methods of approval, frequency of monitoring, responsibilities and how the process will be managed.

The acceptable methods of supplier approval will depend on the raw material and the risks associated with it (e.g. the output of clause 3.5.1.1). They will include one or more of the following activities:

- Certification to the relevant BRCGS Standard, such as the Global Standard Food Safety; Packaging Materials; Storage and Distribution; Agents and Brokers; or another of the GFSI-benchmarked schemes. The site must confirm the validity of the certification. This will include:
  - Confirmation of the certification status (e.g. this can be confirmed on an independent database; for BRCGS Standards it can be confirmed in the BRCGS Directory). Photocopies of certificates are not recommended and on their own are not considered suitable validation of certification status. During the BRCGS audit the site may be asked to demonstrate its validation process.

Clause	Requirements
Interpretation *continued*	• Confirmation that the certification remains up to date (e.g. by receiving confirmation of successful completion of the recertification processes or by recording certificate expiry dates and completing checks for ongoing certification). • Ensuring that the raw materials are within the scope of the certification. Where the product has been excluded from the scope of certification it cannot be assumed that all of the processes relating to its manufacture have been conducted in accordance with the certification requirements. For example, different facilities or equipment may be used; different raw material suppliers or risk assessment; or different staff training. Therefore the site will need to undertake additional supplier approval processes to ensure the material is satisfactory and any risks are appropriately managed. A successful site audit covers at a minimum product safety, traceability, HACCP, product security and the food defence plan (i.e. systems to protect the product from theft and malicious activity), product authenticity and good manufacturing processes. This audit must be completed by an appropriately experienced and competent auditor (i.e. someone who has completed training in auditing techniques, has experience of auditing, and has knowledge of the product, ingredient or processes being audited). Non-conformities should be addressed (e.g. in an agreed action plan with timescales) unless they are critical to product safety or legality, in which case supply should not be permitted until the non-conformities have been satisfactorily addressed. When deciding the type of supplier audit to complete the company should consider the risks associated with the raw material and supplier, using this information to decide the format and duration of the audit, and whether the risk assessment indicates that some or all of the requirements can be completed remotely, or whether an entirely on-site audit is required. If the raw material supplier is independently audited to another standard that is not GFSI-benchmarked, this may be acceptable as an alternative to the site completing its own audit of the supplier providing that: • the scope of the audit meets the requirements of the Standard (i.e. at a minimum product safety, traceability, HACCP review, product security and food defence, food authenticity and good manufacturing practices) • the site has a copy of the full audit report (not just a certificate) • the supplier can demonstrate the competence of the auditor. Where risk assessment (completed as part of this clause) indicates that a supplier is low risk (e.g. due to history of trading with the site or the nature of the raw materials traded) the completion of a supplier questionnaire with a focus on food safety and quality may be sufficient. If a supplier questionnaire is the only mechanism used to assess a supplier (i.e. there are no additional activities such as supplier audits) then it is important that the questionnaire (and replies from the ingredient supplier) contains all the relevant information to allow the site to confidently make a decision on approval. The auditor will expect to see, and will challenge, risk assessments. Approval and the associated risk assessments must be up to date. The site should therefore consider reviewing the assessment whenever there is a significant change (e.g. new suppliers, new countries of origin or new materials).

Clause	Requirements
3.5.1.3	There shall be a documented process for ongoing supplier performance review, based on risk and defined performance criteria. The process shall be fully implemented. Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status. Records of the review shall be kept.
Interpretation	**Ongoing monitoring** Although it is important to know how and why suppliers are approved, it is also vital to ensure that ongoing approval is justified. The site is free to determine how it confers continuing approval on its suppliers, but it is important that the site uses a risk-based approach. The defined performance criteria can be determined by the site and should depend on the supplier's performance. However, it is important that product safety, authenticity, legality and quality are included within all supplier reviews. Therefore, while a company may wish to include other criteria (e.g. financial considerations or reliability of delivery schedules) these additional criteria must not outweigh the need to fully assess food safety, authenticity, legality and quality considerations. As a guide, typical criteria may include: • known risks associated with the raw material or supplier • supplier approach to emerging concerns • incidences of contamination or non-conforming raw materials • quality of material supplied. The frequency of ongoing approval is also important, and this is left to the site to determine. However, where approval is based on supplier questionnaires, these must be reissued at least every 3 years. Good practice is to ensure that a system of proactive communication is in place, where suppliers inform the company of any changes or challenges. The site must be able to demonstrate to an auditor that the monitoring and ongoing review it uses is appropriate, justified and risk-based.
3.5.1.4	The site shall have an up-to-date list or database of approved suppliers. This may be on paper (hard copy) or it may be controlled on an electronic system. The list or relevant components of the database shall be readily available to the relevant staff (e.g. at goods receipt).
Interpretation	**Approved suppliers list** The company must also maintain an up-to-date list of approved suppliers based on the outcome of the supplier approval process. This list can either be in hard copy (i.e. paper) or electronic format (such as an approval database). It is expected that all purchased raw materials (including packaging) will be from the suppliers on the list unless it is an emergency purchase covered by clause 3.5.1.7. The auditor may refer to the list to facilitate the effective sampling of supplier approval records.

Clause	Requirements
Interpretation *continued*	The list (or relevant sections of it) should be available where goods are taken in, and be accessible to anyone who needs it at the points at which it should be used. This is likely to include purchasing where this activity is carried out at the site (i.e. not at a corporate facility).
3.5.1.5	Where raw materials (including primary packaging) are purchased from companies that are not the manufacturer, packer or consolidator (e.g. purchased from an agent, broker or wholesaler), the site shall know the identity of the last manufacturer or packer, or for bulk commodity products the consolidation place of the raw material. Information to enable the approval of the manufacturer, packer or consolidator, as in clauses 3.5.1.1 and 3.5.1.2, shall be obtained from the agent/broker or directly from the supplier, unless the agent/broker is themselves certificated to a BRCGS Standard (e.g. Global Standard Agents and Brokers) or a standard benchmarked by GFSI.
Interpretation	**Purchasing from agents and brokers** Potential product safety risks need to be understood for all raw materials, including those that have been purchased through an agent or broker (see glossary). The purpose of this clause is therefore to ensure that essential information relating to traceability, product safety, authenticity, food defence, etc. is maintained and relevant details communicated, where a site has purchased a raw material from an agent or broker, or a wholesaler (i.e. not the manufacturer, packer or consolidator). The site will need sufficient information to: • ensure traceability • enable timely action in the event of an incident in the supply chain • enable the approval of the last processor of the raw material, the last point of packing or the consolidation place for bulk commodity products, as described in clause 3.5.1.2. The Standard is not prescriptive on the methods of communication used, and this information may be provided directly by the manufacturer, processor, packer or consolidator or alternatively through the agent or broker, depending on the contractual arrangements for data handling and communication agreed between the site and the agent/broker. For the purposes of the Standard, a place of consolidation of bulk materials is a location where a number of smaller batches are mixed to form a single bulk material (e.g. where a number of farms supply grain, which the grain merchant combines in a silo before sale, or where a cooperative arranges for a group of small growers to combine their crops for onward sale to customers). The important difference between consolidation and other types of storage or trade of materials is the mixing or combining of materials from multiple sources or batches, so that it is no longer possible to identify the individual supplier/batch for any specific portion of the bulk material (of course, for traceability purposes, it must still be possible to identify all of the suppliers/batches contributing to the bulk). Therefore, where a trader receives individually traceable units of product (e.g. sacks of material), each of which can be individually traced from supplier to customer, this does not count as a place of consolidation. The bulk material may be sold to one customer or divided and sold to multiple customers.

Clause	Requirements
Interpretation *continued*	Where the agent or broker is certificated to the Global Standard Agents and Brokers, the wholesale module of the Global Standard Storage and Distribution, the relevant traded products/goods scope of the Global Standard Food Safety or Global Standard Packaging Materials, or a GFSI-benchmarked equivalent, then the site simply needs to know the identity of the manufacturer, packer or place of consolidation of the material (i.e. the location/company where the material underwent the last process other than storage or distribution). In this situation, the requirement to approve the processor, packer or consolidator is not applicable, as the requirements of these Standards ensure that effective systems for supplier approval and traceability are in place. However, the site will still be expected to know the identity of the processor, packer or consolidator.
3.5.1.6	The company shall ensure that its suppliers of raw materials (including primary packaging) have an effective traceability system. Where a supplier has been approved based on a questionnaire instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least every 3 years. This may be achieved by a traceability test. Where the supplier is not the manufacturer, packer or consolidator of the raw material (e.g. purchased from an agent, broker or wholesaler) and approval is based on a questionnaire instead of certification or audit, the verification of the traceability system shall be carried out on the last manufacturer, packer or consolidator of the raw material. Where a raw material is received directly from a farm or fish farm, further verification of the farm's traceability system is not mandatory.
Interpretation	**Supply chain traceability** It is important for the integrity of products that appropriate traceability systems operate throughout the supply chain. Therefore sites must ensure that their raw material suppliers (including primary packaging suppliers) have suitable traceability systems in operation. This assurance can be obtained from certification, auditing or by directly testing traceability. Examples of acceptable traceability include: • The raw material supplier is certificated to a GFSI-benchmarked standard. Assessment of traceability systems forms part of these audits and therefore no additional action is required to comply with the requirements of this clause; however, a communication mechanism should be in place, such that if the raw material supplier were no longer certificated, the site would be made aware of this change. • The raw material supplier is audited by the site and the audit includes an assessment of the traceability systems. This would comply with the requirement as traceability has been assessed. The audit should be repeated at least every 3 years. • Verification of a supplier's traceability system where approval has been based solely on a questionnaire with no additional testing (unless the raw material is a primary agricultural product purchased directly from a farm or fishery, where additional testing of the traceability systems is not mandatory). This verification could include, for example: • A test of the raw material supplier's traceability. For example, as part of the site's traceability test (see clause 3.9.3), a relevant ingredient is highlighted. The ingredient and batch details are forwarded to the supplier to enable them to complete the traceability test for the specific batch of raw materials and forward the relevant records back to the site.

Clause	Requirements
Interpretation *continued*	• A worked example from the raw material supplier, which clearly explains the traceability process. • A detailed description of the traceability system provided by the raw material supplier. Information received during the traceability verification should be incorporated into the supplier approval process (clause 3.5.1.2). Where the supplier is not the manufacturer, packer or consolidator of the raw material (e.g. purchased from an agent, broker or wholesaler) and approval is based on a questionnaire instead of certification or audit, the verification of the traceability system required by this clause shall be carried out on the last manufacturer, packer or consolidator of the raw material. Therefore, where the: • agent/broker is certificated to a BRCGS Standard or a standard benchmarked by GFSI, the assessment of supplier approval forms part of these audits and therefore no additional action is required to comply with the requirements of this clause (see clause 3.5.1.5 for further information) • last manufacturer, packer or consolidator is certificated to a BRCGS Standard or a standard benchmarked by GFSI, the assessment of supplier approval forms part of these audits and therefore no additional action is required to comply with the requirements of this clause • last manufacturer, packer or consolidator is audited as part of the supplier approval process, and the audit includes an assessment of the traceability systems, this would comply with the requirement as traceability has been assessed. Traceability verification is a requirement for each raw material supplier. Therefore any traceability test (because the supplier approval is based solely on a questionnaire) should be designed to test the raw material supplier's systems and not to trace every single material they produce. Where a site purchases multiple ingredients from the same raw material supplier, it is not a requirement to complete a traceability test for every single ingredient purchased; only to complete the traceability test for each supplier from which ingredients are purchased. The frequency of the traceability verification should link to the supplier approval programme; that is, the traceability is verified on first approval of the supplier, and then at least every 3 years. It is good practice to phase these verifications over the 3-year period rather than trying to complete them for all sites at once. Therefore sites that are new to certification (i.e. at their initial audit) may not have fully completed the traceability assessment for all of their suppliers, but should be able to demonstrate verification of the traceability system for at least a third of the suppliers in the first year, prioritising the higher-risk materials; two-thirds completed within the second year; and all suppliers by the third year. During the BRCGS audit the auditor will not undertake a test of raw material suppliers' traceability systems but they will review the site's processes and the information received from its raw material suppliers. Issues arise with raw materials from time to time so it is beneficial to consider the monitoring of any materials that may need further transparency within the supply chain. This ensures that the site is proactive, not reactive, potentially mitigating the risk of future concerns about raw materials.

Clause	Requirements
3.5.1.7	The procedures shall define the actions required in either of the following circumstances: • an exception to the supplier approval processes in clause 3.5.1.2 occurs (e.g. where raw material suppliers are prescribed by a customer) • information for effective supplier approval is not available (e.g. bulk agricultural commodity products). In both the above situations, product testing is used to verify product quality and safety. When a site produces customer-branded product, the customer shall be made aware of the relevant exceptions.
Interpretation	**Exception procedure** In cases where emergency supplies (e.g. where an established supplier is unable to fulfil an order), bulk commodity purchases or purchases from a supplier prescribed by a customer make it impossible to operate the approval processes in clause 3.5.1.2, the site must have a procedure detailing how these exceptions are to be handled. The process will include an assessment of the risk of the purchase and the completion of appropriate checks or tests to mitigate any risk. For example, this may include: • 100% inspection of the product • certificates of analysis • increased microbiological sampling • review of a third-party audit report • a formally agreed specification • confirmation of compliance with customer codes of practice. Where raw materials are obtained from a customer-designated supplier (e.g. packaging or when contract packing), the site must ensure that information is obtained about the product and supplier so that potential risks to other products are assessed and controlled. Where the materials are used to produce a customer-branded product, the exceptions must be communicated to the customer.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

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

Interpretation

Verification procedures need to be in place to demonstrate that materials (including ingredients and primary packaging) from approved suppliers meet agreed specifications and do not compromise the safety, legality, quality or authenticity of products.

Clause	Requirements
3.5.2.1	The company shall have a procedure for the acceptance of raw materials and primary packaging on receipt based upon the risk assessment (clause 3.5.1.1). Acceptance of raw materials (including primary packaging) and their release for use shall be based on either one or a combination of: • product sampling and testing • visual inspection on receipt • certificates of analysis (specific to the consignment) • certificates of conformance. A list of raw materials (including primary packaging) and the requirements to be met for acceptance shall be available. The parameters for acceptance and frequency of testing shall be clearly defined, implemented and reviewed.

Interpretation

Acceptance of raw materials

The acceptance or goods-in system must include a documented procedure which requires checks to be completed and any non-conformities recorded. The procedure should document:

- who is authorised to accept conforming materials and reject non-conforming batches
- the checks and tests that must be completed, and at what frequency
- the acceptance criteria (e.g. the maximum or minimum values for tests that need to be completed)
- management of non-conforming product (this should also include ingredients that must be kept 'on hold' pending further testing or investigation), and the actions to be taken.

In the first instance raw materials are normally checked for the accuracy of the order; for example:

- visual inspection (e.g. for cleanliness, damaged packaging and spills, pest infestation, pallet condition)
- to ensure that the correct materials and quantity have been delivered
- to confirm the grade of material delivered
- to confirm that the raw material matches the specification
- to assure that the shelf life meets the minimum requirements
- the traceability of the raw material can be maintained (e.g. that appropriate traceability information has been received).

In addition, specific checks will be based on the risk assessment (clause 3.5.1.1) and the specification (section 3.6), and will include one or more of the following:

- specific raw material testing to ensure conformance with the specification before acceptance or use
- temperature checks (particularly for chilled or frozen materials) and storage instructions (refrigeration, freezing, or segregation for allergens)
- the accuracy of printed packaging and labels
- sampling (where required) which should include the timing, method and responsibility for completion, as well as retention of samples
- certificates of analysis specific to the consignment (i.e. specific to batch, date or lot codes included in the delivery) showing results relevant to the identified risks
- certificates of conformance specific to the consignment

Clause	Requirements

Interpretation
continued

- all legal requirements; for example, EU legislation includes labelling requirements for foods and some additional specific requirements for certain food types (e.g. country-of-origin labelling of meat).

Goods-in acceptance procedures must be fully implemented and therefore it is expected that the procedures and any testing or sampling requirements will be available in the goods receipt area. This may, for example, take the form of a product acceptance matrix identifying each material's acceptance criteria and, where applicable, the sampling frequency.

Records of the raw material checks for each batch of material must be maintained. They are likely to be assessed as part of the traceability challenge completed during the audit (see Part III, section 2.2 of the Standard).

Figure 10 shows an example of a good receipt matrix showing the product requirements, frequency of checks and acceptance criteria.

SUPPLIER'S NAME	PRODUCT(S) SUPPLIED	REQUIREMENTS	FREQUENCY OF CHECKS	ACCEPTANCE CRITERIA
Full Name of Approved Supplier	List of products that the supplier is approved for (the supplier may have products in their range that they are not approved to supply for example due to cost or quality concerns)	Information pertaining to the specific ingredient e.g. special storage conditions or the need for raw material testing or QA release	Frequency with which the activity must be completed	Critical limit must be clearly documented
A Browns	Unsalted Butter	• CoC • Temperature control of vehicles/delivery	All deliveries	CoC to confirm compliance with specification (BrownsButter V1) Temperature < 4°C
	Salted Butter	• CoC • Temperature control of vehicles/delivery	All deliveries	CoC to confirm compliance with specification (BrownsButter V2) Temperature < 4°C
A Smiths	Gluten Free Rice Flour 123 Grade X	• CoA for Gluten Content • Requires QA testing & release	All deliveries	CoA: Gluten <10mg/kg TQA: Test Gluten <10mg/
	Maize Flour (<500micron)	• CoC • Requires QA testing	CoC: All deliveries QA: Quarterly	CoC to confirm compliance with specification (SmithsMaize V1). QA: Test Gluten <10mg/kg

In addition to the tests listed above all deliveries will be checked for:

- Cleanliness of delivery vehicle – no spillages permitted, no odours likely to taint materials
- Integrity of packaging – damaged packs to be rejected
- Pest control – no evidence of pest ingress

Figure 10 Example of a receipt matrix

Records of each delivery and the checks that have been carried out must be carefully maintained. Figure 11 shows an example of a goods-in acceptance sheet.

Clause	Requirements

Interpretation
continued

DATE/ TIME	SUPPLIER	INGREDIENT	CODING	BBE/UB	CHECKS REQUIRED	RESULTS	ACCEPTABLE/ COMMENTS	BY
When it arrived	Who is it from? Are they on the approved supplier list?	What it is? Include detail (e.g. grade)	Batch or Lot Codes & any traceability information	BBE or UB for stock rotation	Required checks for the ingredient	Results of the checks	If acceptable release into production/ store. Ensure any out of specification results and subsequent actions are recorded. If on-hold waiting QA or tests results note this	Record who did these activities
24/1/20 9am	A Browns	Unsalted Butter	ABB1301	1/3/20	Vehicle Pest Packaging CoC Temperature	OK OK OK CoC OK 3°C	All tests acceptable. Chill store	MN
24/1/20 3.30pm	A Smiths	Gluten Free Rice Flour 123 Grade X	123X_01_20	31/12/20	Vehicle Pest Packaging CoA Gluten	OK OK OK CoA OK	On-hold awaiting gluten test results	MN

In the latter example (Gluten Free Rice Flour) the QA department need to update the record when the results become available and ensure ingredient is either released into production (acceptable results) or disposed of (unacceptable results)
e.g. Gluten results <10ppm received 31/1/20 signed QA.

Figure 11 Example of a goods-in acceptance sheet

Following the goods receipt checks the site will need to take appropriate action to manage the ingredient. Typically this will be one of the following:

- Accept the batch of ingredient, enter it into the site's systems for traceability and stock control and move it into the appropriate storage area until it is required for production. It is important that temperature-sensitive ingredients are moved in a timely fashion and not left sitting in goods receipt for a prolonged period.
- Put the batch of raw material 'on hold' awaiting further paperwork from the supplier, product testing or quality assurance release. The site will need to have a clear policy on labelling and taking action to ensure materials that are on hold are not accidentally used.
- Reject the batch of raw material as it does not meet the required standards. The appropriate site representative will need to contact the raw material supplier and agree the next steps.

Again, a clear procedure is needed to ensure the ingredient is either segregated and labelled to ensure that it is not accidentally used, or is not off-loaded from the delivery vehicle.

Clause	Requirements
3.5.2.2	Procedures shall be in place to ensure that approved changes to raw materials (including primary packaging) are communicated to goods receipt personnel and that only the correct version of the raw material is accepted. For example, when labels or printed packaging have been amended, only the correct version should be accepted and released into production.
Interpretation	**Communicating changes to goods receipt** It is common for raw materials, including primary packaging, to change throughout the life of a product because of the nature of supply or changes to the product. When this occurs, this requirement is designed to ensure that changes are communicated throughout the organisation so that only the relevant materials are shipped onto the site to eliminate the risk of accidental inclusion of out-of-date raw materials or packaging in the product. The Standard does not prescribe the methods used, and it is common for a site to use a mixture of procedures; for example, using and checking unique raw material codes which are changed when a raw material changes. This is particularly pertinent with packaging materials where print has been changed to reflect changed raw materials and, potentially, allergens. Good practice would ensure that approved packaging samples are supplied to the goods-in team with the relevant part codes that can be visually checked by goods receipt staff. It is worth noting that the procedures developed for this clause will need to work with a number of clauses throughout the Standard, including, for example: • clause 5.2.2 – the design of packaging and labels, which includes the need for checks of the accuracy of the printed information • clause 5.5.3 – mechanisms to ensure that obsolete packaging is disposed of in a timely fashion and not incorrectly or accidentally used • clause 6.2.1 – mechanisms to ensure that only the correct packaging is delivered to the production line.

3.5.3 Management of suppliers of services

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

Interpretation

Supplier approval must include the suppliers of services that could potentially affect product safety, authenticity, legality or quality; for example, the use of agencies to provide temporary staff, laundries, maintenance of equipment (e.g. refrigeration units), waste removal or transport.

Clause	Requirements
3.5.3.1	There shall be a procedure for the approval and monitoring of suppliers of services. Such services shall include, as appropriate: • pest control • laundry services • contracted cleaning • contracted servicing and maintenance of equipment • transport and distribution • off-site storage of ingredients or packaging (other than at the supplier's facilities) prior to delivery to the site • off-site packing of products • laboratory testing • catering services • waste management • providers of product safety training • product safety consultants. This approval and monitoring process shall be risk-based and take into consideration: • risk to the safety and quality of products • compliance with any specific legal requirements • potential risks to the security of the product (i.e. risks identified in the vulnerability and food defence assessments).
Interpretation	**Approval and monitoring of service providers** The site must document its procedure for the risk-based approval and monitoring of suppliers of services to ensure that these suppliers are competent and capable of providing the service to the required level. Approval may include a combination of the following: • membership of a recognised trade association which specialises in the service provided (e.g. pest control) • historical experience with the supplier • legal registration (e.g. waste licences) • third-party certification to a recognised standard (e.g. the Global Standard Storage and Distribution) • evidence of training and competence in food safety. For example, where the site wishes to contract an external product safety consultant, the site may decide to: • have a clear policy/procedure for the selection of consultants • document a contract highlighting the consultant's role and availability (see clause 3.5.3.2) • establish the qualifications, competency and experience of the consultant, and confirm these are acceptable for the intended role • consider the potential product safety, authenticity, legality and quality risks associated with the consultant's role within the site. It may be appropriate to undertake audits or questionnaires where a service is performed off site and may present a food safety risk (e.g. laundry services for high-risk/high-care clothing).

Clause	Requirements
3.5.3.2	Contracts or formal agreements shall exist with the suppliers of services that clearly define service expectations and ensure that the potential food safety risks associated with the service have been addressed.
Interpretation	**Contracts with service providers** Contracts or formal agreements must be in place for the service providers detailed in clause 3.5.3.1 to ensure the correct level of service is provided. Service providers who will be on site will need to receive appropriate training to ensure they complete their activities in a way that will not negatively impact on the safety, quality or legality of products being manufactured (clause 7.1.1).
3.5.3.3	There shall be a documented process for ongoing performance review of suppliers of services, based on risk and defined performance criteria. The process shall be fully implemented. Records of the review shall be kept.
Interpretation	The performance of the supplier should be formally reviewed at a frequency appropriate to the service. For example, a cleaning service could be assessed as part of the internal audit process (section 3.4) and records maintained of feedback on performance to the cleaning company. Other services, such as pest control or laundry, may be reviewed with the supplier on a 6-monthly or annual basis and a record kept of the review (e.g. minutes of the meeting).

3.5.4 Management of outsourced processing

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

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

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

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

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

Interpretation

This section applies to products that are included within the scope of a site's certification but which have a process step that is outsourced to another company or site. This includes products or intermediates that are partially processed at another location (even a site within the same organisation or group) before being returned to the site. This typically happens when there is a need for specialist equipment (e.g. agglomeration of powders or freeze drying); alternatively the product may be sent to a region with a lower-cost economy for a very labour-intensive part of the process.

The scope of the report and any certificate will only reflect the activities undertaken at the site where the audit was undertaken. Therefore, packing of products by third parties (e.g. contract packing) and products that are entirely manufactured at a separate site (i.e. where co-manufacturing occurs), rather than just part of the manufacturing process being outsourced, are not covered by these requirements, since in both of these situations, the individual sites may be separately certificated and traceability coding should be able to identify at which site the product was manufactured.

For example, consider a simple manufacturing process, as shown in Figure 12.

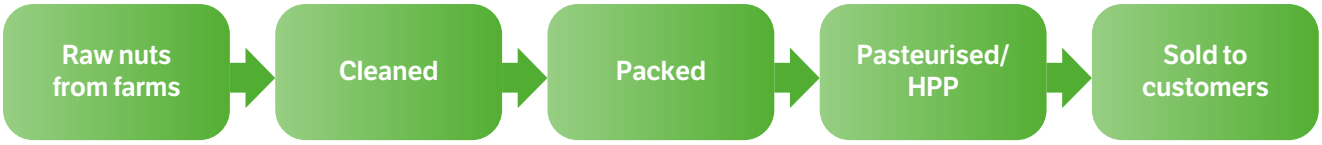

Figure 12 Example of a simple manufacturing process

A number of different production models exist for this product, as shown in Figure 13, and these affect the scope and applicability of the Standard.

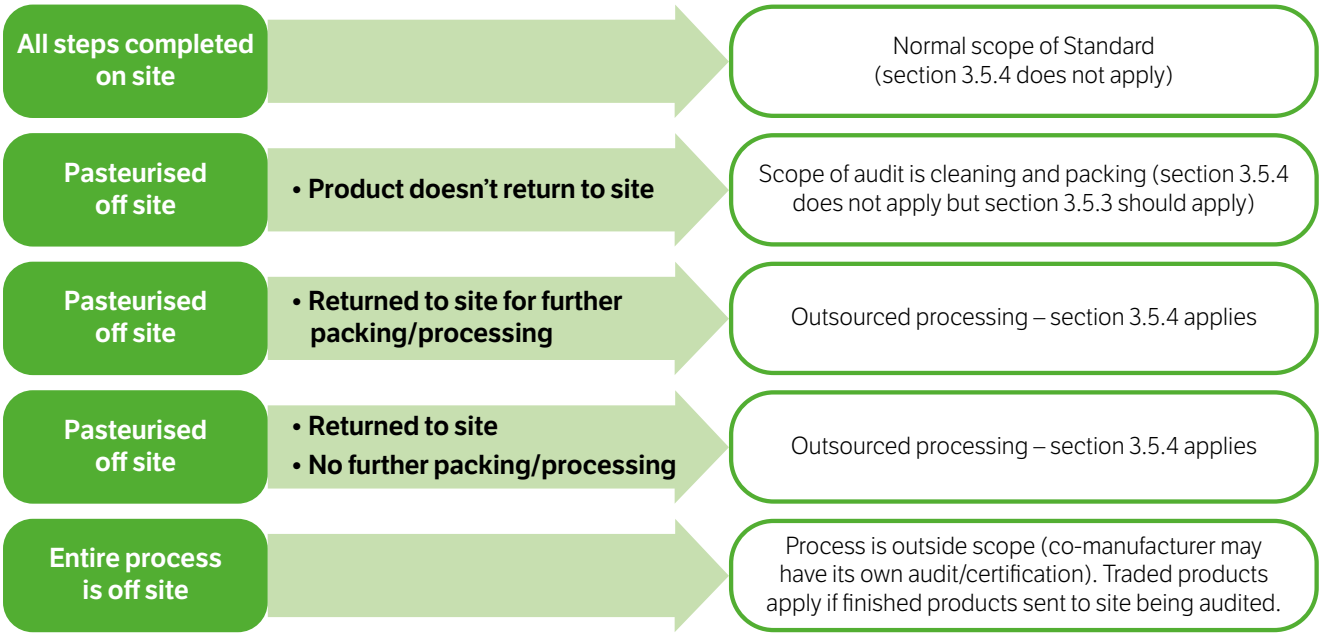

Figure 13 Different types of production models (which may affect the scope and applicability of the Standard)

Clause	Requirements
3.5.4.1	The company shall be able to demonstrate that, where part of the production process (i.e. any intermediate process step) is outsourced or undertaken off site, and subsequently returned to the site, this has been declared to the customer and, where required, approval granted.
Interpretation	**Brand owner approval** Customers (e.g. brand owners) must be notified of any intention to outsource part of the production process. (Some customers require the opportunity to formally approve or reject this type of outsourcing.) For example, if this is clearly detailed on the approved product specification, then it would demonstrate that the customer has agreed the process. This requirement is not limited to retail-branded products or to certain markets but applies to any product manufactured on behalf of a customer.

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

Interpretation	**Outsourced processor approval** The company must document its procedure for approval and monitoring of outsourced processors. This needs to include the methods of approval, frequency of monitoring, responsibilities and how the process will be managed. The acceptable methods of approval will depend on the nature of the activity performed and its associated risks, and will include one or more of the following: • Certification to the relevant BRCGS Standard or another of the GFSI-benchmarked schemes. The site must confirm the validity of the certification. This will include:

Clause	Requirements
Interpretation *continued*	• Confirmation of the certification status (this can be confirmed, for example, on an independent database; for BRCGS it can be confirmed in the BRCGS Directory). Photocopies of certificates are not recommended and on their own are not considered suitable validation of certification status. During the BRCGS audit the site may be asked to demonstrate its validation process. • Confirmation that the certification remains up to date (e.g. by receiving confirmation of successful completion of the recertification processes or by recording certificate expiry dates and completing checks for ongoing certification). • Ensuring that the activities are within the scope of the certification. • A successful site audit covers at a minimum product safety, traceability, HACCP review, product security and food defence plan, product authenticity plan and good manufacturing processes. This audit must be completed by an appropriately experienced and competent auditor (i.e. someone who has completed training in auditing techniques, has experience of auditing, and has knowledge of the product, ingredient or processes being audited). Non-conformities should be addressed (e.g. in an agreed action plan with timescales) unless they are critical to product safety or legality, in which case supply should not be permitted until the non-conformities have been satisfactorily addressed. If the outside processor is independently audited to another standard that is not GFSI-benchmarked, this may be acceptable as an alternative to the site completing its own audit of the processor providing that: • The scope of the audit meets the requirements of the Standard (i.e. at a minimum product safety, traceability, HACCP review, product security and food defence plan, product authenticity plan and good manufacturing practices). • The site has a copy of the full audit report (not just a certificate). • The processor can demonstrate the competence of the auditor. The auditor will expect to see, and will challenge, risk assessments. The site must be able to demonstrate to the auditor that the monitoring and ongoing review it uses is appropriate, justified and risk-based.
3.5.4.3	Where any processes are outsourced, including production, manufacture, processing or storage, the risks to the product safety, authenticity and legality shall form part of the site's food safety plan (HACCP plan).
Interpretation	The HACCP (or food safety plan) is the foundation of product safety processes and it is therefore vital that any outsourced processing is incorporated into the HACCP plan to ensure that any risks to product safety, authenticity and legality are identified and appropriate controls applied.
3.5.4.4	Requirements for outsourced processing shall be agreed and documented in a service specification (similar to a finished product specification). This shall include any specific handling requirements for the products.
Interpretation	The company must ensure that product safety, authenticity, legality and quality are maintained during outsourced processing and the return of products to the site. Therefore a service specification shall be in place for all outsourced processes, which details the activities to be completed and any specific handling requirements needed to maintain the safety, authenticity, legality or quality of the product.

Clause	Requirements
3.5.4.5	Any outsourced processing operations shall: • be undertaken in accordance with established contracts which clearly define any processing requirements • maintain product traceability.
Interpretation	**Contracts and traceability** Contracts must be in place for the approved processors detailed in clause 3.5.4.2 to ensure: • the correct level of service is provided • the processing requirements are clearly defined in terms of the work to be undertaken, the product, ingredient specification, and any relevant safety, quality, legality or authenticity requirements. There must be documented mechanisms to ensure traceability is maintained throughout the process. Records relating to the traceability of individual batches of processed ingredient or product must be available.
3.5.4.6	The company shall establish inspection and test procedures for products where part of the processing has been outsourced, including visual, chemical and/or microbiological testing. The frequency and methods of inspection or testing shall depend on risk assessment.
Interpretation	**Acceptance and test procedures** A documented acceptance procedure must identify the checks to be made when outsourced processing is complete. When products that have been processed are returned to the site, this procedure could form part of the goods receipt system. Acceptance procedures may, for example, include: • visual inspection • chemical, microbiological or allergen testing • hold/release requirements for the specific material (e.g. to allow additional testing or quality assurance checks). The requirements (both acceptance methods and the frequency of any checks or tests) must be based on risk assessment of the nature of the ingredient or product, the process and the outside processor undertaking the processing; for example, the processor may handle allergens that could potentially contaminate the processed product. The acceptance procedure must document any non-conformities, the person(s) authorised to accept conforming materials and reject non-conforming batches, and the action to be taken in the event of a non-conformity.

3.6 Specifications

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

Interpretation

The company must be assured of the quality of the products purchased. This includes any raw material or service that can affect food safety – for example, water and cleaning chemicals used, as well as services such as pest control, cleaning services or distribution.

Specifications for in-house intermediate products (work in progress) must be developed where they need to be checked and where they have an impact on product safety, authenticity, legality and quality.

A finished product specification must exist for all products covered under the certification scope, which ensures that required legislation and customer expectations are achieved.

Specifications must also be available for any product or service that can affect the integrity of the finished product. These should be sufficiently detailed to allow the company to understand and agree the product or service parameters; for example, specifications for cleaning chemicals should contain details on the components, usage instructions and material safety data.

Current specifications must be available for relevant personnel in order to ensure the specifications are being appropriately fulfilled. This may be the complete specification or parts thereof, or relevant details may be developed as production reference sheets, such as simple photographic specifications.

Clause	Requirements
3.6.1	Specifications for raw materials and primary packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements. The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological, physical or allergen standards).
Interpretation	**Raw material and packaging specifications** Specifications for all raw materials, including primary packaging materials, must be provided and adequately detailed. They must include the defined limits for all parameters critical to the safety, legality and quality of the product. They must also include details of packaging. The specifications may be in the format provided by the supplier or in the company's own format, as long as the information controlling the product's quality and safety are clearly defined.
3.6.2	Accurate, up-to-date specifications shall be available for all finished products. These may be in the form of a printed or electronic document, or part of an online specification system. They shall include key data to meet customer and legal requirements and assist the user in the safe usage of the product.

Clause	Requirements
Interpretation	**Finished product specifications** Specifications must be in place detailing all finished products. These specifications must be up to date (i.e. they must accurately represent the current version of the product) and should be reviewed whenever changes occur to the product, process or formulation. Good practice is therefore to ensure that the company has a system of change control where changes in products are identified before manufacture commences, that relevant amendments are made to the specification in a timely manner and that only the correct version of the specification is available to staff (see clause 3.6.4 for further details). The format of the specifications should be agreed with the customer to ensure that all relevant customer requirements are incorporated. This may, for example, be printed documents, electronic files or an online database. In the case of the company's branded products, it is acceptable to have an internal specification setting parameters for the manufacture of a product and a technical data sheet for customer use containing the key information for the safe use of the product, including but not limited to: • ingredients, including the presence of allergens • nutritional information • preparation or cooking instructions • storage instructions • shelf-life/code information • quantity. Specifications must be accurate and the control of amendments and approval of specifications should therefore be laid down in a documented procedure. This procedure should also detail who can approve the amendments.
3.6.3	Where the company is manufacturing customer-branded products, it shall seek formal agreement of the finished product specifications. Where specifications are not formally agreed, the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place.
Interpretation	**Formal agreement of specifications** Customer-branded, finished product specifications must be formally agreed with the relevant customer and must, wherever possible, be signed by both parties. However, where the customer's signature or approval is not formally available, proof that specifications have been issued (such as an email request for formal acknowledgement or specifications on customer IT specification systems) is required. In this situation the site must be able to demonstrate it is following a formal process agreed with the customer.
3.6.4	Specification review shall be sufficiently frequent to ensure that data is current or at a minimum every 3 years, taking into account product changes, suppliers, regulations and other risks. Reviews and changes shall be documented.

Clause	Requirements
Interpretation	**Review of specifications** Specifications must be reviewed whenever changes occur to the product, process or formulation. Where no known changes have occurred, the specifications must be reviewed at least every 3 years, or more frequently if required by a specific customer, to ensure they remain completely up to date and accurate. Evidence that a review has been completed needs to be available and this should be achieved through the addition of a signature and date to the specification or through the use of a matrix showing specifications and the latest review date and reviewer. The control of the amendment and approval of specifications should be laid down in a documented procedure. The procedure should also detail who can approve the amendments. Some sites, companies or customers use cloud-based services which are able to notify the user when there has been a change to the data. In these cases, the site should have a mechanism to review the specification or change to understand whether there is any impact to product safety, the HACCP or food safety plan, or the production processes. This requirement is also reflected in clause 2.12.3, which explains how the HACCP or food safety plan needs to be reviewed whenever raw materials change.

3.7 Corrective and preventive actions

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

Interpretation

The objective is to ensure there are clear procedures to deal with problems that have the potential to affect safety, authenticity, legality or quality, ensuring that the finished product and consumer safety are not compromised.

Corrective and preventive actions are applicable to a wide range of non-conforming situations; they are not limited to BRCGS audit results, non-conforming products and complaints. The statement of intent therefore includes some examples of situations in which corrective and preventive actions are required, but this list is by no means definitive. The aim is for information from all issues associated with the safety and quality management system to be used to make improvements, not just those requiring immediate action.

Clause	Requirements
3.7.1	The site shall have a procedure for handling and correcting issues identified in the food safety and quality management system. The site procedures shall include the completion of root cause analysis and implementation of preventive action.

Clause	Requirements
Interpretation	**Management of corrective actions** There must be a documented procedure for handling issues in the food safety and quality system which have a potential adverse effect on product safety, authenticity, legality or quality. All issues or non-conformities generated by the site (e.g. non-conforming product, internal audits and site inspections, third-party audits or customer complaints, product recalls, product testing (including inspections, quality assurance tests and laboratory testing)) must be subject to corrective action. Good practice is for corrective action to be completed as soon after detecting the non-conformity as possible (this is particularly important where the non-conformity could affect product safety, legality or quality – see clause 3.7.2). An important part of an effective corrective action process is the identification of the root or underlying cause of the non-conformity and the implementation of suitable action to prevent recurrence. Root cause analysis is a process of conducting an investigation into an identified problem to allow the investigator(s) to understand the fundamental cause and put it right. While there are a number of techniques for undertaking root cause analysis, one of the most common and simplest to use is the 'five whys' technique. The technique is based on repeatedly digging deeper into the cause of a problem by asking 'Why …?' to get to the root of the issue. Usually, the root cause becomes evident after five steps, but this is not fixed and further investigation should be completed where required. This is described in more detail in the example in clause 3.7.2. Some clauses in the Standard specifically require root cause analysis but it is up to the site to establish a procedure for its completion. Root cause analysis procedures should include: • a set of parameters that will initiate the use of an appropriate tool (i.e. the site must define when the analysis will be completed if it is not already prescribed by the Standard) • who is trained and/or authorised to complete the analysis • the methods that the site will use to conduct the analysis • the records which detail the analysis and any subsequent preventive actions • the methods for the verification of the completed actions. The auditor will expect to see a documented procedure that includes this information, as well as evidence of any root cause analysis and preventive action that the site has carried out. It is worth noting that in some geographies the analysis of trends may be a legal requirement. For example, in the EU, the Microbiological Criteria for Foodstuffs (EC) No 2073/2005 states that food business operators (FBOs) shall analyse trends in test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

Clause	Requirements
3.7.2	Where a non-conformity places the safety, authenticity or legality of a product at risk, or where there is an adverse trend in quality, this shall be investigated and recorded including: • clear documentation of the non-conformity • assessment of consequences by a suitably competent and authorised person • the corrective action to address the immediate issue • completion of root cause analysis to identify the fundamental cause (root cause) of the non-conformity • appropriate timescales for corrective and preventive actions • the person(s) responsible for corrective and preventive actions • verification that the corrective and preventive actions have been implemented and are effective. Root cause analysis shall also be used to prevent recurrence of non-conformities, and to implement ongoing improvements when analysis of non-conformities for trends shows there has been a significant increase in a type of non-conformity.
Interpretation	**Non-conformities with associated safety, authenticity, legality or quality risks** Non-conformities with the potential to affect product safety, authenticity, legality or quality must be recorded, and the responsibility for investigating the cause of problems and ensuring that an adequate response is taken must be assigned to specified personnel. Action needs to be undertaken as soon as possible after the detection of the non-conformity, but there may also be a need for long-term action to prevent further occurrence of the non-conformity. All actions undertaken must be documented. The records will include: • details of the non-conformity and when it occurred or was identified • assessment of the potential consequences of the non-conformity by a suitably competent and authorised person • details of the action taken to address the immediate issue and dates or timescales for completion of the actions (i.e. corrective action) • root cause analysis to identify the fundamental or root cause of the non-conformity • details of the preventive action taken to address the root cause and dates or timescales for completion of the actions • identification of who is authorised and responsible for the actions • details of the verification checks to ensure the action has been implemented and is effective. Where there is a significant trend in a specific type of non-conformity, root cause analysis must be used to investigate the trend and implement action to prevent recurrence. All corrective actions should be completed in a timely fashion. In practice this will depend on the nature of the activity and the potential consequences of a delay. For example, stopping the production line would happen immediately but receiving and fitting a new or replacement part may be a prolonged process. The actions should be included in a regular review of activities and systems. The site must assess the consequences of any delay in action and ensure that product integrity and safety are not jeopardised. Where set timescales are not met, the reason for the delay should be recorded and reviewed by the appropriate site management to ensure ongoing product safety and, where necessary, provide appropriate resources.

Clause	Requirements
Example	**Root cause analysis using the 'five whys' technique** An operator is instructed to perform a simple action, 'Weigh out ingredient A'. However, the operator inadvertently uses ingredient B instead. The immediate reaction would probably be that this was operator error. Although this may be accurate, it does not establish the reason why the error occurred or prevent it from happening in the future. Using the five whys technique, the root cause analysis should ask and answer a series of questions: • **Why did the operator make the error?** The operator was unfamiliar with the procedure. • **Why was an operator who was unfamiliar with the procedure asked to complete it?** He had been trained but there was no supervision or sign-off of the training to confirm it was satisfactory. • **Why was the training not satisfactory?** The two ingredients looked identical. • **Why weren't the ingredients clearly labelled?** The labels had been removed during cleaning and not replaced. • **Why weren't the labels replaced?** The cleaning staff did not consider the significance of the delay or the potential for an error. • **Why were the ingredient containers being used if they had not been set up correctly for manufacture?** Checking the labels did not form part of anyone's duties. The conclusion of a root cause analysis should be to identify what should be changed to prevent recurrence of the error. In this example, the conclusion might be to: • update the training procedure • introduce a training sign-off procedure to ensure training is understood • replace labels – if practical, with ones that cannot be removed. Where labels must be removed occasionally, ensure that post-maintenance line checks include a check of signage • ensure that an individual (e.g. the production manager) is authorised and responsible for post-cleaning line sign-off • ensure that cleaning staff fully understand and are trained in the need to return labelling (and all equipment) to a fully operational state. Now that the root cause analysis has been completed, it is easy to see how this incident occurred. The causes were: • an incomplete training procedure • a faulty cleaning process • lack of post-cleaning check procedures. The next step of the process is for the site to identify and implement suitable preventive action to ensure the problem does not occur again (where a non-conformity has multiple causes it is important that the preventive action addresses all of these). For example: • update the training procedure to ensure sign-off (and possibly a supervision step) • replace ingredient labels ideally with ones that cannot be removed • if labels must occasionally be removed, ensure that post-cleaning line checks include a signage check • ensure an individual is authorised and responsible for post-cleaning line sign-off • ensure cleaners fully understand and are trained in the need to return labelling (and all equipment) in a fully operational state. BRCGS has produced a guideline on root cause analysis which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.

3.8 Control of non-conforming product

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

Interpretation

The objective is to ensure there are clear documented procedures to deal efficiently with any non-conformity that has the potential to affect product safety or quality. There is also a need to ensure that any non-conforming product or raw material is physically removed from the production process.

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

Interpretation

Management of non-conforming product

The control of non-conforming product must be described in a documented procedure (in this context the implicated product could be any material, such as an ingredient, final product, packaging, or a combination of these). Procedures must include:

- ensuring that all staff are aware of the need to report issues that may affect product safety, authenticity, legality or quality, and to whom. This may be covered as part of the induction process for production staff
- the system for labelling and identification of non-conforming product. This may include both direct labelling and computer-based records.
- segregation or isolation of non-conforming product. Ideally, the product must be physically segregated by moving it to an identified area within the production site, or clearly marked so that it cannot be confused with in-process material or finished product. The use of electronic inventory systems to 'electronically isolate' the material is also acceptable. It is often good practice to confirm the effective control of remaining product by completing a documented inventory; i.e. verifying the amount of non-conforming product that has been isolated with the quantities recorded in the production and dispatch records.
- procedures for handling returned product; for example, goods receipt actions, secure storage and notifications of returned product to relevant managers.

Clause	Requirements

Interpretation *continued*	• referral to the brand owner where required. The brand owner may need to be notified of quality issues and would expect to be contacted where issues affect product safety. Agreement may need to be reached before the held products are released for sale. Contacting brand owners is not usually necessary where the decision is to destroy, downgrade or rework product, unless this notification is a contractual requirement of the brand owner
	• details of staff responsibilities, including which staff are authorised and responsible for decisions relating to non-conforming products. The final decision on what to do with held product should be taken by an experienced, technically competent manager. Only a limited number of personnel must have the authority to lift the hold notice or remove product from the isolation area
	• records of all products placed on hold. These must include:
	  • details of the product quantity and code
	  • the reason for isolation
	  • action taken or required to assess the suitability of the product
	  • the final decision on what to do with the product; for example, rework, downgrading or destruction of the product
	  • the name of the person authorising the decision and date
	  • confirmation of the action taken
	  • any further actions required to prevent recurrence (this may link to an investigation of corrective actions; see section 3.7)
	• the 'on hold' procedure employed while an investigation is completed
	• procedures for the effective safe disposal of product.
	
	It is usual to maintain a log of products which are on hold and to undertake periodic physical checks of held stock to ensure that accidental release has not occurred. The summary of products held and actions taken must be reviewed as part of the management review process.
	
	Non-conforming product is a key prompt to initiate root cause analysis, particularly when there has been an increase in incidents of the same type (e.g. mis-packing).

3.9 Traceability

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

Interpretation

As well as being a legislative requirement, traceability is a risk management tool, allowing food businesses and authorities to withdraw or recall products that have been identified as unsafe. It is therefore a fundamental requirement. A traceability system needs to be established at all stages of production, processing and distribution, identifying from whom raw materials have been obtained and to which customers finished product has been supplied. Note that the Standard requires forward and backward traceability throughout the production process. This means that the site should know where the material has come from (i.e. the direct supplier) and to whom finished product is dispatched.

There is no requirement for the site to trace raw materials all the way back to the source (e.g. farm) unless the source is the direct supplier to the site.

The system must ensure that products supplied to customers are adequately labelled or identified to facilitate traceability. Traceability details need to be retained in a format that allows access in a timely manner.

BRCGS has published a traceability guideline which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.

Clause	Requirements
3.9.1	The site shall have a documented traceability procedure designed to maintain traceability throughout the site's processes. At a minimum this shall include: • how the traceability system works • the labelling and records required. Where applicable, the traceability system shall meet the legal requirements in the country of sale or intended use.
Interpretation	**Traceability procedure** Sites are free to utilise their own traceability systems; no specific tool or technique is required by the Standard. Nevertheless, it is imperative that the site documents its traceability procedure so that it can be used and understood by the relevant personnel. This is particularly important at times of stress, when it is likely that the procedure will be relied upon to ensure at-risk product is identified and recalled or withdrawn in a timely manner. Some countries have specific legislation relating to traceability. The site will therefore need to ensure that any legislative traceability requirements in the country of sale or intended use are met.
3.9.2	Identification of raw materials (including primary packaging), intermediate/semi-processed products, part-used materials, finished products and materials pending investigation shall be adequate to ensure traceability.
Interpretation	**Identification of raw materials and finished product** Products and materials may be identified by physical labelling, by recording systems identifying the allocation of materials to production or mixing areas, or through the use of computerised bar-coding systems. The level of traceability may need to be agreed between the company and its customers, but the system used must be capable of linking all raw material lot codes to finished product codes. This will enable finished product to be identified if a particular batch of raw material needs to be recalled. The limitations of any system must be recognised, as can be demonstrated by the problems associated with bulk storage. Products such as sugar may be delivered with clear batch identification; however, if they are emptied into a single storage tank that is mixed with earlier deliveries, the reduction in accurate traceability is compounded by the potential for product to be trapped in dead zones during filling and emptying. If a particular delivery is identified as being contaminated, the entire product in the storage tank would need to be disposed of, as well as several lot codes of finished product, as the company would not be able to identify the specific batch of finished product that contained the contaminated material. A similar limitation will exist if recyclable packaging is collected from several sources and combined to form a single batch.

Clause	Requirements
Interpretation *continued*	The traceability system needs to include primary packaging (a full definition of primary packaging is available in the glossary, Appendix 1). Note that processing aids (i.e. substances that are used within the process but are not required to be declared as an ingredient, such as sodium alginate for the clarification of beer) are included in the definition of raw materials (see glossary, Appendix 1) and therefore need to be included in the traceability system. All test results (clause 3.9.3) must be traceable to specific batches of product or ingredient. Consider how the traceability system operates in practice (with the effective physical identification of ingredients and products). For example, if bulk containers are labelled, consider how the information is presented to ensure it is legible and accurate. Common non-conformities include the ineffective labelling of part-used packs in production, work in progress, and storage areas leading to potential errors. Strict controls on material identification, traceability and segregation are also required to preserve the integrity of any claims made, such as organic status. Where logos are used that make specific claims about production systems (e.g. farm assurance), full traceability must be demonstrated (see also section 5.4). Apart from batch or lot codes, traceability information will usually include date codes to ensure that only ingredients, intermediates and products within the appropriate shelf-life period are used. Particular care is needed for decanted ingredients, work in progress and products stored in bulk where the packaging has been removed.
3.9.3	The site shall test the traceability system across the range of product groups to ensure traceability can be determined from the supplier of raw material (including primary packaging) to the finished product and vice versa. For food raw materials and finished products (i.e. including printed packaging and labels with food safety and legal information), the test of the traceability system shall include a quantity check/mass balance. The traceability test shall include a summary of the documents that should be referenced during the test, and clearly show the links between them. The test shall occur at a predetermined frequency, at a minimum annually, and results shall be retained for inspection. Traceability should be achievable within 4 hours.
Interpretation	**Tests of the traceability system** Good practice is for the site to have a procedure or document that highlights the traceability system that is used at each step in the production process. It could include, for example, how incoming raw material batch numbers are captured, and how the outgoing product is traced and labelled. The process flow diagram developed as part of the HACCP plan (see clause 2.5.1) may be useful to ensure all steps are captured. The site's traceability system must be tested at least annually, or more frequently if required by a customer. (Note that the frequency of traceability tests relating to provenance and origin claims is covered separately in clause 5.4.5.) Where traceability for all products manufactured by the site is the same or similar, then a minimum of one traceability test a year must be completed. However, if there are significant differences or specific traceability challenges relating to one product or group of products, additional tests specifically related to that product or group of products may be needed. Traceability testing may be completed as part of a real product recall or withdrawal scenario if one has occurred, since the objective is to test the system and identify areas for improvement, rather than supply records of a 'test' for its own sake.

Clause	Requirements
Interpretation *continued*	The system must provide traceability forwards and backwards; therefore the system should be tested in both directions. For example, a raw material could be selected and traced forwards to show in which finished products it was used. A finished product should also be selected and traced backwards to show all the raw material batch codes (including primary packaging) that were used to produce it. The tests should include identifying which customers received the finished products and which suppliers provided the raw materials. The traceability test must also include the traceability of the primary packaging materials. Although there are many benefits to complete supply chain traceability (i.e. from the farm through all stages of processing, distribution and storage, through to the retailer or food service company), this clause does not require sites to complete full supply chain traceability tests. The scope of the traceability test required here is from the suppliers of the raw material, through the site's processes, to the site's customers. The site is also expected to compile a summary of the documents that should be referenced during the test, and clearly show the links between them. This is of benefit to both the site and the auditor, as it ensures all relevant documents are retrieved, and explains the traceability system. The test of traceability should be timed and full traceability would be expected to be achieved within 4 hours. This is to reflect the need for rapid traceability in the event of a recall. Where traceability takes longer than 4 hours, review the areas where the retrieval of information is slow in order to identify improvements. For all food products, and printed packaging and labels which have product safety information, the tests must also include a quantity check or mass balance exercise. It is not expected that the full mass balance exercise would always be achievable within 4 hours. The objective is to be able to account for the usage of a full batch of a raw material. This helps to ensure that the traceability systems are capable of operating effectively should a product recall be required based on the recall of an ingredient. The mass balance exercise is usually undertaken as follows: • Select a batch code of a particular specific raw material. • Identify the quantity of the raw material supplied under that batch code. • Identify the recipes in which the ingredient is used. • Use production schedules and batch make-up sheets to calculate the quantities of the selected batch of ingredient used in each product. • Calculate the quantity of any unused part of the batch in the warehouse. • Reconcile the quantity delivered against the amounts used plus any residual unused stock. In some instances quantity checks may take a great deal of time and resource to complete successfully. It is unlikely that the mass balance exercise will be able to account for all materials to 100% accuracy. However, the company needs to justify any discrepancies and demonstrate understanding of the nature of the variance. This may be inherent in the product characteristics (e.g. dehydration of fresh ingredients), or be ascribed to typical wastage on equipment or portion variances. Where the site adds subsequent deliveries to a bulk silo, the test should clearly show how this has been managed. The principle is to ensure that the traceability system is effective. Mass balance is a key measure of its workability and highlights areas for improvement.

Clause	Requirements
Interpretation *continued*	During the BRCGS audit, the auditor will ask the site to complete at least one 'vertical' audit. At a minimum this will include the traceability of a specific batch of product or ingredient through the site's production, processing and distribution processes, and a review of the site records related to the product or ingredient. Records will include, for example, supplier approval, goods receipt, process records (such as temperature monitoring), metal detector checks and dispatch records. However, the vertical audit is not expected to include records that would only be held at other points in the supply chain (e.g. the raw material supplier's processing records). This vertical audit is in addition to the review of the site's own traceability tests. The final audit report will include a summary of the vertical audit results. The vertical audit will also include a mass balance exercise and a review of the systems relating to the accuracy of labelling (clause 5.2.1). Further information on the content of the audit, including the vertical audit, can be obtained from BRCGS' auditing techniques document. This may be viewed online at **BRCGS Participate**. BRCGS publishes a separate best-practice guideline on traceability, which may be purchased from the **BRCGS Store** or viewed online at **BRCGS Participate**.
3.9.4	Where rework or any reworking operation is performed, traceability shall be maintained.
Interpretation	**Rework** Many sites undertake rework or recycling activities, where raw materials, work in progress or final product that has left the normal production but is still safe, legal and of the appropriate quality, is reprocessed. There may be several reasons for completing rework, including to: • reincorporate the material into a batch of the same product (either the batch currently being manufactured or to enable the materials to be stored for inclusion in a future production) • incorporate the material into a batch of another product with similar ingredients • process the material to meet the requirements of an alternative customer. Where rework is undertaken, procedures must be in place to ensure that traceability is maintained.

3.10 Complaint-handling

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

Interpretation

Complaints are key sources of information, informing the site of potential concerns and providing the opportunity for continual improvement; for example:

- in the event of a complaint relating to product safety, authenticity, legality or quality, they may require escalation into emergency plans such as a product withdrawal or recall
- the company's attitude to complaints and complaint-handling processes may indicate the company's product safety and quality culture; for example, the timeliness and robustness of complaint investigation and the appropriateness of any actions.

Therefore, an effective complaint-handling system needs to be operated by the company. The objective of the complaint investigation process should be to identify and correct causes of complaints, and one measure of an effective system should be a reduction in the number of complaints as a proportion of production volume.

Clause	Requirements
3.10.1	All complaints shall be recorded and investigated, and the results of the investigation of the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.
Interpretation	**Documentation and action** The company should ensure there is a clear process for customers (and potentially consumers) to raise legitimate complaints about the products. This is usually via the contact information on product labels. Where products are supplied into food service or through intermediaries, every effort should be made to ensure that complaints raised are relayed to the complaints department of the site. All complaints need to be captured to a specified location to ensure they are adequately assessed and investigated, and the results of this investigation recorded. A documented complaints procedure is therefore required and the inclusion of a standardised complaint form may be useful. Complaints must be handled by appropriately trained staff to ensure that a proactive system identifies the severity, and therefore the significance, of any complaints received. Actions must be appropriate to the seriousness of the complaint. A rapid response would be required for serious issues (such as a glass complaint) or where a number of complaints are received, suggesting a widespread problem. Investigation must be completed within a defined timeframe and feedback provided to the complainant wherever contact details are provided.
3.10.2	Complaint data shall be analysed for significant trends. Where there has been a significant increase in a complaint, or a serious complaint, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.
Interpretation	**Trend analysis** Data on customer complaints must be analysed to identify trends. A root cause analysis must be carried out where there is evidence of an emerging trend or a serious complaint. This is to help ensure problems are identified and improvements made to prevent recurrence as far as practicable. This may include, for example, an analysis of foreign-body complaint types as complaint numbers per number of units produced, with data by shift or by production line. This data must be communicated to relevant staff and may include graphical displays on staff noticeboards or discussion at routine operations meetings.

Clause	Requirements
Interpretation *continued*	Trend analysis may demonstrate that certain complaints are associated with customer abuse of the product (e.g. not following cooking instructions). A root cause analysis of these complaints should be undertaken to establish whether the underlying cause can be managed by the company. For example, could on-pack instructions be made clearer to reduce customer abuse and therefore the number of complaints? BRCGS publishes a separate best-practice guide to complaint-handling, which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.

3.11 Management of incidents, product withdrawal and product recall

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

Interpretation

Incidents are events that may result in the production of unsafe, illegal, non-conforming product or products that are not authentic, and risks to consumer safety. An emergency situation may also occur as a result of a sudden, unforeseen crisis that requires immediate action. An effective emergency plan must be in place so that if at any stage an incident occurs that impacts food safety, authenticity, legality or quality, it will be managed effectively. The incident may be directly related to the product, the disruption of key services such as power and water, or environmental influences such as fire or flood.

The plan must be understood by relevant staff and must be routinely tested so that it can readily be put into practice, as incidents occur when least expected. The importance of a tried and tested procedure, ensuring that personnel know who does what and when, cannot be underestimated.

Clause	Requirements
3.11.1	The company shall have procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, authenticity, legality or quality. This shall include consideration of contingency plans to maintain product safety, authenticity, legality and quality. Incidents may include: • disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications • events such as fire, flood or natural disaster • malicious contamination or sabotage • product contamination indicating a product may be unsafe or illegal • failure of, or attacks against, digital cyber-security. Where products which have been released from the site may be affected by an incident, consideration shall be given to the need to withdraw or recall products.
Interpretation	**Documented incident and emergency procedures** In the event of an incident or emergency situation, the company must be ready to instigate actions as promptly and efficiently as possible. Therefore the site must have a documented incident management plan. The objective of the plan must be to minimise risk to consumers and potential disruption to business. Systems must be in place and used to ensure that

Clause	Requirements
Interpretation *continued*	information is collated and quickly assessed by staff who understand its significance and who can develop an appropriate action plan. The site might establish a crisis management plan that could address the points listed here, and any additional risks which are outside the scope of the Standard. A documented incident management procedure is required. Although it may not be possible to detail exactly what action will be taken, as this will depend on individual circumstances, the company should consider: • standard responses to a range of potential disasters, such as fire, flood or the loss of essential services • the provision of alternative resources for energy, water, transport and any potential options for subcontracting production • how to handle acts of potential malicious contamination or extortion • management of unsafe or illegal products; for example, due to contamination or authenticity concerns • details of staff responsibilities, including which staff are authorised and responsible for making decisions relating to non-conforming products. The number of incident management team members should be appropriate for the size of the business • a plan to handle the logistics of product traceability and the recovery or disposal of affected product and stock reconciliation (i.e. comparing the amount of implicated product with the amounts known to have been destroyed, returned or retained in storage) • methods to communicate with key contacts, both internal and external, such as telephone and email contact details (including office hours and out-of-hours details) • the communication process, and the way in which enquiries from customers and the media are handled (this can be critical to the effective management of the situation and ultimate business recovery) • corrective action that needs to be taken before production can recommence • root cause analysis and preventive actions. Sites should reference their root cause procedure (clause 3.7.1), so that relevant preventive actions can be completed • procedures to withdraw or recall affected products. These details must be kept up to date by periodic verification. Customers and suppliers may need to be involved in the development of documented procedures as they may have their own requirements for crisis planning. With more data being stored digitally and in cloud services, the site needs to be aware that such data is valuable to those who might extort or blackmail companies. Even though cloud services can be relatively secure, digital attacks and failures of systems pose a significant risk and the site needs to ensure that digital data is secure by using, for example, password protection, anti-virus software, firewalls and/or data backup systems. Some organisations have published advice on cyber-security; for example, the National Cyber Security Centre's 10 Steps to Cyber Security. Good practice following an actual recall is to assess the effectiveness of the plan to identify and implement any appropriate learning or improvements. This process can form part of the evidence of compliance with clause 3.11.3.

Clause	Requirements
3.11.2	The company shall have a documented product withdrawal and recall procedure. This shall include, at a minimum: • identification of key personnel constituting the recall management team, with clearly identified responsibilities • guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained • an up-to-date list of key contacts (including out-of-hours contact details) or reference to the location of such a list (e.g. recall management team, emergency services, suppliers, customers, certification body, regulatory authority) • a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner • details of external agencies providing advice and support as necessary (e.g. specialist laboratories, regulatory authority and legal expertise) • a plan to handle the logistics of product traceability, recovery or disposal of affected product, and stock reconciliation • a plan to record timings of key activities • a plan to conduct root cause analysis and to implement ongoing improvements, to avoid recurrence. The procedure shall be capable of being operated at any time.

Interpretation

Documented withdrawal and recall procedure

A product recall is defined as any activity that involves the return of an unfit product from customers and final consumers, whereas a withdrawal is the return of out-of-specification or unfit products from customers, but not from final consumers (see glossary for full definitions).

The site must have a documented recall and withdrawal procedure. At a minimum, it must include:

- details of the recall management team members, including their roles, responsibilities and contact details. In larger businesses the recall team will involve head office personnel and it may be run from the head office. In this case the links between the production-site management and the recall team need to be clear
- guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained. Although causes for recall are often unpredictable, defined responses to known risks (e.g. identification of pathogens in routine product sampling) could be documented
- an up-to-date list of key contacts (e.g. recall management team, suppliers, customers, the certification body and regulatory authorities). A recall may occur at any time; therefore office hours and out-of-hours contact details must be provided
- a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner. The communication process and the way in which enquiries from customers and the media are handled can be critical to the effective management of the situation and ultimate business recovery. The use of professional resources to assist in communication management may sometimes be advisable
- details of external agencies providing advice and support as necessary (e.g. specialist laboratories, regulatory authorities and legal expertise)
- a plan to handle the logistics of product traceability, recovery or disposal of affected product and stock reconciliation

Clause	Requirements
Interpretation *continued*	• a log of activities created as the event unfolds and real-time observations, which could, for example, be used in discussions with customers or regulatory authorities. This may be valuable during a post-incident review to consider improvements to incident management processes • reference to the root cause analysis procedure, so that relevant preventive actions can be introduced. In the event of a product recall, it is obviously important that actions are completed in a timely fashion. Therefore, the aim of noting key times in the plan is to ensure that this will happen during both tests of the system and during any actual incident. There are various times that should be recorded, including: • when the incident or test started • times of internal communications and key decisions • when traceability and mass balance exercises were started and completed • communication to customers or regulatory authorities.
3.11.3	The incident management procedures (including those for product recall and withdrawal) shall be tested, at least annually, in a way that ensures their effective operation. Results of the test shall be retained and shall include timings of key activities. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary.
Interpretation	**Tests of the withdrawal and recall procedures** The incident management procedure must be tested at least annually. This test must include a test of the product withdrawal and recall processes which form part of the incident management procedure. It should be emphasised that traceability is only part of this procedure and therefore a repeat test of the traceability will not, on its own, be sufficient to demonstrate that the site is meeting this requirement. The aims of testing the full procedure are to: • demonstrate that the system works • highlight any gaps and where the system requires improvement • demonstrate how quickly the required information can be collated, and thereby corrective action taken, such as materials being isolated and quarantined • act as a training exercise for personnel to ensure that clear roles and responsibilities are undertaken in the event of a real withdrawal situation. The test of the recall and withdrawal procedure must include verification of the decision-making process, traceability of raw materials through to finished product, verification of contacts, and timings of key activities. Records must be kept of tests of the recall and withdrawal procedure and must include a review of the result of the test and any action taken for improvement. If the site has had an actual withdrawal or recall which fully tested its recall procedures, then this would be a substitute for a recall test as long as records are maintained, an analysis of the effectiveness of the recall procedure is carried out, and any areas for improvement are identified and acted upon. In larger businesses the recall team may involve head office personnel and the test may be run from the head office. In this case the links between the production site management and the head office recall team need to be clear.

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

Interpretation

Notification of recalls to the certification body

Where there is a significant incident related to product safety, authenticity or legality the site manufacturing or processing the implicated product is required to notify their certification body of the situation. The types of situation that should be notified include:

- all product recalls
- any situation where the regulatory authority insists on action (e.g. an enforcement notice) due to product safety or legality concerns
- legal proceedings with respect to product safety or legality
- adverse media attention relating to product safety
- any food safety incident with the potential to harm a consumer
- any food safety-related product withdrawal (it is worth noting that only product safety-related withdrawals need to be notified to the certification body; other types of product withdrawal, such as those related to product quality, do not need to be notified).

The aim of this notification is to ensure that the integrity of the certificate is maintained by allowing the certification body to assess whether the incident affects the certification status of the site.

It is important that action is taken in a timely manner; therefore this initial notification, that a notifiable incident has occurred, must be completed within 3 working days of the recall or other action taking place.

The company must also provide sufficient information to enable the certification body to assess any effects of the incident on the ongoing validity of the current certificate. Therefore, as a minimum, the company must forward copies of its corrective action, root cause analysis and preventive action plan. Note that this additional information may take some time to collate and evaluate prior to communication to the certification body, especially in the case of a complex incident. Therefore, it is not expected that this will be available at the time of the initial notification, but may be submitted to the certification body at a later date. It must, however, be submitted within 21 days of the incident.

Where appropriate, the certification body can request further information or conduct a full or partial re-audit of the site to confirm certification.

4 Site standards

4.1 External standards and site security

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

Interpretation

This part of the Standard is one of the most straightforward. It requires that the manufacturing facility is fit for purpose, both externally and internally, and that operations are conducted in an orderly fashion so as not to jeopardise the safety, legality or quality of the product.

This section also includes the security systems that must be in place to control access to both external and internal areas of the site, buildings and product, including the records of all visitors to the site.

Clause	Requirements
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site (from potential contaminants, flooding etc.), they shall be reviewed in response to any changes.
Interpretation	**Local activities and site environment** Local activities and the site environment must not have an adverse impact on finished product integrity. (A site plan or map that indicates neighbouring activities may be useful.) Points to consider may include: • derelict buildings, rubbish dumps, wasteland, etc. which could harbour pests • adjacent watercourses at risk of flooding • neighbouring companies and the nature of their business (e.g. presenting air or odour taint potential). Appropriate measures, such as additional pest or flood control, must be put in place and reviewed to ensure they are continually effective (e.g. by inclusion in internal audit schedules).
4.1.2	The external areas shall be maintained in good order. Where grassed or planted areas are located near buildings, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to mitigate the risk of contamination of the product.
Interpretation	**Maintenance of external areas** External areas must be maintained in good order and the condition of the site included in audit procedures. Overgrown areas can harbour pests; therefore, where areas are planted, they must be tended regularly. For example, good practice is to have a 0.5 m clear zone between the bottom of vegetation and external walls. Drainage in external areas is expected to deal with normal quantities of rainfall without long-term pooling of water. If natural drainage is inadequate, external drainage must be installed. To prevent potential contamination by dust, mud etc., all traffic routes under the control of the company must be suitably surfaced and maintained in good order. It is recognised that

Clause	Requirements
Interpretation *continued*	traffic routes may have a variety of surfaces, and contamination risk to products will be influenced by other factors, such as weather conditions. The principle is to ensure that products are not placed at additional risk of contamination through the inappropriate surfacing of routes where products are transferred. Risk may also be reduced by a combination of procedures, such as the suitable protection of products while in transit, or wash-down of transit vessels prior to entering production areas.
4.1.3	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird-roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).
Interpretation	**Maintenance of buildings** The outsides of buildings must be monitored and maintained in a condition such that they do not present a risk of product contamination. For example, pipework must be appropriately sealed to prevent pest entry, bird nesting sites must be eliminated (e.g. by using appropriate netting), and ingress of water and other contaminants must be prevented.
4.1.4	Policies and systems shall be in place to ensure that access to the site by staff, contractors and visitors is controlled. A visitor recording system shall be in place. Contractors and visitors, including drivers, shall be made aware of the procedures for access to the site. Only authorised personnel shall have access to production and storage areas. Contractors working in product processing or storage areas shall be the responsibility of a nominated person. Staff shall be trained in site security procedures.
Interpretation	**Access to the site** There must be a visitor-reporting or monitoring procedure. When visitors or contractors come on site, they should not be able to enter production areas without first reporting to site representatives, who will: • make them aware of site rules; for example, relating to access • issue them with any protective clothing necessary for the areas they are visiting. Good practice is to include details of the name, company, date, time of entry and exit, as well as the purpose of the visit. Only authorised personnel should have access to production and storage areas. Therefore, these areas should have designated access points, which should be directly monitored or locked with, for example, keys issued to nominated personnel, key-code locks or alarmed. Contractors or visitors working in these areas must be the responsibility of a nominated member of staff. It is normally good practice for them to be accompanied by the nominated staff while in production and storage areas. All staff must be trained in the company security procedures and form part of the security arrangements. They should be encouraged to make enquiries on or report unknown persons in the facility. They must not compromise their personal safety; suspicious activities should always be referred to security staff (where they are available).

4.2 Food defence

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

Interpretation

The objective is to ensure that the safety of finished products is not jeopardised through malicious actions, tampering or unauthorised persons.

The following clauses mirror those concerning food fraud (section 5.4), so the site can choose to consider food defence and food fraud together, if that is a more effective use of time and resource, or separately if the company prefers, providing both food authenticity and food defence are robustly assessed and managed.

Good practice, especially in larger companies, is to use a multi-disciplinary team that includes different roles within the company; for example, quality assurance, technical management, production, security and human resources. In smaller companies this may not be possible, but consideration should be given to the inclusion of all relevant colleagues or expertise.

In companies with multiple sites, some or all of the food defence threat assessment may be developed in one of two ways:

- centrally; for example, by a head office; or
- locally at each individual office.

Where it is completed centrally it is important to ensure that the assessment and resultant food defence plan remain relevant to the specific sites and their activities. This may be achieved by, for example:

- including members from the relevant sites in the food defence team
- ensuring that the study is reviewed by senior members of staff located at the relevant sites
- including the assessment and plan in the scope of the internal audit programme.

The BRCGS auditor will look for evidence of checks against local site activities and sign-off of the completeness and accuracy of the study.

BRCGS will publish additional guidance on food defence, which may be purchased from the **BRCGS Store** or viewed online at **BRCGS Participate**.

Clause	Requirements
4.2.1	Where personnel are engaged in threat assessments and food defence plans, the individual or team responsible shall understand potential food defence risks at the site. This shall include knowledge of both the site and the principles of food defence. Where there is a legal requirement for specific training, this shall be in place.
Interpretation	**Competency of the food defence team** It is important that personnel completing food defence threat assessments are competent to develop the plan; they need to understand the risks they are trying to prevent. Therefore, it is expected that within the team there will be knowledge of the principles of food defence and the site.

Clause	Requirements
Interpretation *continued*	The Standard is not prescriptive regarding how this knowledge is demonstrated and may include, for example: • training (e.g. a training course in food defence) • experience (e.g. demonstrable knowledge of the site such as security-related duties, or length of service at the site) • other competency (e.g. the completeness and effectiveness of the threat assessment and its implementation). Where there is a legal requirement for specific training, for example, in the US FSMA, the site is expected to be able to demonstrate that this has been appropriately completed. In the event of the site not having the appropriate in-house knowledge, external expertise (e.g. food safety consultants) may be used; however, reference should be made to clause 1.2.4 and section 3.5.3.
4.2.2	The company shall undertake a documented risk assessment (threat assessment) of the potential risks to products from any deliberate attempt to inflict contamination or damage. This threat assessment shall include both internal and external threats. The output from this assessment shall be a documented food defence plan. This plan shall be kept under review to reflect changing circumstances and market intelligence. It shall be formally reviewed at least annually and whenever: • a new risk emerges (e.g. a new threat is publicised or identified) • an incident occurs where product security or food defence is implicated. Where applicable, the food defence plan shall meet the legal requirements in the country of sale or intended use.
Interpretation	**Documented assessment of security** The company must undertake a threat assessment of the risks inherent to the operation to prevent malicious intervention. The threat assessment needs to consider both external threats (e.g. individuals or organisations gaining unauthorised access to the site, building or products) and internal threats, such as malicious tampering by staff who are authorised to be on site. Each area (e.g. warehouses, processing areas and external storage areas) needs to be assessed in terms of how vulnerable the product is to contamination. Sensitive or restricted areas, such as open product areas, are likely to be the most vulnerable; the vulnerability of the packaged product will depend on the nature of the packaging. Details of IT systems and data protection should also be included in the assessment. The output of the threat assessment must be a food defence plan, which details: • the identified risks • the mitigation strategy; i.e. the steps or mechanisms used to avoid or mitigate the identified risks (see clauses 4.2.3 and 4.2.4). The food defence plan must be reviewed periodically; for example: • when there is a change to the site or buildings • when new market intelligence or supply chain information indicates a new or changed threat

Clause	Requirements
Interpretation *continued*	• following an incident where product security or food defence systems are implicated. This may include all forms of incident, as well as any customer complaints indicating that current food defence measures are not effective • at least annually. Records of the review need to be available for the audit. Where there are legal requirements relating to food defence (e.g. in the US FSMA), the site must be able to demonstrate that its food defence plan meets these requirements.
4.2.3	Where raw materials or products are identified as being at particular risk, the food defence plan shall include controls to mitigate these risks. Where prevention is not sufficient or possible, systems shall be in place to identify any tampering. These controls shall be monitored, the results documented, and the controls reviewed at least annually.
Interpretation	**Additional controls to mitigate risks** The site's food defence plan may result in the need to take additional measures to mitigate risks to raw materials or product. This may include extra verification or testing when raw materials are delivered, or additional wrapping with tamper evidence on pallets. Whatever the measure, it should be appropriate and validated to ensure that it is effective. The auditor will expect to see the documented plan (clause 4.2.2) and the methodology of determining which products, materials or areas require additional control. The additional measures and procedures should be documented and the auditor will expect to see these measures in action at the time of the audit. Ideally the controls used should prevent the threat from occurring; however, where this is not possible, the controls should mitigate risk and use tamper evidence so that malicious activity can be seen and addressed in a timely manner, before it becomes a product safety issue. The systems must be reviewed at least annually, including the controls identified in the plan, to check whether they are still effective and relevant.
4.2.4	Areas where a significant risk is identified shall be defined in the food defence plan, monitored and controlled. These shall include external storage and intake points for products and raw materials (including packaging). Staff shall be trained in food defence procedures.
Interpretation	**Authorised access** The basic principle is that only authorised staff should have access to production and storage areas. Levels of access for various areas at the site may differ between employees. Restriction of access to areas where sensitive materials are stored (e.g. laboratories, maintenance areas or document storage areas) should also be in place. Where appropriate, areas should be locked when not in use.

Clause	Requirements
Interpretation *continued*	All staff must be trained in the company food defence procedures. This is not the same as the training described in clause 4.2.1. There, the staff involved in the threat assessment and development of the site's food defence plan must have knowledge of the principles of food defence and the site, whereas this clause requires all staff to be trained in the relevant food defence procedures; i.e. in the relevant site procedures that have been developed as a result of the food defence threat assessment. Where a site wishes to combine this training with the security training described in clause 4.1.4, this is acceptable providing both topics are sufficiently covered.

4.3 Layout, product flow and segregation

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

Interpretation

The physical layout and flow of processes, materials and personnel must be identified, designed, managed and maintained to protect product integrity and prevent contamination, whether physical, chemical or microbiological.

Clause	Requirements
4.3.1	The site shall assess the production risk zones required for the products manufactured, processed or packed at the site, using the definitions in Appendix 2 of the Standard.
Interpretation	**Production risk zones** All sites need to ensure that the production facilities are suitable for the types of products they are manufacturing, processing or packing. This includes an assessment of the production risk zones needed for the prevention of microbiological contamination. Full details of the definitions of the production risk zones recognised by the Standard are given in Appendix 2 of the Standard. However, in summary, the Standard recognises six zones: • high-risk and high-care zones for chilled or frozen and ready-to-eat products where there is a risk of contamination • ambient high care for products where there is a risk of contamination with vegetative micro-organisms originating from raw materials and the products are stored in ambient conditions (rather than chilled or frozen) • low-risk areas • enclosed product areas (e.g. storage areas where products are fully enclosed within packaging and production areas where the product is fully enclosed within the equipment or pipework) • non-product areas (i.e. areas such as offices, where products are not taken at any stage in their manufacture or storage).

Clause	Requirements
Interpretation *continued*	It is important to note that the high-risk, high-care and ambient high-care production zones usually only apply to part of a factory's production processes. These zones typically start when products exit a microbiological kill step and include all the processes and steps until the products are enclosed in packaging. The auditor will expect to see a documented assessment comparing the products manufactured, processed or packed on site with the definitions within Appendix 2 of the Standard. Where a site identifies the need for a high-risk, high-care or ambient high-care production zone, the relevant clauses from section 8 will apply to those areas.
4.3.2	There shall be a map of the site. At a minimum, this map shall define: • production risk zones, where product is at different levels of risk from pathogen contamination – for example, high-risk, high-care, ambient high-care, low-risk and enclosed product areas (see clause 4.3.1 and Appendix 2) • access points for personnel • access points for raw materials (including packaging), semi-finished products and open products • routes of movement for personnel • routes of movement for raw materials (including packaging) • routes for the removal of waste • routes for the movement of rework • location of any staff facilities, including changing rooms, toilets, canteens and smoking areas • production process flows • any areas where time segregation is used to complete different activities (for example, time segregation for high-care areas).
Interpretation	**Site map** The aim of the site map is to provide an overview of all the locations within the site, areas where the product is at different levels of risk from the general environment and the movements of products, materials and people. It can then be used to support the site's risk assessments and subsequent prevention of contamination; for example, by identifying the locations where potential hazards (e.g. allergen cross-contamination) can occur. The site map will be expected to illustrate the locations of critical facilities and activities, as detailed in the requirement, including: • production risk zones (e.g. high-risk areas, high-care areas, low-risk areas, and enclosed product areas; see clause 4.3.1). The object of identifying the production risk zones is to ensure that the standards of environmental hygiene, particularly those concerning equipment, buildings, cleaning and personnel hygiene, are appropriate for the work being undertaken. It also allows the product and personnel flows to be reviewed, to ensure they do not compromise product safety • access points for personnel clearly showing the routes into, and out of the site and production areas

Clause	Requirements
Interpretation *continued*	• access points for raw materials, semi-finished products and open products • routes of movement for personnel. If it is necessary to allow access through production areas, good practice is to identify designated walkways that ensure there is adequate separation from materials. Wherever possible, all facilities should be designed and positioned so that the movement of personnel is by simple, logical routes • routes of movement for raw materials • routes of movement for the removal of waste • routes of movement for rework • the location of staff facilities, including changing rooms, toilets, canteens and smoking areas • areas where time segregation is used; in other words, where the same production area is used as both a high-care and a low-risk production zone at different times, with time segregation being used to separate the products with different risks (see Appendix 1 for definitions). Sites which have identified the need for high-risk, high-care or ambient high-care areas (see clause 4.3.1) will also need to include the location of the pathogen control step(s) on the map (see clause 8.1.1). The Standard is not prescriptive on the format of the map, providing all of the relevant information is available. For example: • It is often useful to put the required information on several overlapping maps rather than a single diagram. • In complex sites a schematic diagram may be of greater benefit than a map.
4.3.3	Contractors and visitors, including drivers, shall be made aware of the requirements of the areas they are visiting, with special reference to hazards and potential product contamination.
Interpretation	**Contractors and visitors** Contractors and visitors (including drivers) must be made aware of all access restrictions and procedures related to them. Visitors should be told when they sign in and the information should be specific to the areas they will be visiting. Contractors who visit regularly should be trained to a similar level as employees, and a record of the training retained.
4.3.4	The movement of personnel, raw materials, packaging, rework and/or waste shall not compromise the safety of products. The process flow, together with the use of demonstrably effective procedures, shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products.

Clause	Requirements
Interpretation	**Movement of personnel, raw materials, packaging, rework and waste** The HACCP or food safety plan must identify the potential risks associated with all production risk zones and the appropriate controls (including the level of prerequisite programmes) for the safe production of the products. A combination of process flow and procedures (e.g. the prerequisite programme and work instructions) will be used to minimise risk to raw materials, packaging and products. Particular attention needs to be paid to the movement of personnel, raw materials, packaging, rework and waste, to ensure that the routes taken are defined and product safety is not compromised. For example, the removal of unnecessary packaging, such as debagging or removing outer boxes, should take place in a designated area, usually prior to transfer to production areas, in order to avoid potential foreign-body risks from discarded packaging. The procedures developed to ensure product safety must be documented and validated as effective, and the appropriate staff must be trained. For example, where sites are receiving packaging through 'hole in the wall' operations, suitable controls should be in place to ensure that there is no risk to the product and the materials are treated appropriately. For example, an adjacent factory might deliver packaging materials on a conveyor or belt, as is often the case in dairy packing and carbonated beverages.
4.3.5	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.
Interpretation	**Work and storage space** Premises must be designed to allow sufficient working space and storage capacity so that all operations are carried out properly under safe, hygienic conditions, thereby reducing the potential for cross-contamination between activities because of close proximity. For example, overfull refrigerated storage may lead to doors being left open for extended lengths of time because of difficulties in accessing required materials. This would lead to a non-conformity. Consideration should be given to all activities, including inspection, cleaning, pest control and maintenance, as well as manufacturing operations.
4.3.6	Temporary structures constructed during building work or refurbishment etc. shall be designed and located to avoid pest harbourage and ensure the safety and quality of products.
Interpretation	**Temporary structures** Temporary structures (e.g. those constructed during building work or refurbishment) must be designed and located to avoid pest harbourage, unsanitary conditions and potential contamination of products. For example, where walls have to be knocked through during installation or expansion work, the integrity of the unit must be preserved to avoid pest entry, and scaffolding used in open product areas must be of the appropriate hygienic standard. Risk assessment of temporary activities or structures should be completed prior to their introduction.

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

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

Interpretation

The design, construction and maintenance of the interior of the facility must support effective cleaning and protect products from contamination.

The type of finish to walls, floors and ceilings must, at a minimum, meet the requirements laid down in any applicable legislation for the industry, and be suitable for the intended purpose.

Where a site has different production risk zones (see clause 4.3.1), good practice is to consider whether there are different facility requirements for each zone.

Clause	Requirements
4.4.1	Walls shall be finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.
Interpretation	**Walls** This clause refers to the condition of the internal surfaces of the walls (other aspects of the wall's condition are covered separately in clause 4.1.3). The walls in areas handling raw materials and preparing, processing, packing or storing product must be kept in a sound condition and must be easy to clean and, where necessary, to disinfect. For example, walls must have a smooth, impervious finish with sealed surfaces, be in a good state of repair and be free from flaking paint. Tiling of walls is best avoided but, if present, must be in good condition, with no cracks or loose tiles. Ledges (e.g. from ducting or piping) should be kept to a minimum or designed to facilitate cleaning (e.g. with a slope to avoid dust collection). Vulnerable wall surfaces or corners (e.g. where vehicles pass in close proximity) should be protected from damage (e.g. with properly sealed metal plating or barriers). Junctions (including 'wall to floor', 'wall to ceiling' and 'wall to wall') should be maintained in good condition to facilitate cleaning (e.g. by being appropriately sealed).
4.4.2	Floors shall be suitably hard-wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious, be maintained in good repair and facilitate cleaning.
Interpretation	**Floors** The floors in areas handling raw materials and preparing, processing, packing or storing product must be kept in a sound condition and be easy to clean and, where necessary, to disinfect. Floors must be constructed of materials that are impervious, hard-wearing, repairable and resistant to chemical attack so that they can withstand appropriate cleaning procedures.

Clause	Requirements
4.4.3	Drainage, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety. Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain. Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage.
Interpretation	**Drainage** Drainage must be designed and maintained to ensure that product contamination risks are minimised. For example, drainage design might include methods to prevent flow back and pest ingress, and routeing of waste systems to prevent dripping on products, packaging or ingredients. Due consideration must be given to drainage from any internal laboratories or other hazardous operations undertaken on site to ensure that blockages or the presence of micro-organisms could not result in the contamination of processing areas. Drainage systems must not constitute a potential risk to product (e.g. from potential leakage) when passing through or over production areas. Where feasible, the design of equipment must ensure that process waste water (e.g. condensate drainage from refrigeration or temperature-controlled areas, or sink waste water) goes directly to a drain to minimise contamination risk. Where significant amounts of water are used (e.g. where wet cleaning is carried out) and direct piping to a drain is not possible, floors must have adequate falls to cope with the flow of effluent (i.e. pooling of water should not occur) as this constitutes a splash hazard and, therefore, a contamination risk. Note that the additional requirements for drainage in high-risk and high-care areas are covered in section 8.2.
4.4.4	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.
Interpretation	**Ceilings and overheads** Ceilings and overheads in areas handling raw materials and preparing, processing, packing or storing product must be appropriately designed and kept in a sound condition to avoid the risk of contamination to product. Prevention of the accumulation of dirt, minimising condensation and mould growth, and facilitating cleaning should all be considered. In rooms with high ceilings that are difficult to clean or maintain, line covers over open product could reduce the risk of contamination.
4.4.5	Where suspended ceilings or roof voids are present, adequate access to the void shall be provided to facilitate inspection for pest activity, unless the void is fully sealed.

Clause	Requirements
Interpretation	**Suspended ceilings** Where suspended ceilings are used (or roof voids are present), access must be available for pest control purposes, even if this roof void is not normally used, unless it can be demonstrated that the void is entirely sealed. Refrigeration equipment is often located in the roof void, and access will be required for maintenance.
4.4.6	Where elevated walkways, access steps or mezzanine floors are adjacent to or pass over production lines which have open products, they shall be: • designed to prevent contamination of products and production lines • easy to clean • correctly maintained.
Interpretation	**Elevated walkways, access steps and mezzanine floors** Mezzanine floors, access steps and suspended or elevated walkways (for example, in production areas or over production lines) should be safeguarded to ensure they do not present a contamination risk to products below. This is particularly necessary where open products or open raw materials are handled and any contamination could have an immediate impact on the product (e.g. walkways over a production line where open products are processed). Their design could include features such as solid treads (rather than perforated material), back plates and enclosed sides to prevent items from falling into the production area below, for example, from footwear. The cleaning methods for these floors, steps and walkways should not allow waste materials or cleaning materials (e.g. wash water) to fall onto equipment or the production line below; for example, by using minimal amounts of water to reduce the likelihood of splashing or dripping onto materials below. Sites should include any elevated walkways, access steps and mezzanine floors in the procedures concerning installation and maintenance activities with the express intention of ensuring that they (and their use) do not pose a hazard to the product both: • when initially designed and installed, and • during use (e.g. due to erosion or 'wear and tear'). For example, by including the mezzanine floor, access steps or elevated walkway in the programme of documented inspections of the factory environment (see clause 3.4.4), the site should be able to facilitate prompt corrective action in the event of any problems.
4.4.7	Where there is a risk to product, windows and roof glazing which are designed to be opened for ventilation purposes shall be adequately screened to prevent the ingress of pests.
Interpretation	**Use of windows for ventilation** Where there is a risk to product, such as in production or storage areas, windows and roof glazing that are designed to be opened for ventilation purposes must be adequately screened to prevent ingress of hazards such as pests or dust (e.g. by the use of mesh of an appropriate size to cover the windows).

Clause	Requirements
4.4.8	Doors (both internal and external) shall be maintained in good condition. At a minimum: • external doors and dock levellers shall be close fitting or adequately proofed • external doors to open product areas shall not be opened during production periods except in emergencies • where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.
Interpretation	**Doors** Doors and doorway equipment must be maintained in good condition, be easy to clean and kept clean, and provide an adequate level of pest proofing for the site. They should re-establish continuous contact with the floor when lowered. Doors through which vehicles (such as forklift trucks) travel should be inspected and door frames should be fitted with close-fitting metal plates for protection. External doors to open product areas where activities such as raw-material handling, preparation, processing and packing occur must not be opened during production, except in emergencies. Where external doors to enclosed product areas are opened, suitable precautions must be taken to prevent pest ingress (e.g. strip curtains – see clause 4.4.11 for further details). Sites should be aware that the doors themselves can be a source of physical contamination, particularly where they are designed to rise from floor contact to above the product as it is carried through (e.g. the potential for drip and therefore contamination of product as it passes through the doorway). It is not necessary to remove such doors, but sites should assess whether it is necessary to carry out mitigating steps, such as covering the product before it goes through the doorway. Mechanical and electronic doors should be included in any planned or condition-based maintenance programmes (i.e. they should be maintained and repaired in a timely fashion).
4.4.9	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.
Interpretation	**Lighting** Adequate lighting must be provided to allow: • staff to be able to monitor quality and defects • the correct operation of processes • effective cleaning • a safe working environment. Note that some countries have specific legislation relating to minimal standards of lighting within the workplace. The site will need to be aware of these legislative requirements if it is located in a relevant country or region. In the absence of specific legislation, industry guidelines state that preparation, processing and packing areas should generally be illuminated to a minimum intensity of 200 lux, with inspection areas requiring higher illumination such as 500 or 750 lux. All areas need to be considered; for example, poor lighting in storage areas may hinder effective cleaning or inspection.

Clause	Requirements
4.4.10	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.
Interpretation	**Ventilation and extraction** Adequate ventilation and extraction must be provided, particularly in areas where very dusty operations are carried out (e.g. in dry-ingredient handling areas) or where there is potential for condensation build-up (e.g. in cooking areas). Where air socks are used, the need for them to be cleaned and maintained should be considered. The frequency of this cleaning should be based on risk.
4.4.11	Where plastic strip curtains are present, these shall be maintained in good condition, clean, fitted correctly (e.g. to prevent pest ingress or for temperature control), and shall not pose a food safety risk.
Interpretation	**Strip curtains** Strip curtains are a common way of providing protection from hazards, or to facilitate environmental controls; for example, to: • prevent ingress of pests or dirt (e.g. where there are external doors into production or storage areas) • help regulate temperature, air pressure or air flow • provide a hygiene barrier (i.e. preventing activities in one area from posing a risk to products or materials in neighbouring areas). Where strip curtains are used, they must be controlled to ensure they achieve the intended purpose and do not pose a food safety risk. For example, they must be: • well fitting (usually defined as 'as close to the floor as possible', with no missing strips or gaps) • repaired or replaced in a timely manner when damage does occur (while slight scratches are unlikely to pose a food safety risk and therefore may not require immediate action, missing strips or gaps caused by damage may allow pest ingress or contamination and will require timely action) • in use whenever relevant site activities are occurring, and not tied back when they should be operational • kept clean (to ensure they are not a source of product or raw material contamination; for example, to prevent microbiological, physical, chemical or allergen contamination). Ideally, strip curtains will be designed to be easy to clean. Good practice is to include strip curtains in the inspection and maintenance programmes (see clauses 3.4.4 and 4.7.1) to facilitate timely identification of any concerns and the timely implementation of corrective action.

4.5 Utilities – water, ice, air and other gases

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

Interpretation

The utilities included within this requirement are specifically water, steam, ice, air and other gases that need to be controlled to ensure they do not constitute a contamination risk to product. Other commonly considered utilities, such as electricity, natural gas or fuel, are not included within these requirements.

Clause	Requirements
4.5.1	All water (including ice and steam) used as a raw material in the manufacture of processed food, the preparation of product, hand-washing or equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use, be fit for purpose and pose no risk of contamination according to applicable legislation. Where water is stored and handled on site (e.g. in storage or holding tanks), these shall be managed to minimise food safety risks. The microbiological and chemical quality of water shall be analysed as required by legislation or at least annually. The sampling points, scope of the test and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage.

Interpretation

Water supply

Water used must be provided in sufficient quantities (e.g. for cleaning operations), pose no contamination risk (e.g. be potable), be fit for the intended purpose and conform to relevant legislation by being suitably treated or drawn from mains supply. Where required by legislation, private water supplies and treatment plants should be approved by local or national authorities.

The frequency of water analysis must be based on risk, including:

- legislative requirements for testing
- historical information
- the source of the water (e.g. mains supply or bore-hole)
- specific site concerns (e.g. duration of water storage or the use of lead pipes)
- treatments given to the water
- its usage.

The water is expected to comply with national legislation (e.g. EU directive 98/83/EC and its subsequent amendments) or, in the absence of this, with World Health Organization (WHO) standards for drinking water. The scope of testing completed by the site should be based on risk; for example:

- if the site has lead pipes, then tests should include the presence and concentration of lead
- if historical or published information indicates that the supply in the region has high levels of nitrate, then tests should incorporate this information.

Clause	Requirements
Interpretation *continued*	Water quality tests must be completed at least annually and be based on a risk assessment. If the water is supplied by a water supply company, a chemical analysis from the water company will suffice for the chemical requirements, unless there are other risks identified in the delivery system (e.g. lead pipes). Alternatively, testing should be carried out at the site to ensure that the water is tested and approved at the point of use. Where water is extracted from bore-holes and/or sites have on-site treatment facilities, additional checks will be required to ensure that the water is not contaminated either at the bore-hole or during treatment and that the treatment remains effective. The water should be sampled at appropriate points of use and this should be documented in a sampling plan (see clause 4.5.2). Where water is stored and handled on site (e.g. in storage or holding tanks), the site must assess any additional controls or testing needed to maintain food safety; for example, any limitation on the maximum storage time, operational controls to prevent microbiological contamination, or any monitoring of the condition of the tanks themselves (e.g. to ensure corrosion cannot become a source of product contamination). Where ice or steam is used in production or is in contact with food, it must be produced from potable water or pose no risk of contamination according to applicable legislation, and must be included within the sampling plan. Where legislation specifically allows the use of non-potable water (e.g. in the washing of raw fish or livestock), the water must meet all legislative requirements for that process. The site will also need to have established through the HACCP process that the water does not present a risk to the final products (e.g. by introduction of chemical contaminants) or to other products within the processing environment.
4.5.2	An up-to-date schematic diagram shall be available of the water distribution system on site, including water source, holding tanks, water treatment and water recycling as appropriate. The diagram shall be used as a basis for water sampling and the management of water quality.
Interpretation	**Water distribution** The aim of this requirement is to identify the key components of the water distribution system and how the components interconnect, particularly where potable and non-potable water are present. A fully detailed architect's diagram showing the complete pipework system is not required; a general plan, map or schematic diagram is sufficient. The plan should enable the site management and auditor to assess potential hazards in the distribution system and ensure that adequate management systems are in place to negate the hazards. For example, water-holding tanks may present a microbiological hazard if not covered; water pooling may occur if the water flow is not controlled; and where water is recycled (e.g. for can cooling), the water may need to be treated and sometimes filtered to ensure a satisfactory water quality. The source of the water shall be included in the diagram (e.g. a bore-hole, an on-site reservoir or the mains supply), along with any on-site water-treatment processes. The best water sampling points to assess the quality of water should be deduced from this plan.
4.5.3	Air and other gases used as an ingredient or that are in direct contact with products shall be monitored to ensure this does not represent a contamination risk. Compressed air that is in direct contact with the product shall be filtered at point of use.

Clause	Requirements
Interpretation	**Monitoring of gases and steam** Compressed air, steam or gases used as an ingredient or directly in contact with food must be monitored to ensure they do not contaminate the product. The main risks to consider are: the carry-over of boiler water-treatment chemicals in steam; dust particles in compressed air; and oil used as a lubricant in compressed-air systems. The level of monitoring needs to be based on an assessment of potential risk. Steam generated from potable water free from additives, for instance, is not likely to present a risk. Compressed air in direct contact with products needs to be filtered prior to use, and the filters checked and maintained to ensure they remain effective. The gauge of filtration (e.g. mesh size) and frequency of checks should be documented and based on risk assessment, taking into account the source of the air, the type of compressors used and the condition of the pipework (e.g. evidence of corrosion). The compressor suppliers or experts should be consulted to establish any potential risks and any necessary testing. The objective of using filters is to prevent dust particles and lubricating oil from the compression system contaminating the products. Therefore a single central filter, in close proximity to the compressor, but remote from the food-related use of the compressed air, is unlikely to provide sufficient product protection. The site must be able to justify the effectiveness of the filtration system employed. If gases are used, such as in modified atmosphere packing, they must be demonstrated as being of an appropriate quality. Usually such gases are supplied in a compressed form in metal cylinders and the supplier management process (approved suppliers and specifications, with certificates of conformance if required) would be sufficient. In these circumstances, the site would not be expected to undertake its own checks. Compressed gases are generally considered to be microbiologically safe and the Standard does not require routine testing of such gases unless a specific risk has been identified. There may be additional risks where gases are produced on site and these would need to be evaluated through a risk assessment. Additional information can be obtained from the British Compressed Air Society and the European Industrial Gases Association.

4.6 Equipment

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

Interpretation

'Suitability of equipment for its intended purpose' includes the condition of the equipment, so that it does not pose a product contamination hazard; its ability to be effectively cleaned; and its capability of producing safe food products.

The site will need to consider the requirements:

- when purchasing new equipment or equipment that is new to the site (for example, second-hand or reconditioned equipment)
- when hiring equipment for a designated period
- where equipment is stored (storage conditions must ensure the safety and integrity of the equipment so that it cannot become a source of contamination; for example, equipment should be stored clean and in such a way that it does not harbour pests)

- when designing equipment that will be built by the company, e.g. by on-site engineers.

Movable equipment needs to be controlled to ensure that it cannot be a source of product contamination; for example, by restricting its use to designated areas, or using documented procedures to prevent contamination when moving it between areas.

Risk assessments and resultant controls must be proportionate to the likely risk to the product; for example, the equipment's proximity to product (e.g. use in production areas or open product areas), its significance to the production process, and its complexity (for example, a new production line or part of a production line will need significantly more consideration than a small item such as a plastic scoop).

There are a number of clauses within the Standard that may need to be considered in conjunction with this section; for example:

- Equipment maintenance and condition monitoring is covered in section 4.7.
- New equipment that includes measuring devices should be calibrated according to the requirements in section 6.4.
- Risks associated with new products or new production processes are covered in section 5.1; this will include the equipment associated with these new products and production processes.

There are a number of standards and industry guidelines that provide detailed recommendations for equipment; for example:

- EN 1672-2:2009 – Food Processing Machinery – Basic Concepts – Hygiene and Cleanability Requirements
- ISO 14159:2002 – Safety of Machinery — Hygiene Requirements for the Design of Machinery
- GFSI Benchmark JI (for building and equipment manufacturers) and JII (for building and equipment users).

Sites will need to ensure any applicable legislative requirements (for example, in the EU, the Machinery Directive 2006/42/EC) are met.

Clause	Requirements
4.6.1	There shall be a documented purchase specification for any new equipment detailing the site requirements for the equipment. This may, for example, include: • any relevant legislation • where applicable, requirements for food contact surfaces to meet legal requirements • details of intended use of the equipment and the type of materials it will be handling. Depending on its intended use, new equipment to site (including second-hand equipment) may require authorisation from a multi-disciplinary team. The supplier should provide evidence that equipment meets these site requirements prior to supply.
Interpretation	**Equipment purchase specifications** The process for the purchase of new equipment must start prior to the actual purchase of the equipment, with an equipment purchase specification (sometimes referred to as user requirements). The aim of the clause is not to introduce onerous documentation for all equipment, but to ensure that new equipment meets the site's needs; for example, it is suitable for its intended use and is designed to eliminate or manage any identified food safety hazards.

Clause	Requirements
Interpretation *continued*	For the purposes of the Standard, new equipment can be defined as equipment bought directly from a manufacturer, second-hand equipment bought by the site (therefore new to the site) or equipment that has been refurbished externally. It does not include small parts such as screws or other non-food contact fixings. Purchase specifications need to contain sufficient information to ensure product safety and suitability of the equipment. This means that the actual amount of detail in the purchase specification will be dependent on the type of equipment being purchased. For example, a simple plastic scoop is only likely to need a very simple set of user requirements, with minimal food hazards identified, whereas a new production line is likely to require significantly more details regarding, for example, product types, production rates and food contact requirements. Purchase specifications usually include: • reference to any relevant legislation • requirements for food contact surfaces (i.e. where product will be in contact with the equipment) • intended use of the equipment • types of materials that will be used (this is particularly important for food contact surfaces, since potential migration from equipment may be affected by the composition of the food material, e.g. high fat or acidic materials can increase potential for migration). Good practice is to consider who within the company can authorise the purchase of new equipment. For re-purchases of simple equipment, this may be simply a case of identifying who is authorised to order the product; however, for complex machinery (such as a new production line), there may need to be input from multiple departments, such as engineering, technical, hygiene and finance. This is to ensure that all critical food safety requirements have been considered and included within the specification. Note that where equipment is purchased from suppliers in other regions or countries, legislative requirements may vary, and additional communication of requirements may facilitate the purchasing process. The site should retain evidence of the specification developed, and evidence provided from the supplier demonstrating that the equipment meets these requirements, as this provides evidence of due diligence in the event of a challenge or incident. During the BRCGS audit, the auditor will expect to see evidence of the purchase specification for any new equipment, the specification's suitability for the specific equipment, equipment purchase matching the specification, and, as detailed in clauses 4.6.2–4.6.7, commissioning of equipment, hygiene requirements, routine maintenance, etc. Note that the clause relates to the purchase of new equipment. It does not require a site to retrospectively develop specifications for equipment that was purchased prior to the publication of the Standard, or prior to its decision to become certificated for the first time.
4.6.2	The design and construction of equipment shall be based on risk, to prevent product contamination. For example, the use of the correct seals, impervious surfaces or smooth welds and joints, where they are exposed to product and could otherwise result in foreign-body, microbiological or allergen contamination of the product. Equipment that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.

Clause	Requirements
Interpretation	**Equipment in direct contact with food** The aim of this requirement is to ensure that equipment is not a source of product contamination, and that it complies with relevant food contact legislation where such legislation exists (for example, in the EU, the Food Contact Materials – Regulation (EC) 1935/2004 and its subsequent amendments). The clause provides some examples of potential issues, including: • Food contact surfaces should be smooth and impervious; for example, to prevent accumulation of material that could lead to microbiological or allergen contamination of the product. • Welds and joints should form a flat surface (again to prevent microbiological or allergen contamination). Other well-documented issues have included the purchase of equipment (especially plastic items) not designed for food use leading to the migration of chemicals into food products. The company must consider the risks associated with the equipment (including any risks associated with its design, construction and installation) and ensure that significant risks have been controlled. This can, for example, be achieved by use of a hygienic design risk assessment, which uses hygienic design principles to consider the risks of foreign-body, microbiological, allergen or chemical contamination of the product. Before using the equipment, the company will need to have evidence that the risks have been considered, and of the suitability of the equipment, and must confirm its acceptability for food contact surfaces. For new equipment, this will usually form part of the purchase specification process (see clause 4.6.1). Where such evidence is not available (for example, when purchasing second-hand equipment) and the contact material is not a recognised food-safe material (such as certain grades of stainless steel), an additional assessment should be carried out to ensure safe use and to prevent food safety risks. The risk assessment should consider factors such as: • the nature of the food contact surface and its known characteristics • the length of contact time with the food • the nature of the food and its potential for contamination (e.g. fatty or acidic foods are often at increased risk from migration of contaminants from plastic materials). During the BRCGS audit, the auditor will not inspect every seal, bolt or food contact surface, but will: • need to understand the site processes; for example, they may review the documented process and their suitability, whether they have been used in practice, and the completeness of relevant records • inspect a small number of relevant examples of equipment where there is a food safety or quality implication; this may, for example, be completed during the inspection of equipment hygiene (see clause 4.11.1).

Clause	Requirements
4.6.3	A documented, risk-based commissioning procedure shall be in place to ensure that food safety and integrity is maintained during the installation of new equipment to site. Installation work shall be followed by a documented hygiene clearance procedure. New equipment to site shall be inspected by an authorised member of staff before being accepted into operation. The commissioning procedure shall include the update of any other site procedures that are affected by the new equipment, for example, training, operating procedures, cleaning, environmental monitoring, maintenance schedules or internal audits. The design and placement of equipment shall ensure that it can be effectively cleaned and maintained.

Interpretation

Equipment design and construction

The aim of this clause is to ensure there is a formal process for the introduction of equipment that is new to the site (see the interpretation for the statement of intent for this section), which ensures that product safety and integrity is maintained, when the equipment is introduced into and used within the production and storage areas.

The hazards associated with any specific item of equipment will vary considerably dependent on the nature of the equipment and its intended use. Using the previous example, a new plastic scoop is likely to require minimal commissioning, whereas a completely new production line is likely to require an extensive commissioning process.

Therefore the commissioning procedure should be risk-based, allowing the site the flexibility to complete the appropriate activities for the specific equipment. Examples of commissioning activity might include installation and sign-off of equipment, trials operating the equipment, cleaning validation and maintenance checks.

In order to facilitate routine cleaning, operation, inspection and servicing, equipment must be appropriately positioned (e.g. access provided under, inside and around it). Where equipment is permanently sited, it should be properly secured and sealed to the floor to prevent the accumulation of food debris underneath, where it cannot be cleaned. It has been well documented that, where equipment or fixtures allow organic matter and/or pathogens to collect and survive, this can subsequently cause product contamination as pathogens such as *Salmonella* or *Listeria* can survive for prolonged periods in these conditions if left undisturbed.

The site must ensure that the safety and integrity of product is not jeopardised during installation (e.g. equipment is not contaminated either by products used during installation such as sealants, nuts and bolts; by lubricants; or by packaging that has been removed from the equipment). Good practice is to schedule installation of larger or more complex equipment outside production hours. Where this is not practicable, suitable precautions must be taken to prevent contamination of products; for example, the use of screening to protect adjacent production lines.

Clause	Requirements
Interpretation *continued*	Following installation, equipment must be cleaned and inspected prior to use. An authorised member of staff (e.g. the production manager) is required to formally accept equipment into operation following this inspection, to confirm that all relevant installation, commissioning and cleaning activities have been completed satisfactorily. Records need to be maintained (e.g. signing the appropriate engineering record or line start-up check sheet) to demonstrate that the equipment has been inspected and is acceptable for use. The commissioning procedure must include the updating of any other relevant site procedures that are affected by the new equipment; for example, training, operating procedures, cleaning, environmental monitoring, maintenance schedules or internal audits. This is to ensure that all staff have access to the relevant procedures and understand how to complete their activities correctly. Note that the auditor will not stop equipment operating or the production flow in order to inspect equipment.
4.6.4	A procedure shall be in place to manage the movement of static equipment in production areas, to ensure that food safety is managed and the integrity of the equipment is maintained.
Interpretation	**Movement and repositioning of static equipment** Static equipment is defined as pieces of equipment that are not ordinarily moved or are moved only in exceptional circumstances; for example, due to redesign of the production area, relocation to another site or necessary maintenance that cannot be completed *in situ*. There must be a documented procedure which covers how food safety and equipment integrity will be maintained during movement of the equipment. Good practice is to complete a risk assessment to determine the specific risks and controls needed. The procedure may include: • the type of equipment to be moved • how the movement will occur (e.g. whether specialist equipment or contractors are required) • requirements for re-installation • authorisation (which staff are authorised to permit movement) • responsibility (which staff will be responsible for managing the movement) • staff training (e.g. on the procedure to ensure they understand the risks involved) • records required to demonstrate all necessary controls were completed • post-movement cleaning (see, for example, clause 4.7.4).
4.6.5	Equipment that is not used or is taken out of service shall be cleaned and stored in a manner that does not pose a risk to the product. Equipment stored in internal production and storage areas shall be kept clean. Food contact equipment that has been stored but is not in daily use shall be cleaned and, where necessary, disinfected prior to use.

Clause	Requirements
Interpretation	**Storage of equipment** Appropriate precautions must be put in place to prevent product contamination resulting from storage of equipment; for example, dirt or dust accumulation, harbourage of micro-organisms, and potential pest activity if the equipment has not been fully cleaned before being stored. Where equipment is stored within production or storage areas, it must be kept in a clean and hygienic condition (see clause 4.11.1). This might, for example, include: • a documented cleaning procedure (see clause 4.11.2) • periodic inspections, checks or condition monitoring (see clause 3.4.4) • labelling to indicate that the equipment cannot be used without cleaning or sign-off • management through the food safety plan or HACCP (e.g. clause 5.1.2). Where equipment is intended for food contact, the equipment must be cleaned and, where necessary, disinfected prior to next use. It is good practice to inspect the equipment once out of storage to ensure it is fit for purpose.
4.6.6	Mobile equipment (e.g. forklift trucks, pallet trucks, scissor lifts and ladders) used in open product areas shall not pose a risk to the product. Where the use of mobile equipment in external areas cannot be avoided and poses a risk to the product, the equipment shall be cleaned and disinfected prior to entering production areas.
Interpretation	**Mobile equipment** The aim of this requirement is to ensure that mobile equipment does not pose a risk to the product, including, for example, microbiological, allergen, chemical or foreign-body risks. The site will therefore need defined procedures to ensure that any mobile equipment used in open product areas is used in such a way as to maintain product safety. This could, for example, include: • a log of all mobile equipment • approved users and training for users • dedicated equipment: only used in designated open product areas • condition monitoring, to ensure items remain suitable for use in an open product area • cleaning and maintenance schedules. Where the use of equipment in external areas cannot be avoided, and there is a risk of product contamination, additional procedures are required to ensure this risk is minimised. These may include: • completing a risk assessment to identify areas/products where there is a risk of product contamination (the Standard does not require cleaning and disinfection of every piece of equipment every time it is used in an external area, but that the site should identify when there will be a risk to product, and ensure that appropriate cleaning is completed to prevent this risk)

Clause	Requirements
Interpretation *continued*	• defining where equipment can be used • specific cleaning and disinfection procedures prior to re-entry into production areas where a product contamination risk exists. In addition to explaining how the cleaning will be completed, it may be useful to identify the parts of the equipment that need to be cleaned (for example, tyres, wheels and the underbody may be a greater risk than other areas of the equipment). Note that where a site operates multiple production risk zones (see Appendix 2 of the Standard), the additional requirements in section 8 of the Standard relating to the movement of equipment between production risk zones will also need to be considered.
4.6.7	Battery-charging equipment shall not be stored in open product areas (unless the batteries are fully sealed and/or maintenance-free) or where there is a risk to products.
Interpretation	**Battery-charging equipment** Mobile equipment may require battery-charging equipment. Where required, the battery-charging equipment must not be stored or used in an open product area, unless the batteries are fully sealed and maintenance-free, to prevent the risk of chemical contamination of food products due to battery leakages or gases being emitted. Good practice is to identify locations where battery-charging is permitted.

4.7 Maintenance

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

Interpretation

To ensure that all equipment (including fixtures, fittings, cleaning tools and utensils), is suitably maintained and does not pose a product contamination risk (for example, due to foreign bodies created by the equipment), it must be controlled by a documented and effective maintenance system.

Planned maintenance may be completed internally or via contracted services. Maintenance undertaken internally must be documented (e.g. in the form of a plan or schedule) and records of the maintenance activity kept. For equipment that is maintained under external contracts, evidence of contractual agreements must be available.

Clause	Requirements
4.7.1	There shall be a planned preventive maintenance schedule or condition monitoring system which includes all plant, processing equipment and mobile equipment. The maintenance requirements shall be defined when commissioning new equipment and reviewed after repairing existing equipment.

Clause	Requirements
Interpretation	**Documented maintenance schedule** All plant, processing equipment and mobile equipment must be included in a planned preventive maintenance schedule or condition monitoring system. Planned preventive maintenance is simply a schedule of proactive maintenance or servicing designed to prevent product contamination and reduce the potential for breakdowns. The identified maintenance tasks are completed at defined frequencies based on a risk assessment. This can be supported by condition monitoring where equipment is inspected at a set frequency for problems. The aim is to identify and correct any problem before product contamination or equipment breakdown occurs. The frequency of preventive maintenance or condition monitoring should be based on risk assessment; for example, considering the likelihood of occurrence of a problem (e.g. previous occurrences of the problem or equipment manufacturer's recommendations) and the likely risk of product contamination if the equipment fails (e.g. proximity to open product). Activities should be documented, and appropriate corrective action taken where issues are highlighted. Maintenance and condition monitoring requirements must be: • established as part of the commissioning process for new equipment • reviewed after repairs to equipment, to ensure that current monitoring and preventive maintenance activities remain appropriate.
4.7.2	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment damage, the equipment shall be inspected at predetermined intervals, the inspection results documented and appropriate action taken.
Interpretation	**Equipment inspection** Where there is a risk of foreign bodies contaminating product – for example, due to wear, erosion, loose or missing parts, or damage to equipment or pieces of machinery (e.g. sieves, mills, equipment covers) – there must be a periodic check of the equipment. A documented check procedure must be carried out at defined intervals (e.g. at process start-up, at start of shift, during product changeover, and after cleaning or maintenance). Inspection results must be documented and, where appropriate, action taken.
4.7.3	Where temporary repairs are made, these shall be documented and controlled to ensure that the safety or legality of products is not jeopardised. These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale.

Clause	Requirements
Interpretation	**Temporary repairs** Temporary repairs must be suitable, kept to a minimum and used only in an emergency. They must be controlled (i.e. documented and notified to a shift leader) to ensure that the safety or legality of product is not jeopardised, and a system must be in place to demonstrate that a permanent repair (or replacement of the equipment) is planned within a defined timescale (e.g. a works order). The Standard is not prescriptive regarding the timescales for permanent repairs, as what is practicable will vary from site to site and according to the nature of the repair and any associated product safety risks. Typically, a full permanent repair is expected as soon as a replacement piece is available, or as soon as the line can be shut down. In all cases, the expectation is that the safety and legality of the product will be maintained in the interim. In an organisation with a strong food safety culture, production staff should be knowledgeable about food safety, be empowered and feel ownership of compliance with the Standard, so that they feel confident about informing the relevant individual or department when a repair or adjustment needs to be made.
4.7.4	The site shall ensure that the safety or legality of products is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work shall be followed by a documented hygiene clearance procedure. Equipment and machinery shall be inspected by an authorised member of staff to confirm the removal of contamination hazards, before being accepted back into operation.
Interpretation	**Post-maintenance cleaning** The site must ensure that the safety and legality of product is not jeopardised during maintenance and cleaning operations. There are a number of ways that products can be contaminated during maintenance activities; for example, by: • products or materials used during maintenance, such as sealants, nuts and bolts that are either not used correctly or not removed from the line after maintenance (for example, spare bolts, containers of lubricant, etc. need to be removed from the area when maintenance is complete) • machinery parts that have broken or disintegrated and have not been adequately removed • maintenance tools that have not been stored in a suitably clean condition. Good practice is to schedule maintenance work outside production hours. Where this is not practical, suitable precautions must be taken to prevent the contamination of products; for example, by removing the item to be maintained from the production area, or by using suitable screening to protect both the production line and any adjacent equipment or production lines. A procedure must be in place to ensure that, following maintenance work, equipment is cleaned and inspected prior to use. An authorised member of staff (e.g. the production manager) is required to formally accept equipment back into operation following this inspection to confirm that maintenance and associated cleaning have been completed satisfactorily. Records need to be maintained (e.g. by signing the appropriate engineering record or line start-up check sheet) to demonstrate that the equipment has been inspected and is acceptable for use.

Clause	Requirements
4.7.5	Materials and parts used for equipment and plant maintenance shall be of an appropriate grade or quality. Those materials (such as lubricating oil) that pose a risk by direct or indirect contact with raw materials (including primary packaging), intermediate products and finished products shall be food grade and of a known allergen status.
Interpretation	**Use of food-grade materials** Materials used for equipment and plant maintenance that pose a risk of direct or indirect contact with raw material, intermediates or final product must be of food grade and the presence of any allergens must be known and managed accordingly. Documentary evidence of the food-grade status must be held (for example, in a declaration by the supplier, on product data sheets or by demonstrable compliance to a recognised standard such as ISO 21469 for lubricants, or the US Code of Federal Regulations, e.g. 21 CFR 178.3570).
4.7.6	Engineering workshops shall be kept clean and tidy, and controls shall be in place to prevent transfer of engineering debris to production or storage areas.
Interpretation	**Engineering workshops** The engineering workshop must be controlled to minimise the potential for contamination of product. Consideration should be given to location and design, as well as procedures for control. For example, where it is not possible to avoid having an entrance directly from the engineering workshop to the production area, procedures must be in place to avoid contamination risks (e.g. by debris being carried inadvertently into the production or storage areas). These procedures may include changes of footwear and protective clothing, or matting specifically designed to collect any small pieces of debris from footwear (e.g. swarf mats). Workshops need to be kept clean and tidy, operated in a controlled manner, and included in the housekeeping and cleaning procedures. The provision and location of hand-washing facilities for engineers entering the factory should be considered.

4.8 Staff facilities

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

Interpretation

This section focuses on staff facilities from the perspective of eliminating product contamination.

Appropriate staff facilities must be provided to enable staff to adhere to company policies (e.g. the correct storage of protective clothing and personal belongings) to ensure the risk of product contamination is kept to a minimum. This must include adequate facilities to accommodate staff fluctuations, such as high production times, seasonal variations or the use of agency staff.

Washing, changing and toilet facilities provided for visitors and contractors must be of a standard that allows non-staff members to meet suitable levels of hygiene. Best practice is that visitors and contractors follow exactly the same changing routine as staff (e.g. change in changing areas and not in management offices).

Clause	Requirements
4.8.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear).
Interpretation	**Changing facilities** Designated changing facilities must be provided for all staff (including visitors and contractors). The location and position of facilities is an important consideration, and this must be the subject of a risk assessment to ensure the protection of protective clothing from contamination before entering the production areas. The size of the facilities needs to be adequate for the number of staff working at the factory and at times of peak staff numbers (e.g. at the start and end of shifts or when there are seasonal fluctuations). Where changing facilities cannot be located with direct access to the production, packing or storage areas without recourse to an external area, a risk assessment must be used to identify where additional procedures need to be implemented (e.g. providing cleaning facilities for footwear where footwear is worn outside, or the donning of additional protective clothing on entry to production areas).
4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material-handling, preparation, processing, packing and storage areas.
Interpretation	**Storage of personal items** To prevent staff from bringing personal items (e.g. keys, mobile phones or coins) into production and storage areas where they could contaminate products (e.g. as foreign bodies), there must be sufficient and suitably secure storage for employees' belongings. Storage for bulky items such as motorbike leathers and helmets should be provided, as well as for smaller items such as jewellery and food. Storage areas should be designed to facilitate good practice and cleaning (e.g. lockers with sloping tops to prevent the accumulation of rubbish and raised off the floor to facilitate cleaning).
4.8.3	Outdoor clothing and other personal items shall be stored separately from production clothing within the changing facilities. Facilities shall be available to separate clean and dirty production clothing.
Interpretation	**Segregation of personal items from work clothing** Separate storage facilities for personal items and work clothing are necessary to prevent cross-contamination of clothing via the locker. This can be achieved by: • using a locker with a divider to separate work clothing from personal clothing • enclosing protective clothing in a bag, such as a laundry bag, before use • providing a separate area for the hanging of work clothing.

Clause	Requirements
Interpretation *continued*	Because of the potential for cross-contamination, clean protective clothing must be segregated from dirty protective clothing (e.g. through the provision of separate locker areas or a dedicated collection point for dirty laundry).
4.8.4	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-washing facilities shall provide, at a minimum: • advisory signs to prompt hand-washing • a sufficient quantity of water at a suitable temperature • water taps with hands-free operation • liquid/foam soap • single-use towels or suitably designed and located air driers.
Interpretation	**Hand-washing facilities** Dedicated hand-washing facilities must be provided at entrances to production areas and, where appropriate, at additional points within production areas. This is to ensure that hands are physically washed, rather than just sanitised, before starting work and as necessary during the working day. In some low-risk operations, the hand-wash prior to entry to the production area may be in a changing facility or toilet rather than within the entrance to the actual production area. In some dry environments where water is avoided, gel or alcohol sanitisers may be used in the production areas in place of hand-washing facilities, although staff will still be required to wash their hands before entering the production area. The hand-washing facilities must be equipped with the following: • hand-washing signage to prompt hand-washing at the relevant points in the process • appropriate instructions for use, considering the language needs of staff (e.g. including pictorial instructions). For example, good practice is to instruct staff on how to wash in a thorough and appropriate manner and for the correct length of time (usually at least 20 seconds) • water in sufficient quantities and at a suitable temperature. The publication *WHO Guidelines on Hand Hygiene in Health Care* (recommended by Codex Alimentarius) highlights that warm water is more effective at cleaning than cooler water, with 40°C being demonstrably more effective than 20°C. It also notes that warm water is preferable to hot water because repeated exposure to hot water increases the risk of dermatitis (comfortably warm is generally considered to be about 45°C) • taps that have hands-free operation (e.g. knee- or foot-operated taps or those with movement sensors) • liquid or foam soap solution • suitable hygienic hand-drying facilities (either single-use hand towels or suitably designed and located hand driers; roller towels are not acceptable as they are not single use). Where single-use towels are used, suitably designed and located bins should also be provided. Good practice is that hand sanitiser is also provided at all hand-washing facilities. (Hand sanitiser is always required for high-risk and high-care operations – see clause 8.4.1.) The provision and location of hand-wash basins are expected to follow industry best practice within that sector, including a risk assessment for breakage or damage. For some low-risk operations where hand-washing facilities are only provided within toilets before re-entering production, the requirements for hand-washing facilities will also apply to toilet areas.

Clause	Requirements
4.8.5	Toilets shall be adequately segregated and shall not open directly into production or packing areas. Toilets shall be provided with hand-washing facilities comprising: • basins with soap and water at a suitable temperature • adequate hand-drying facilities • advisory signs to prompt hand-washing. Where hand-washing facilities within toilets are the only hand-washing facilities provided before re-entering production, the requirements of clause 4.8.4 shall apply and signs shall be in place to direct people to hand-washing facilities before entering production.
Interpretation	**Toilets** Toilets must be adequately segregated from production areas and must not open directly into production or packing areas. There should be an intermediate ventilated space between the toilet cubicle and any production area to prevent foul odours from entering production areas. The hand-washing facilities provided in toilets must be equipped with: • appropriate instructions for use, considering the language needs of staff • sufficient water at a suitable temperature (clause 4.8.4) • soap (in any format) • suitable hand-drying facilities (in any format). Where hand-washing facilities within toilet facilities are the only ones provided before re-entering production, the requirements of clause 4.8.4 apply, including suitable signage to direct staff to wash their hands prior to entering production areas.
4.8.6	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations. Electronic cigarettes shall not be permitted to be used or brought into production or storage areas.
Interpretation	**Smoking areas** Facilities in line with national legislation must be provided for those staff wishing to smoke. These facilities must not be located within the packing or production areas where there is open food or ingredients, or where smoke could reach product or ingredients. Indoor facilities must have sufficient extraction to the exterior of the building. Procedures for protective clothing and hand-washing must be in place whenever staff enter or leave production and packing areas (clause 7.4.1); therefore suitable facilities for staff to remove their protective clothing before smoking and for washing their hands afterwards must be provided. Signs must direct them to the hand-washing facilities. There must be sufficient and appropriately positioned facilities for the waste generated by those persons smoking. Where electronic cigarettes (e-cigs) are permitted on site, instructions for use must comply with national and local legislation. Electronic cigarettes must not be taken into storage, processing or production areas.

Clause	Requirements
4.8.7	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.
Interpretation	**Staff food** Suitable storage facilities must be provided for food brought on site by staff, enabling it to be stored in a hygienic manner. Where refrigerators are provided for staff food, they should be kept clean, maintained and operated at an appropriate temperature. Refrigerators used for production materials and shelf-life samples must not be used for storing staff foodstuffs. Food (including sweets and chewing gum) must not be taken into storage, processing or production areas, as it may constitute a risk to the product. Food must be adequately controlled when stored in other areas. All food and drink must be consumed in designated areas away from food-handling, production and storage areas. Where appropriate, designated outside areas can be provided for staff to eat food; where provided, these must have an appropriate control of waste. Drinking of water from purpose-made dispensers by using disposable conical cups or spill-proof containers may be allowed, provided it is confined to a designated area, minimising the risk to product, and suitable disposal facilities are provided.
4.8.8	Where catering facilities (including vending machines) are provided on the premises, they shall be suitably controlled to prevent contamination of products (e.g. as a source of food poisoning, the use of allergenic ingredients or introduction of new allergenic material to the site).
Interpretation	**Catering facilities** Where the company provides a canteen or other food service (including food vending services) for members of staff, the kitchens and cold-storage areas need to be suitably controlled to prevent the contamination of products (e.g. by microbiological or allergen contamination). In the absence of specific legislative requirements and assessments for the control of hazards in catering facilities, a study based on HACCP principles should have been carried out on any catering facilities provided for the staff. The risks identified should be effectively controlled – in particular, those associated with staff hygiene, cleaning, cross-contamination between raw and cooked foods, and storage conditions. Where hot food is prepared within a site's facilities, additional safe food-handling may be required; for example, the WHO's Five Keys to Safer Food Manual promoting safe food-handling highlights the need to: • keep clean – wash hands and keep kitchens and food preparation areas washed and sanitised • separate raw and cooked foodstuffs, and keep the utensils or equipment used for handling them separated • cook or reheat products thoroughly

Clause	Requirements
Interpretation *continued*	• store food at appropriate temperatures to maintain food safety; for example, using fridges and freezers, and keeping cooked food hot before serving • use water of an appropriate quality to ensure that it is not the source of a food safety hazard. The Standard requires sites to consider whether there are risks of product contamination from catering activities and vending machines, and, where appropriate, ensure that suitable company policies are in place to manage these risks. For example, in some operations (e.g. sites manufacturing a product with an allergen-free claim), specific allergens may present a particular risk. These sites should specify any relevant company policies to confectionery vending suppliers and catering facilities. At the BRCGS audit, there will be a basic inspection of the kitchen facilities. Catering facilities should be part of the site's own internal audit or hygiene inspection programme.

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

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

Interpretation

The risk of foreign-body and chemical contamination must be minimised through the consideration of potential sources and the implementation of control procedures within the HACCP or food safety plan. Areas to consider include storage, processing, equipment, maintenance, building structures, cleaning operations and personnel.

Staff facilities and communal areas such as entrance corridors also need to be considered to ensure that their design and the processes carried out within them do not pose a risk to products (e.g. the presence of staples or drawing pins on open noticeboards). Regular documented inspections (clause 3.4.4) must be carried out to verify that these controls are in place.

It is often useful for sites to consider physical contamination controls in three tiers, as shown in Figure 14.

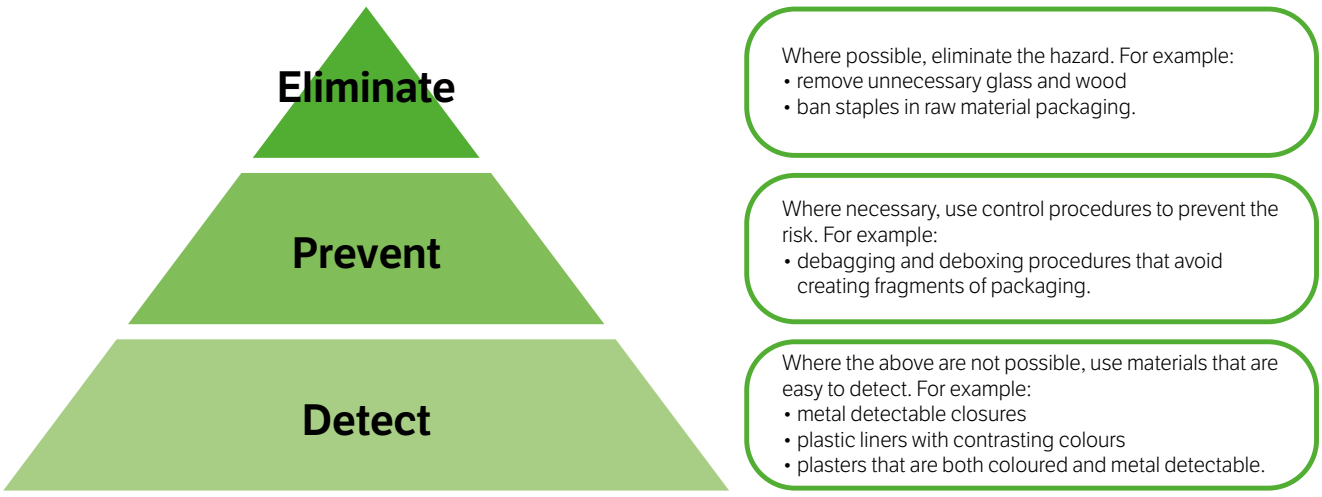

Figure 14 Three-tier approach to physical contamination control

4.9.1 Chemical control

Clause	Requirements
4.9.1.1	Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include, at a minimum: • an approved list of chemicals for purchase • availability of material safety data sheets and specifications • confirmation of suitability for use in a food-processing environment • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • a designated storage area (separate from chemicals used as raw materials in products) with access restricted to authorised personnel • use by trained personnel only • procedures to manage any spills • procedures for the safe, legal disposal or return of obsolete or out-of-date chemicals and empty chemical containers.

Interpretation

Storage and handling of non-food chemicals

Non-food chemicals present a potential product contamination or taint risk if they are not stored and handled correctly. The site needs to demonstrate controls for non-food chemicals, including the following:

- an approved list of chemicals for purchase – this is to prevent inappropriate chemicals from being purchased. This applies to all cleaning chemicals, pesticides and other chemicals which may be used in the production environment
- material safety data sheets and specifications provided by the supplier. These should be up to date and accurate for the chemicals currently used by the site
- confirmation that the chemicals are suitable for use in a food-processing area (i.e. they are non-tainting and not highly toxic). For example, cleaning chemicals must be selected to avoid the risk of product tainting (chemicals such as phenolics and those that are strongly scented are not suitable)
- avoidance of strong-scented products
- identification of chemicals (e.g. labelling of all containers) at all times, to minimise the potential for inadvertent use
- designated storage with restricted access limited to authorised personnel. Potentially harmful chemicals (e.g. sodium hypochlorite) must be suitably stored to prevent inadvertent product contamination. Sites should ensure that safe-use/storage instructions from the manufacturer are implemented (e.g. store acid and alkaline materials away from each other and store powders above liquids to prevent subsequent reaction in the event of spillage. Good practice also includes supplying cleaning chemicals to production areas ready diluted (for use with verified auto-dosing systems) and to ensure that stocks of cleaning chemicals not required for the current production or cleaning activity are stored away from the production area
- ensuring that chemicals that are food raw materials are stored separately from non-food chemicals, to prevent potential contamination from non-food materials into the food raw materials
- use of chemicals by trained personnel only, as evidenced by training records

Clause	Requirements
Interpretation *continued*	• application of procedures to manage any spills, to ensure they do not pose a risk to product safety; for example, good practice is to provide bunded areas around appropriate chemical and oil tanks and ensure that relevant staff are trained in the spillage procedures. Procedures must be in place for the safe, legal disposal of obsolete or out-of-date chemicals and empty chemical containers, to ensure chemical waste is disposed of in the correct manner (for example, by disposing of chemicals and containers in accordance with legislative requirements, using licensed waste disposal contractors, and by returning them to the manufacturer). Procedures must cover unused chemicals (i.e. those that are no longer required) and empty containers. Chemicals that are likely to come into direct contact with foods when used as intended (e.g. materials such as oils or lubricants used on machinery), as well as terminal sanitisers that are designed to be used without rinsing with water, should be confirmed as suitable for food use. (This would not include general detergents and cleaning materials, as these should not come into direct contact with food.) Consideration may need to be given to the legislative requirements of specific countries, states or territories. For example, legislation may require that materials do not contain toxic or prohibited substances, that lubricants are suitable for food use or that terminal sanitisers meet applicable standards (e.g. the Biocidal Products Regulation (EU) No. 528/2012).
4.9.1.2	Where strongly scented or taint-forming materials have to be used, for instance for building work, procedures shall be in place to prevent the risk of taint contamination of products.
Interpretation	**Strong scents and taints** Wherever possible, strongly scented or taint-forming materials must not be used. However, where these are necessary (e.g. for some building work), procedures must be in place to avoid the risk of taint contamination of products. For example, relevant information must be requested from contractors, detailing the chemicals to be used and the controls (such as the extraction of fumes) that will need to be in place. A risk assessment of the information should be completed prior to commencement of the work.

4.9.2 Metal control

Clause	Requirements
4.9.2.1	There shall be a documented policy for the controlled use and storage of sharp metal implements including knives, cutting blades on equipment, needles and wires. This shall include a record of inspection for damage and the investigation of any lost items. Snap-off blade knives shall not be used.
Interpretation	**Sharp metal implements** Where sharp metals such as knives, needles or cheese wires are used, there must be a documented policy. This will outline: • the controls in place • inspection and breakage/loss reporting procedures • storage when not in use • other controls, such as the numbering of knives or the use of issue and return logs.

Clause	Requirements
Interpretation *continued*	The company should aim to ensure that shards of missing metal are located and that the source of any loose metal is identified. Snap-off blades (i.e. where the old segment of blade can be snapped off to reveal a new sharp edge) are a source of potential metal contamination and are not permitted in any area of production or storage. Other metal items, such as non-production blades, engineering tools and equipment, must be stored away from production areas to minimise their potential for contaminating product. For example, spanners used for adjusting machinery should not be left out, but should have a designated place for storage, such as a locked toolbox fixed to a wall.
4.9.2.2	The purchase of ingredients and packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided. Staples, paper clips and drawing pins shall not be used in open product areas. Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.
Interpretation	**Staples, paper clips and similar metallic items** Staples are often used in packaging. However, their use needs to be considered, since they are a potential source of contamination and the purchase of ingredients or packaging materials containing them must be avoided. Where ingredients with potential foreign bodies cannot be avoided, there need to be controls to manage these hazards. Staples, paper clips and drawing pins (i.e. thumb tacks or pin tacks) or other metal closures must not be used in open product areas.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Clause	Requirements
4.9.3.1	Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination.
Interpretation	**Exclusion of unnecessary materials** The aim of this clause is to protect consumers from potentially serious physical hazards that could occur if glass, brittle plastic, ceramics or other similar materials in open product areas of the site, are broken and form fragments which could subsequently contaminate product. The company must undertake an assessment of glass and other brittle items in open product areas, and any areas where there is a risk of contamination of product or packaging and, wherever possible, remove these items. Where it is not possible to remove all items, they must be protected against breakage (e.g. by the use of adhesive plastic sheeting, reinforcement or shielding) and included on a register for inspection purposes (clause 4.9.3.2). This does not apply to glass or brittle materials used to pack final products, which are covered separately in section 4.9.4.

Clause	Requirements
4.9.3.2	Procedures for handling glass and other brittle materials (other than product packaging) shall be in place where open products are handled or there is a risk of product contamination. These procedures shall include, at a minimum: • a list of items detailing location, number, type and condition • recorded checks of the condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise the potential for product contamination.

Interpretation

Documented handling procedures

Procedures for handling glass and similar materials (other than packaging, which is covered in section 4.9.4) need to be documented to ensure that the risks of product contamination are managed.

The documentation must include:

- a list or register of items, detailing their location, number, type and condition. When creating the list, it is important to be realistic; the objective is to remove brittle items where possible and create a list of items for inspection which present a real risk of breakage and contamination of products (i.e. those that are in open product areas or where risk assessment shows there is a genuine risk to product). (The list could also detail the frequency with which the items must be checked.)
- recorded, routine inspections to verify the condition of these items. Inspections must be carried out at a specified frequency based on risk assessment; some areas may be checked more frequently than others because of their potential to form a foreign-body hazard in the product. (For example, a factory identifies part of the production line which has plastic-laminated line covers that may chip or break. The condition of this section of the line is specifically checked daily prior to production, because it is above open food and any breakage or damage is likely to result in a foreign-body issue. The same factory has a brittle plastic dial cover on a control panel on the exterior of a piece of equipment not close to open product. This is checked only monthly, as a break and subsequent foreign-body issue is unlikely to arise.)
- maintaining a record of the inspection even when there is no change in the condition of the inspected items. Any non-conformities highlighted in previous inspections, but not permanently repaired, should also be checked to confirm no additional deterioration has occurred
- the procedures that allow cleaning or replacement of items in a way that minimises potential risk to products (e.g. replacing bulbs in fly-killing devices).

Further guidance

Developing an effective glass control programme

To start with, carry out an assessment of the glass and brittle plastic items in open product areas and, wherever possible, remove them (see clause 4.9.3.1). If the item cannot be removed, it must be protected against breakage (e.g. with adhesive sheets or reinforcements) and included on a register for inspection purposes (an example is shown in Figure 15).

When creating a list of items for inspection, it is important to be realistic. The objective is to create a list of items that represent a real risk of breakage and product contamination. For example, the window above the production line is likely to be high-risk, as any breakage is likely to contaminate the product. But the window in the Director's office, on the other side of the site, does not need to be included unless there is a genuine risk of product contamination if the window breaks.

Clause	Requirements
Further guidance *continued*	The frequency of the inspections must be based on risk assessment. The quality of the risk assessment is important as some items will probably be checked infrequently because of their lower risk status, whereas others may require frequent checks because of their prominent location and associated risk. For example, checking the window above the production line is likely to form part of the daily line start-up procedures. You must ensure you have a contingency procedure in place that allows the reporting and timely management of any breakage (i.e. if an item is found to be damaged or broken during an inspection or if an item breaks during use). There are a number of risk assessment techniques that can be used within food sites and the Standard is not prescriptive about which should be selected. However, there are two key considerations in relation to glass and brittle materials: • the potential for damage or breakage • the location and consequently the likelihood of a broken fragment contaminating a food product. **The importance of good documentation and record-keeping** Five key documents are required: • a list of items giving details of their location, number, type and condition • a risk assessment defining the required frequency of checks • records of the routine inspections to verify the condition of these items (see examples in Figures 16 and 17) • procedures that allow the cleaning or replacement of items in a way that minimises potential risk to products • a procedure for the management of any breakages (see clause 4.9.3.3). A record of the checks must be maintained even when there is no change to the status of the item (see examples in Figure 16 and 17). This is to demonstrate that the checks were made, so that in the event of a breakage you can be confident that the item was intact at the previous scheduled inspection, allowing any investigation or action to focus on a defined time period.

Examples

ITEM	LOCATION	NUMBER	TYPE	CONDITION	FREQUENCY OF INSPECTION (REFER TO RISK ASSESSMENT FOR FULL DETAILS)
Windows	Production	6	Glass	Fully intact Protected using adhesive sheeting	Monthly
Protective Guard	On production line 1	1	Rigid Plastic	Fully intact	Daily (NB Recorded on line start up records)

Figure 15 Example of a glass register

Clause	Requirements

Examples
continued

MONTHLY GLASS CHECK

Month: _____ Date Checked: _____

Checked By: _____

AREA/ITEM	DAMAGED OR MISSING (Y/N)	COMMENTS/ACTIONS

Figure 16 Example of a glass/brittle plastic check record

GLASS CHECK

AREA/ ITEM	DAMAGED OR MISSING (Y/N)	COMMENTS/ ACTIONS	DATE	CHECKED BY

Figure 17 An alternative glass check record, where different individuals perform checks on different dates

4.9.3.3

Procedures detailing the action to be taken in the event of breakage of glass or other brittle items shall be implemented and include the following:

- training of staff in the correct procedure
- quarantining the products and production area that were potentially affected
- cleaning the production area
- inspecting the production area and authorising production to continue
- changing of workwear and inspection of footwear
- specifying those staff authorised to carry out the above points
- recording the breakage incident
- safely disposing of contaminated product.

Clause	Requirements
Interpretation	**Breakage procedures** There must be documented procedures detailing the course of action to be taken when a breakage of a glass, brittle or hard plastic material, ceramic or similar item occurs. This must be based on risk assessment (therefore, the action taken may depend on the area in which the breakage occurred) and should include: • who has been trained to clear up broken items safely while minimising risks to product safety • isolation, inspection and management (e.g. product disposal) of potentially contaminated product (raw materials, packaging, final product etc.) • isolation of potentially contaminated area (e.g. specifying a 10-m exclusion zone) • how to clear up the broken item, including any designated equipment such as a brush, shovel and bin • how to clean the area and which cleaning equipment to use – this is important to ensure that glass particles are not transferred on equipment from one area to another • how to dispose of debris • inspection of the production area after cleaning, and the authorisation to recommence production • changing of production clothing (staff and cleaners) • inspection of footwear (staff and cleaners) • records to keep • identification of authorised staff to complete each of the above actions. The site should consider how to remove broken items, particularly larger items, from the premises. A designated, authorised contractor may be required.
Further guidance	**Typical steps to take in the event of a glass breakage** In the event of a breakage, the following procedure must be followed: • Notify a responsible person. (The site must identify the supervisors, line managers or production managers who should be notified and they should have sufficient knowledge and authority to take action.) • Where the breakage occurs near open product (e.g. near a production line), production in the area should be stopped. • Isolate the area of the breakage to ensure glass is not inadvertently distributed to other areas. • Discard products in the area that are contaminated or likely to be contaminated. If the break is discovered during a routine inspection, it will be necessary to consider all the products that have been manufactured since the last satisfactory inspection and the possibility that these may be contaminated. • Carefully clear the broken glass. The site should have specific cleaning equipment. • Once the area has been cleaned, it should be inspected and signed off before production resumes. • A record of all breakages should be maintained.

Clause	Requirements
4.9.3.4	Where they pose a risk to product, glass windows shall be protected against breakage.
Interpretation	**Protection of windows against breakage** Where it has been assessed that glass windows (including glazing in walls) pose a risk to product (e.g. where they are in close proximity to production or storage areas), they must be protected against breakage. This could be achieved by the use of adhesive plastic sheeting.
4.9.3.5	Where they pose a risk to product, bulbs and strip lights (including those on electric fly-killer devices) shall be adequately protected. Where full protection cannot be provided, alternative management such as wire-mesh screens or monitoring procedures shall be in place.
Interpretation	**Protection of lights against breakage** The site must assess where light bulbs and strip lights pose a risk to product (e.g. where they are in close proximity to production, storage areas or staff facilities). Where a risk is identified, light bulbs and strip lights must be protected against breakage. All types of lighting must be considered in order to minimise the likelihood of breakage and the spread of glass shards. Depending on the type of lighting used, protection can normally be achieved through the appropriate use of shatterproof light tubes, plastic sleeving or diffusion covers. Where full protection cannot be achieved, alternative methods of management, such as wire-mesh screens or monitoring procedures, must be in place.

4.9.4 Products packed into glass or other brittle containers

Interpretation

Where products are packed into glass or other brittle materials (e.g. ceramic pots), the risk of breakage is increased and the packaging materials themselves present a significant foreign-body risk. These requirements deal specifically with the additional controls required to reduce the risk of contamination. They do not apply where products are not packed into glass or similar brittle containers.

Clause	Requirements
4.9.4.1	The storage of the containers shall be segregated from the storage of raw materials, product or other packaging.
Interpretation	**Storage** There must be dedicated, segregated storage for glass or other brittle containers. Ideally a separate storage room should be used for storage of empty containers. Where the containers are in a shared warehouse, a distinctly separate area must be used. Warehouse product flow must be considered to reduce the risk of broken glass or fragments being carried into raw material storage areas.

Clause	Requirements
4.9.4.2	Systems shall be in place to manage container breakages between the container-cleaning/inspection point and container closure. This shall include, as a minimum, documented instructions which ensure: • the removal and disposal of at-risk products in the vicinity of the breakage; this may be specific for different equipment or areas of the production line • the effective cleaning of the line or equipment which may be contaminated by fragments of the container; cleaning shall not result in the further dispersal of fragments, for instance by the use of high-pressure water or air • the use of dedicated, clearly identifiable cleaning equipment (e.g. colour-coded) for removal of container breakages; such equipment shall be stored separately from other cleaning equipment • the use of dedicated, accessible, lidded waste containers for the collection of damaged containers and fragments • a documented inspection of production equipment is undertaken following the cleaning of a breakage, to ensure cleaning has effectively removed any risk of further contamination • authorisation given for production to restart following cleaning • the area around the line being kept clear of broken glass.
Interpretation	**Breakages** The documented instructions for dealing with breakages must cover those points listed in the requirement. However, where high-speed filling lines are used with automatic breakage detection and cleaning systems, not all these will be practical. In such cases, the site must be able to demonstrate that the system is capable of consistently and safely removing glass fragments, and that factors such as low water pressure which may affect the performance of the acceptance and/or rejection of implicated products are understood, documented and controlled.
4.9.4.3	Records shall be maintained of all container breakages on the line. Where no breakages have occurred during a production period, this shall also be recorded. This record shall be reviewed to identify trends and potential line or container improvements.
Interpretation	**Records** All breakages must be recorded. This record should include: • the location where the breakage occurred • a record of the action taken • sign-off by an authorised member of staff, e.g. a shift leader, production manager or quality assurance representative, who is trained and competent. Where no breakages have occurred during a production period, this must also be recorded. The records must be periodically reviewed to identify trends (the use of a glass breakage map may be useful in identifying any trends in the locations where breakages occur). The results must be reviewed, for example, during the management review of incidents (clause 1.1.4), to identify opportunities to reduce the risk of glass breakages.

4.9.5 Wood

Clause	Requirements
4.9.5.1	Wood should not be used in open product areas except where this is a process requirement (e.g. maturation of products in wood). Where the use of wood cannot be avoided, its condition shall be monitored on a risk-based frequency to ensure it is in good condition and free from damage or splinters which could contaminate products. Wood used for food contact purposes shall be fit for purpose (e.g. free from damage or splinters, free from taint; and wood treatments, where used, are used only in accordance with legislation and approved for food use).
Interpretation	**Wood in open product areas** The use of wood is not permitted in production areas except where it is a requirement of the process (e.g. wooden casks used for some alcoholic beverages, or wooden crates for incoming raw materials in fresh produce packhouses). Where wood cannot be avoided, a procedure must be in place to: • ensure the use of wood is covered by the HACCP risk assessment • identify damaged items • minimise the potential for contamination • ensure that the wood is monitored (e.g. by regular checks on a risk-based frequency to ensure it is in good condition and clean). Wooden pallets should not be present in open product areas unless there is an essential and justified need, which cannot reasonably be avoided. The site must be able to demonstrate that the presence of the pallet will not result in a product contamination risk. For example, controls might include: • not using wooden pallets in open product areas • designated areas for pallet use (e.g. only at the end of the packing line) • inspection of the pallets before entry to the production area. Where wood is intended for food contact purposes, it must be fit for purpose. This may, for example, include being: • free from damage or splinters which could result in foreign bodies migrating into the products • free from chemical contamination which could migrate into the products, including taint • cleaned or managed to prevent microbiological contamination • used only in accordance with any relevant legislation; for example, any wood treatments must be approved for food use, and in the EU, the Framework Regulation EC 1935/2004 stipulates that food contact materials shall not release their constituents into food in quantities which could cause deterioration in the food's organoleptic characteristics (i.e. its taste and smell).

4.9.6 Other physical contaminants

Clause	Requirements
4.9.6.1	Procedures shall be in place to prevent physical contamination of raw materials by raw material packaging (e.g. during debagging and deboxing procedures to remove the packaging).
Interpretation	**Raw material packaging** Raw materials are delivered to sites in a variety of packaging formats composed of different materials (including cardboard boxes, paper liners, plastic bags, sacks, etc.) and with different types of closure (metal fixtures, glue, tape, thread, etc.). Sites must ensure that the risk of these packaging materials contaminating the raw material is prevented. Where packaging is removed from raw materials prior to use, documented procedures must be in place so that staff completing the activity know how to do so without creating a contamination hazard to the raw material.
4.9.6.2	Portable handheld equipment, e.g. stationery items (pens, pencils etc.), mobile phones, tablets and similar portable items used in open product areas, shall be controlled by the site to minimise the risk of physical contamination. The site may consider, for example: • excluding non-approved items • restricting the use to site-issued equipment • ensuring stationery items such as pens are designed without small external parts and are detectable by foreign-body detection equipment, or are used in designated areas where contamination is prevented.
Interpretation	**Control of portable handheld equipment** The aim of the clause is to minimise or prevent potential product contamination from pens and small portable items such as stationery, mobile phones and tablets. The type of control applied will depend on the nature of the process, the site, and the potential for contamination should those items be lost or damaged in the production or storage area. Suitable controls may include: • restricting portable items to those approved and issued by the site • use of metal detectable equipment • restricting approved items to those with no small external parts, so that any breakage will not result in small pieces of undetectable plastic in product. The Standard is not prescriptive in the control mechanisms used. For example, it is common for pens used in production areas to be metal detectable; however, other controls may be more suitable in certain circumstances. Therefore metal detection is provided as an example of a common control. Nor does the Standard require pens to be of a specific design, or state that most pens available on the market are not compliant. The Standard does not require the site to test every batch of pens through its metal detector. It does, however, require sites to consider the design of pens and portable items being used, to ensure that potential food safety hazards have been considered and are managed appropriately.
4.9.6.3	Based on risk, procedures shall be implemented to minimise other types of foreign-body contamination (i.e. types of contamination that are not specifically covered in section 4.9).

Clause	Requirements
Interpretation	**Other types of foreign-body contamination** The aim of this clause is to ensure that sites have considered all of the different types of foreign-body risks that may reasonably be expected to occur within their site, and have introduced suitable controls. For example, this may include significant foreign bodies identified during the development of the food safety plan (see clause 2.7.1) but not already managed through the other clauses in section 4.9. Where risk assessment shows that a genuine risk exists, the site will need to introduce suitable control procedures.

4.10 Foreign-body detection and removal equipment

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

Interpretation

The risk of foreign-body contamination must be minimised using food industry best practice, such as X-ray inspection, metal detection, sieves, magnets or scanner technology.

BRCGS has produced a guideline to foreign-body detection which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.

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

Clause	Requirements
4.10.1.1	A documented assessment in association with the food safety plan (see section 2 – The food safety plan) shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination. Typical equipment to be considered may include: • filters and sieves • metal detection and X-ray detection equipment • magnets • optical sorting equipment • other physical separation equipment (e.g. gravity separation, fluid bed technology).
Interpretation	**Documented assessment** The food safety plan should be the starting point for implementing an effective foreign-body control programme. Potential hazards and their sources must be identified so that appropriate control procedures can be put in place to minimise the likelihood of product contamination. The Standard lists some of the most common forms of equipment used.
4.10.1.2	The type, location and sensitivity of the detection and/or removal method shall be specified as part of the site's documented system. Industry best practice shall be applied with regard to the nature of the ingredient, material, product and/or packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified.

Clause	Requirements
Interpretation	**Type, location and sensitivity** The choice of location for foreign-body detection equipment is vital for its effective use. Equipment should be placed as close to the end of the production process as is practical, so that the whole process (including packing lines) is protected. When selecting equipment and determining the best location for it, the potential environmental effects (e.g. temperature, moisture or speed of line) should be considered and discussed with the equipment supplier. The sensitivity of detectors must be specified and best practice applied, taking into account the nature of the food, contamination characteristics, and the location and aperture size of the detector. For example, it is likely that metal detectors will be sensitive to ferrous, non-ferrous and stainless steel test pieces, using test sizes according to industry best practice for the particular product type or customer requirements. Good practice is for foreign-body detectors to have adequate security settings so that only authorised personnel can alter them. The Standard expects the detector and its location to be validated at set-up; for example, by adjusting the machine's sensitivity using a range of typical products to establish the most sensitive practical setting which gives rise to consistent rejection without false rejects. The established settings must be recorded and verified through regular checks of the equipment; these checks are generally undertaken using test pieces of a size just above the limit of detection.
4.10.1.3	The site shall ensure that the frequency of the testing of the foreign-body detection and/or removal equipment is defined and takes into consideration: • specific customer requirements • the site's ability to identify, hold and prevent the release of any affected materials, should the equipment fail. The site shall establish and implement corrective action and reporting procedures in the event of a failure of the foreign-body detector and/or removal equipment. Action shall include a combination of isolation, quarantining and re-inspection of all products produced since the last successful test or inspection.
Interpretation	**System monitoring and corrective action** The frequency of testing of the monitoring equipment must be assessed and defined in procedures. The frequency of routine tests should consider: • the need for additional checks at start-up and finish of shifts • product changeovers • the need for regular checks throughout production (hourly testing is expected for many detection systems) • changes in machine settings or following downtime • any specific customer requirements • the site's ability to recover and retest product in the event of a failure. In the event that equipment is discovered not to be working, all of the product that has passed through the detector since it was last verified to be working must be rechecked.

Clause	Requirements
Interpretation *continued*	There must be procedures in place specifying the action required in the event of the detector failing a routine test (e.g. failing to detect or reject a test piece). The people responsible for completing the tests must also be trained in this procedure (clause 7.1.1). The procedures must include a combination of isolation, quarantining and re-inspection of all products produced since the last successful test. If the cause of the failure is a system fault, the fault should be repaired before recommencing production on the implicated line.
4.10.1.4	Where foreign material is detected or removed by the equipment, the source of any unexpected material shall be investigated. Information on rejected materials shall be used to identify trends and, where possible, instigate preventive action to reduce the occurrence of contamination by the foreign material.
Interpretation	**Investigation of rejected material** Products rejected or retained by detection systems can provide valuable information about possible problems arising from raw materials or the production process, and provide an early warning of potential issues. Rejected products should therefore be examined to identify the cause of rejection. Identified causes should be investigated and recorded. The data on rejected and retained product must also be used as the basis for analysing trends. This trend analysis may be used to establish preventive actions to reduce future contamination. Information about false rejects should also be recorded, because this may suggest an error with the detector or indicate that the settings are too sensitive for a particular product and require adjustment.

4.10.2 Filters and sieves

Clause	Requirements
4.10.2.1	Filters and sieves used for foreign-body control shall be of a specified mesh size or gauge and designed to provide the maximum practical protection for the product.
Interpretation	**Mesh and gauge size** To ensure the system provides maximum protection, consideration must be given to mesh and gauge size. The smallest practical size should be used. The size will be documented and details made easily available to staff using the equipment.
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage at a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified, this shall be recorded and the potential for contamination of products investigated and appropriate action taken.

Clause	Requirements
Interpretation	**Routine inspection** Filters and sieves must be monitored to ensure they themselves do not pose a foreign-body hazard and are working effectively. There must be a documented procedure which includes: • the frequency of checks – this should be based on the nature of the sieve (e.g. a perforated-drum sieve is less likely to fail than a wire-mesh sieve), historical evidence of performance, risk to finished product, and the site's ability to recover product in the event of a failure. Sieves are typically inspected at least once per week. The results of sieve monitoring must be recorded • staff responsibilities • the action to be taken when issues are identified. The material from which sieves and filters are manufactured should be considered, to minimise the potential for breakages that lead to foreign-body issues (e.g. where sieves or filters are used as part of a justification for not requiring metal detection, they should be made of non-metallic mesh). Where defective filters or sieves are identified, this must be recorded, the potential for contamination of products investigated, and appropriate action taken. Depending on the type of sieve or filter used, the site may choose to use visual inspection or a sieve analysis which compares results of the sample for particle size retention. This is often useful for quality control purposes.

4.10.3 Metal detectors and X-ray equipment

Clause	Requirements
4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve food safety. Where metal detectors are not used, justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective method of protection (e.g. use of X-ray, fine sieves or filtration of products).
Interpretation	**Requirement for metal detection** The Standard presumes that metal detection provides improved food safety and protection for customers and should form part of the food protection system of a site. Its absence would normally only be based on the use of an alternative, more effective, method of protection (e.g. the use of X-ray, fine sieves or filtration). There will, however, be situations where metal detection does not, on the basis of risk assessment, provide any significant additional protection to the consumer; for example, where whole pieces of fresh produce (e.g. potatoes) are being washed and packed, and any metal contamination would be obvious to the consumer prior to consumption. Where metal detectors are not used, a risk assessment must be available to justify the reasons why. While complaint levels are a factor in making a decision on the necessity for a metal detector, this evidence alone will not be sufficient justification for not using one. (For example, there may be instances of contamination which have not been reported by consumers.) Any justification for the absence of metal detection should be based on the nature of the product, the risk to the consumer, and alternative controls in place at the site which prevent metal contamination. Cost alone is not sufficient reason.

Clause	Requirements
Interpretation *continued*	In all circumstances where products are manufactured to a customer's specification, sites must comply with any customer requirement for metal detection of their products. The decision tree in Figure 18 provides further guidance on the need for metal detection equipment for products not packed into metallic containers. Where the product is packed into metal packaging, an effective alternative test method must be developed (e.g. X-ray or metal-detecting the product at the stage prior to packing, or the use of magnets and product inspection). Failsafes or alarms should be implemented to notify production staff when failure of equipment is likely. It is vital to know when equipment designed to remove contaminated product is not functioning.

Further guidance

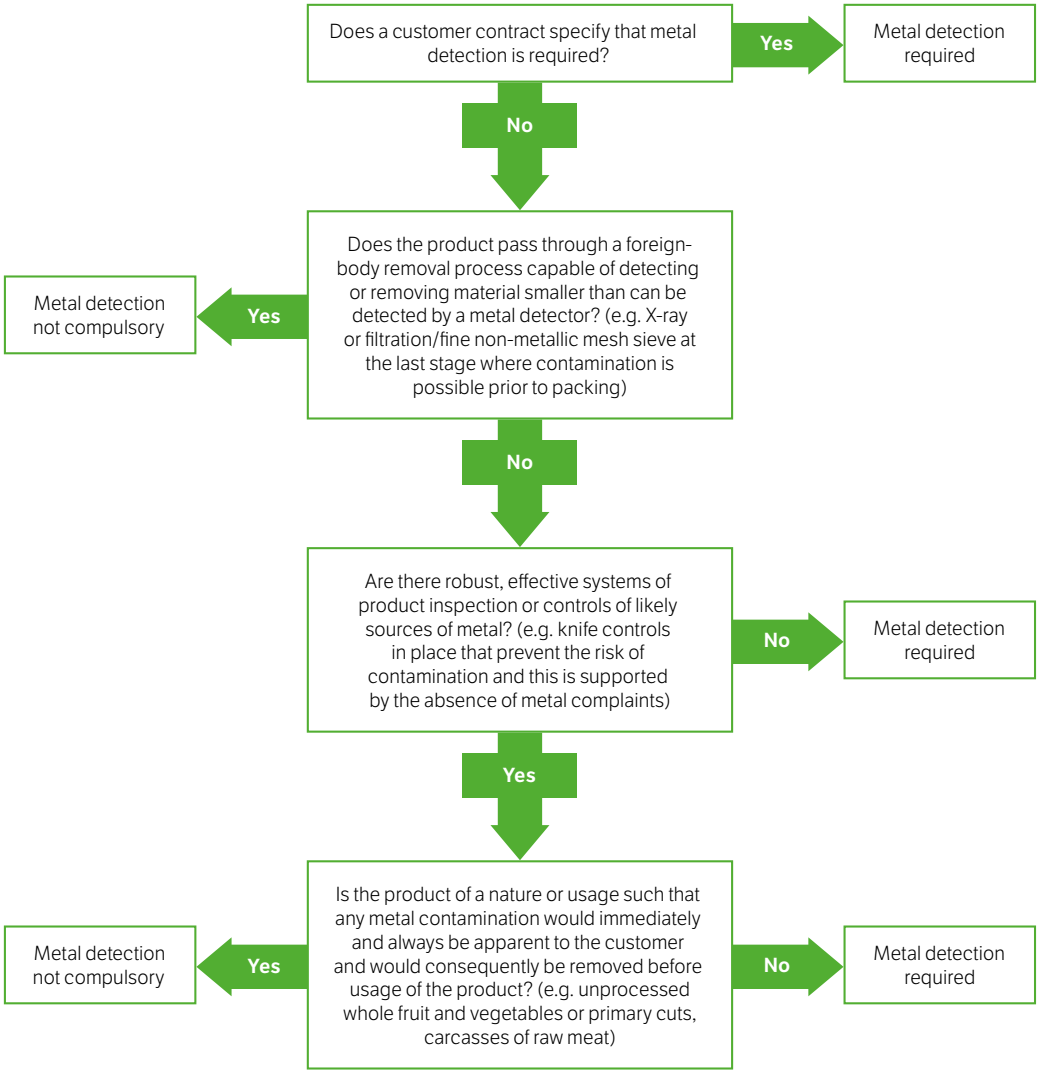

Figure 18 Decision tree for metal detection

Clause	Requirements
4.10.3.2	The metal detector or X-ray equipment shall incorporate one of the following: • an automatic rejection device, for continuous in-line systems, which shall divert contaminated product either out of the product flow or to a secure unit accessible only to authorised personnel • a belt stop system with an alarm where the product cannot be automatically rejected (e.g. for very large packs) • in-line detectors which identify the location of the contaminant to allow effective segregation of the affected product.

Interpretation

Rejection mechanisms

There are a variety of types of metal detector available, and selection will usually be dependent on the product and production process; for example, conveyor-based or gravity feed systems.

Regardless of the design of the metal detector, the objective of this clause is to ensure that rejected products are effectively removed and not accidentally re-introduced into the process flow.

The Standard requires the use of automatic rejection devices incorporated into metal detection and X-ray equipment.

The use of belt stop and alarm systems is considered by some to present a greater risk of 'rejected' product being re-introduced into the process flow than automatic rejection systems where the product is positively rejected into a locked container. The Standard permits the use of either rejection mechanism providing there are sufficient controls in place to prevent implicated product being inadvertently placed back into the product flow.

For belt-stop-style metal detector rejection systems, this will typically include the use of a container into which rejected product is placed, which is secured so that only authorised staff can remove the product (similar to the locked-box system used for automatic rejection systems).

Where automatic rejection is not used, the following additional controls should be considered to ensure that rejected product is effectively segregated and managed:

- The removal of affected product should be restricted to trained, authorised staff. This may be supported by restricting access to the product once the belt has stopped (e.g. by using a locked production line cover and authorised key holders).
- Rejected product may be marked, be destroyed or have its label removed to reduce the risk of re-introduction to the process flow.
- The line restart should be restricted to designated personnel who must verify the location of the 'rejected' product prior to restart (i.e. the control panel/button for restart is secure, locked or security-coded).
- A record should be made of each occasion when the belt stops in response to the detection of metal in a product.

Where the product is packed into metal packaging, an effective alternative test method must be developed – for example, the use of X-ray detectors, metal detection, magnets or product inspection prior to packing.

Clause	Requirements
4.10.3.3	The site shall establish and implement procedures for the operation and testing of the metal detection or X-ray equipment. This shall include, at a minimum: • responsibilities for the testing of equipment • the operating effectiveness and sensitivity of the equipment and any variation to this for particular products • the methods and frequency of checking the detector • recording of the results of checks.

Interpretation

Documented metal detector and X-ray procedures

The site must have documented procedures for the operation (including effectiveness and sensitivity) and routine monitoring of metal detector and X-ray equipment. The procedures will identify the individuals authorised to adjust the system as well as those responsible for completing system tests. Note that clause 6.1.2 applies to metal detectors and X-ray detectors, and good practice is to restrict the adjustment of the systems to a limited number of trained, authorised staff, to ensure that any changes are completed and documented correctly and in a controlled manner.

The set-up and design of the operating procedures will need to consider a number of factors, which will affect the sensitivity of the detector and the effectiveness of the rejection mechanisms, including, for example:

- size and type of product – product size and composition can affect the sensitivity of the detector and therefore its ability to identify
- product packaging – product is normally tested in pack, but certain types of packaging will prevent this
- line operating speeds – there must be sufficient time for the detector to identify the presence of a contaminant and the rejection mechanism to accurately and consistently remove the implicated pack from the product flow
- location of the detector – should be risk-assessed to ensure that the placement efficiently and effectively minimises the risk of foreign bodies in the finished product
- customer-specific requirements – some customers have specific requirements relating to detector sensitivity or frequency of tests
- identification of the least sensitive (sometimes referred to as the weakest) part of the detector, to ensure that any contaminated product will still be rejected, even if the contaminant is located at this weakest point.

The frequency of testing must be based on the quantity and type(s) of product. However, the following should be considered:

- start-up and finish of shifts
- product changeovers
- change in machine settings following downtime for repairs
- customer requirements
- regular checks throughout production (these should consider the site's ability to recover and retest product in the event of a failure; therefore a minimum of hourly testing is typically expected).

The testing procedures must be based on the requirements of clause 4.10.3.4 but must also ensure that all relevant parts of the metal detector are operating correctly (e.g. the timing of the rejection system, the memory reset function and any failsafe alarms).

Clause	Requirements
Interpretation *continued*	The results of the tests conducted must be documented to demonstrate that all requirements of the monitoring procedure were executed and were within the correct working parameters. The Standard does not require routine calibration of metal detectors beyond the verification/checking activities described in this section. However, planned maintenance or servicing may have value depending on the machine, the manufacturer's specification, the contract and/or the operating environment.
4.10.3.4	Metal detector testing procedures shall, at a minimum, include: • use of test pieces incorporating a sphere of metal of a known diameter selected on the basis of risk. The test pieces shall be marked with the size and type of test material contained • tests carried out using separate test pieces containing ferrous metal, stainless steel and typically non-ferrous metal, unless the product is within a foil container where a ferrous-only test may be applicable • a test to prove that both the detection and rejection mechanisms are working effectively under normal working conditions • tests of the metal detector by passing successive test packs through the unit at typical line operating speed • checks of failsafe systems fitted to the detection and rejection systems. In addition, where metal detectors are incorporated on conveyors, the test piece shall be passed as close as possible to the least sensitive area of the metal detector (usually the centre of the metal detector aperture). Wherever possible, the test piece shall be inserted within a clearly identified sample pack of the food being produced at the time of the test. Where in-line metal detectors are used, the test piece shall be placed in the product flow wherever this is possible, and the correct timing of the rejection system to remove identified contamination shall be validated. Testing of in-line metal detectors shall be completed during both line start-up and at the end of the production period.
Interpretation	**Metal detector checking procedures** The company must establish procedures for the operation and routine monitoring of the metal detector. Industry best practice, manufacturers' guidelines and specific customer requirements (clause 4.10.1.3) should be considered when developing these procedures. It is important that the test procedure reflects the normal operation of the production line, to provide confidence that any contamination will be correctly detected and removed during production. For example, the clause requires: • completing tests at typical line operating speeds – to ensure detection and rejection mechanisms operate correctly at intended line speeds • placing test pieces within product packs – to ensure product matrix or packaging does not adversely affect the metal detector • use of successive test packs – to ensure the system can effectively detect and, if necessary, reject, products immediately after a pack has been rejected.

Clause	Requirements
Interpretation *continued*	Many modern designs of metal detector (and other foreign-body detection systems such as X-rays) have failsafe systems – that is, they monitor their own functions and raise an alarm (usually audible) if something stops working. For example, if a product rejection system is powered by compressed air and the air supply fails, this will sound the alarm immediately, allowing staff to investigate the fault, rather than waiting until the next metal detector check finds a problem. Where these systems exist, it is important to run occasional checks to ensure that the failsafe system itself is operating (e.g. that the alarm will sound if one of its functions fails). The Standard does not expect sites to purchase new metal detection equipment if there is no failsafe system on their current equipment. Within the procedure, consideration must be given to where the test pieces are located. To ensure that the least sensitive areas of the metal detector are able to detect the piece, this is usually the centre of the metal detector aperture.
4.10.3.5	X-ray equipment testing procedures shall, at a minimum, include: • use of test pieces incorporating a sphere of suitable material (e.g. a typical contaminant) of a known diameter selected on the basis of risk. The test pieces shall be marked with the size and type of test material contained • tests carried out using separate test pieces • a test to prove that both the detection and rejection mechanisms are working effectively under normal working conditions • tests of the X-ray equipment by passing successive test packs through the unit at typical line operating speed • checks of failsafe systems fitted to the detection and rejection systems. In addition, where X-ray equipment is incorporated on conveyors, the test piece shall be passed as close as possible to the least sensitive area of the X-ray equipment (e.g. this may be close to the X-ray source or close to the X-ray equipment). Wherever possible, the test piece shall be inserted into a clearly identified sample pack of the food being produced at the time of the test. Where in-line X-ray equipment is used, the test piece shall be placed in the product flow wherever this is possible, and the correct timing of the rejection system to remove identified contamination shall be validated. Testing of in-line equipment shall be completed both during line start-up and at the end of the production period.
Interpretation	**X-ray testing procedures** X-ray detectors generally require slightly different test procedures from metal detectors, and therefore sites using X-ray equipment must establish procedures for the operation and routine monitoring of the X-ray equipment. Industry best practice, manufacturers' guidelines and any customer-specific requirements should also be considered when developing these procedures. The procedure must consider: • the test pieces – the type of test material chosen should be based on the materials reasonably expected to form contaminants within the products being tested. A number of different test pieces are likely to be required to ensure all potential hazards are monitored

Clause	Requirements
Interpretation *continued*	• a test to prove that both the detection and rejection mechanisms are effective, to ensure that foreign bodies are removed if present. These tests should be completed with the line running under normal conditions, e.g. with correct line speeds to ensure consistency and accuracy under normal conditions • checking of the failsafe system, to ensure product is removed or held in a separate area (further information regarding failsafe systems can be found in the interpretation for clause 4.10.3.4). The test piece should be passed through the X-ray equipment, ensuring that the least sensitive area is clearly identified, and this should be included in the procedure. Depending on the design of the X-ray equipment, the least sensitive area of the detector may be located close to the X-ray source or the detector. Good practice is to test the system by using test pieces within a clearly identified sample pack of the food being produced at the time of the test. Where in-line X-ray equipment is used, additional consideration will be needed to develop an effective test mechanism. For example, the test piece must be placed in the product flow wherever possible, and the correct timings of the rejection system confirmed, to ensure removal of the test piece. This must be completed at the start-up and end of production. Additional testing, where required, should be based on risk.

4.10.4 Magnets

Clause	Requirements
4.10.4.1	The type, location and strength of magnets shall be fully documented. Procedures shall be in place for the inspection, cleaning, strength testing and integrity checks of magnets used for food safety purposes, including final product testing, e.g. to remove product contamination. Records of all checks shall be maintained.
Interpretation	**Magnets** Some sectors of the food industry (e.g. grinding of cereals and production of coffee) employ magnets to reduce or remove metal fragments in the finished product. Where a magnet is used for these food safety purposes, it is important to document its type (e.g. electromagnet or permanent magnet), location and strength. Magnets are not an alternative to metal detectors, but an additional control mechanism, and factories using magnets must still comply with the requirements of section 4.10.3. The magnet's strength should be designed to ensure that it is sufficient to capture metal foreign bodies. A number of factors should be considered when determining the correct strength; for example, the type of product (e.g. the size of the food particles), the width of the conveyor belt, chute or other equipment in which the magnets are located, and the flow rate of the food or raw material. Documented procedures must be in place to ensure: • routine inspection (e.g. visual inspection for damage and the presence of captured metal fragments)

Clause	Requirements
Interpretation *continued*	• cleaning – the ability of a magnet to capture a foreign body can be hampered if dirt or other material is allowed to collect on the magnet's surface • strength testing (e.g. by using a magnetic meter (measuring the magnet's strength in tesla) or through the use of a third-party calibration service). Records of all checks, recalibrations or servicing must be maintained. Clause 4.10.1.3 requires sites to develop test procedures which consider: • the frequency of testing; for example, to ensure the site can take timely action on implicated product in the event of a test failure • any specific customer requirements. Good practice for monitoring a magnet's performance includes locating a second 'policing' magnet as close to the first as possible. Any metal found on this second magnet indicates that the 'process' magnet is not performing satisfactorily and is failing to remove all metal particles.

4.10.5 Optical sorting equipment

Clause	Requirements
4.10.5.1	Optical sorting equipment used for final product testing shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.
Interpretation	**Optical sorting equipment** Optical sorting devices are commonly used in some industries to remove unsatisfactory products or contaminants from finished products, usually on the basis of colour or variance from a reference material. Where equipment is in use, procedures need to be developed for the maintenance and testing of the equipment. This is usually developed with the manufacturer when the equipment is installed and commissioned. Records of all checks and servicing must be maintained.

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

Clause	Requirements
4.10.6.1	Based on risk assessment, procedures shall be implemented to minimise foreign-body contamination originating from the packaging container (e.g. jars, cans and other pre-formed rigid containers). This may include the use of covered conveyors, container inversion and foreign-body removal through rinsing with water or air jets.
Interpretation	**Procedures** Where packaging containers are supplied to the production site in a rigid format (e.g. empty cans, bottles or glass jars), there is an increased risk of contamination of the container during storage and transit before filling. Glass containers carry the additional risk of damage during transit.

Clause	Requirements
Interpretation *continued*	A rigid container is generally any container that is inflexible and would break into separate pieces (i.e. small fragments) if pressure was applied, which could subsequently be a foreign-body hazard. These containers are normally manufactured from glass, metal or inflexible plastics or ceramics, although other materials may be used. These types of packaging can increase the risk of foreign-body contamination either during the manufacturing process or because of breakages during storage and transit. The site needs to consider the potential risks associated with the containers and introduce appropriate controls to reduce the risk. For example, it is usual for such containers to be inverted and cleaned prior to use and for glass jars and bottles to be subject to automatic or manual (by exception) inspection before use. Where the site uses inversion and cleaning (for example, by air jets), it may be necessary to introduce a dust/debris cover, collector or control measure to restrict the movement of the removed debris and therefore prevent it being moved into a situation where it would become another foreign-body hazard. Documented procedures, based on risk assessment, must be available to address the potential risks.
4.10.6.2	The effectiveness of the container-cleaning equipment shall be checked and recorded during each production. Where the system incorporates a rejection system for dirty or damaged containers, the check shall incorporate a test of both the detection and effective rejection of the test container.
Interpretation	**Effectiveness of container-cleaning** In-line cleaning and automatic rejection systems are not a requirement of the Standard, but the use of such systems is strongly encouraged. Where these systems are present, they must be checked and records maintained of checks. Consideration must also be given to the action required in the event of a breakage after cleaning (clause 4.9.3.3).

4.10.7 Other foreign-body detection and removal equipment

Clause	Requirements
4.10.7.1	Other foreign-body detection and removal equipment, such as gravity separation, fluid bed technology or aspirators, shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.
Interpretation	**Other removal equipment** All foreign-body detection and removal systems need to be operated correctly to ensure that they provide the required level of operation. The clause is applicable to all types of equipment not mentioned elsewhere within the Standard; for example: • gravity separation – a method of separating components in either a suspension or as dry granular materials. Gravity separation relies on the components of the material having different specific gravities and therefore different relative motion under gravity and drag forces

Clause	Requirements
Interpretation *continued*	• fluid bed technology – this technology separates particular matter according to size, shape and/or density • aspirators – another technology for separating contaminants on the basis of size, density or shape. It can also be used in the removal of loose outer casings from a variety of foods; for example, grain hulls. All removal equipment must be checked in accordance with the manufacturer's guidelines and instructions to ensure it is being used in the correct way, such that effective removal of foreign bodies is consistently achieved. All checks must be documented and records retained. Good practice is to ensure any non-conformities are investigated and corrective actions completed in a timely manner.

4.11 Housekeeping and hygiene

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

Interpretation

Housekeeping is general tidiness, and hygiene is standard of cleanliness, sometimes also referred to as sanitation.

The site must be maintained to a suitable level of cleanliness. Control of hygiene must be achieved through schedules of cleaning and policies on housekeeping based on risk assessment. This must be demonstrated through documented and monitored systems. The methods of cleaning themselves must not pose a risk of product contamination (e.g. from cleaning areas adjacent to open product).

Clause	Requirements
4.11.1	The premises and equipment shall be maintained in a clean and hygienic condition.
Interpretation	**Cleanliness of premises and equipment** It is important that the site, manufacturing environment and equipment are routinely cleaned to an appropriate standard of cleanliness to prevent potential contamination (e.g. with allergens or micro-organisms) and to prevent quality issues such as taint from previously manufactured products. The Standard requires (clause 4.11.3) that appropriate limits of acceptable cleaning performance shall be defined. During the course of the audit, equipment that is not currently operating will be opened and inspected to assess whether cleaning has been completed appropriately and in accordance with the site's policies (including the acceptable limits), as well as to assess post-cleaning checks (clause 4.11.5). Production lines that are running will not be stopped for inspection, although records may be checked to ensure equipment was appropriately cleaned and checked prior to use (see clauses 4.11.2, 4.11.3 and 4.11.5).

Clause	Requirements
4.11.2	Documented cleaning and disinfection procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures for the processing equipment and food contact surfaces shall, at a minimum, include: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning, including dismantling equipment for cleaning purposes where required • cleaning chemicals and concentrations • cleaning materials to be used • cleaning records (including records for completion and sign-off) and responsibility for verification. The frequency and methods of cleaning shall be based on risk. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.
Interpretation	**Documented cleaning procedures** Documented cleaning and disinfection procedures must be in place to ensure consistent and effective cleaning and as a guide for training purposes. When documenting such procedures, an emphasis should be placed on the processing equipment and food contact surfaces. The procedures must be in sufficient detail for the cleaning to be carried out to a consistently acceptable standard. In the majority of sites, good practice would normally include six stages of cleaning: • remove gross debris (e.g. sweep or wipe) • rinse with water • wash with detergent solution using hot water • rinse • dry • sanitise. Where equipment requires different levels of cleaning (e.g. between products, or between daily and weekly cleans), each requirement should be clearly detailed and specific to the item of equipment. These procedures need to be reviewed and updated whenever changes to the equipment and areas to be cleaned occur. In addition, a good cleaning instruction would include: • a unique method of reference that can be quoted on paperwork (e.g. cleaning records) • photographs of equipment, which are useful for identifying equipment and for highlighting areas that are difficult to clean, or that form key check/verification points • the appropriate protective clothing or equipment that should be worn when cleaning or handling cleaning chemicals.

Clause	Requirements
Further guidance	**Developing an effective cleaning procedure** In order for cleaning to be effective, it is important that the procedures are designed for the specific item, area or site. A generic, off-the-shelf procedure probably would not guarantee a sufficient standard of cleaning. For example, an identical work surface in an area handling bakery products would need to be treated differently from one in a meat-handling area. This would need to be assessed during the development and risk assessment stage. The complexity of the process and equipment, the types of product manufactured, the ease with which debris can be removed, and the need to manage specific hazards (e.g. specific micro-organisms or allergens) are also factors to consider. Developing a cleaning procedure can be done in a few simple steps: • **Step 1** Set the required standard of cleaning (clause 4.11.3) Consider legislation, customer requirements, industry or category best practice, etc. The risk assessment should consider the prevention of contamination from previous products, as well as address potential microbiological, chemical or allergen concerns. • **Step 2** Develop draft procedures (clause 4.11.2) Ensure all items, areas and equipment are defined and included within the procedures. Think about the order of cleaning too, so that cleaned equipment is not re-contaminated by subsequent cleaning activity. • **Step 3** Validate the draft procedures (clause 4.11.3) Use validation to confirm that the required standard of cleaning (Step 1) is met. The Standard requires that cleaning procedures which form part of a defined prerequisite (i.e. procedures that are used to control a specific hazard such as allergen cross-contamination) must be validated to ensure they are effective and deliver the intended level of cleaning. However, it is also good practice for all cleaning procedures to be validated. • **Step 4** Finalise procedures and associated documentation (e.g. cleaning records and sign-off) Keep records that show what type of cleaning was completed, when it was completed, who did it, and who checked the cleaning and signed it off as acceptable (a requirement of clause 4.11.2). • **Step 5** Train relevant staff (clause 4.11.4). • **Step 6** Complete ongoing monitoring and verification (clauses 4.11.2 and 4.11.5). When developing cleaning procedures, it is often useful to remember: • All equipment and areas must be included. • Cleaning needs should be discussed with equipment and chemical suppliers, who can often provide valuable assistance in identifying suitable cleaning materials. • Validation and verification are needed for cleaning activities – validation before introducing the new procedure, and verification on an ongoing basis. Verification is the application of checks or tests, at regular intervals, to ensure the cleaning procedure is still working and continues to deliver the required level of cleaning. Verification of cleaning may include internal audits, record reviews, swabs or tests of the cleaned equipment, and the assessment of staff to ensure they have a clear understanding of the cleaning procedure.

Clause	Requirements
Further guidance *continued*	• Cleaning procedures should be reviewed whenever there are changes to the area, equipment or processes, including the introduction of new products or the use of new ingredients.
Example of a cleaning record	In addition to cleaning procedures, the Standard also requires records of the cleaning completed. As shown in Figure 19, records for routine cleaning generally include: • what was cleaned • who completed the cleaning • when the cleaning was completed • monitoring, sign-off or confirmation that appropriate cleaning has been completed to a satisfactory standard.
4.11.3	Limits of acceptable and unacceptable cleaning performance shall be defined for food contact surfaces and processing equipment. These limits shall be based on the potential hazards relevant to the product or processing area (e.g. microbiological, allergen, foreign-body or product-to-product contamination). Therefore, acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing, allergen testing or chemical testing as appropriate. The site shall define the corrective action to be taken when monitored results are outside of the acceptable limits. Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard, the cleaning and disinfection procedures and their frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.
Interpretation	**Cleaning performance limits** At a minimum, limits of acceptable and unacceptable cleaning performance must be defined for: • food contact surfaces • processing equipment.

SITE AREA: Production **WEEK COMMENCING:**

			MON		TUE		WED		THU		FRI		SAT		SUN	
METHOD	EQUIPMENT/ AREA	FREQUENCY	Clean Sign	Check Sign	Clean Sign	Check Sign	Clean Sign	Check Sign	Clean Sign	Check Sign	Clean Sign	Check Sign	Clean Sign	Check Sign	Clean Sign	Check Sign
A1	Conveyor 1	Daily														
A1	A2 Bowl Mixer 1	Daily														
A1	A2 Bowl Mixer 2	Daily														
A1	A3 Spiral Chiller	Daily														

DOCUMENT REFERENCE	ISSUE DATE/VERSION NUMBER	ISSUE/AUTHORISED BY

Figure 19 Example of a cleaning record

Clause	Requirements
Interpretation *continued*	The limits need to be based on risk, and this should be used for assessing whether the cleaning undertaken is of an acceptable standard. Acceptable limits may be based on visual inspection, ATP monitoring or specific analysis such as microbiological, allergen or chemical testing. For example, where the cleaning is principally designed to provide a clean processing environment, an assessment of 'visually clean' may be sufficient. However, where the level of cleaning is to ensure a sterile food contact surface to make sure that all traces of an allergen have been removed or to prevent cross-contamination of different meat species, the level of acceptable cleaning performance may need to be based on more rigorous checks such as the results of ATP, microbiological or allergen tests. Where the cleaning procedure forms part of a defined prerequisite (section 2.2) designed to manage a specific hazard (e.g. allergen cross-contamination), then the procedure must be validated to confirm that the specified cleaning method, chemicals and concentrations are capable of consistently achieving the level of performance required. Records of validation must be maintained. When designing and validating cleaning procedures, cleaning chemical residues must be considered so that they cannot become a source of product contamination (e.g. manufacturer's instructions must be followed regarding rinse methods). Cleaning checks should include hard-to-reach locations as well as surfaces and those locations that are easy to reach, effectively confirming satisfactory cleaning of all surfaces and areas. Where results are outside of the acceptable limits, the site's procedures should ensure that corrective action is taken (e.g. by repeating the cleaning process and rechecking the standard of cleaning). The exact action will depend on the type of cleaning, the check methodology and the acceptable levels that have been defined.
4.11.4	The resources for undertaking cleaning shall be available. Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled and, where necessary, planned for non-production periods. Cleaning staff shall be adequately trained or engineering support provided where access within equipment is required for cleaning.
Interpretation	**Training and resources** Appropriate resources are required to ensure that all cleaning is completed correctly and to the appropriate standard. These resources will include: • cleaning equipment • cleaning chemicals (e.g. detergents) • trained personnel. (As per the requirements of section 7.1, all cleaning must be carried out by trained staff. Training records must demonstrate that the relevant training has been completed and must cover all staff involved in cleaning activities, including employment agency and temporary staff.) Where specialist resources or activities are required (e.g. to dismantle or enter large equipment), this must be appropriately scheduled and, where necessary, planned for non-production periods. Full support must be provided by engineering, either by additional training or by having engineering staff present during these cleaning operations.

Clause	Requirements
4.11.5	The cleanliness of equipment shall be checked before equipment is released back into production. The results of checks on cleaning, including visual, analytical and microbiological checks, shall be recorded and used to identify trends in cleaning performance and to instigate improvements where required.
Interpretation	**Cleaning inspection and sign-off** An authorised member of staff (e.g. line supervisor, quality assurance supervisor or production manager) must formally accept equipment back into operation following an inspection, to confirm that the cleaning has been completed satisfactorily. The results of checks on cleaning, including visual or analytical checks, must be recorded. These records must be used to identify trends in cleaning performance and to instigate improvements where required. For example, trends and potential changes could be discussed during management meetings (clause 1.1.4). Where changes in cleaning regimes are required (e.g. to prevent the build-up of micro-organisms, biofilm or scale), companies may need access to relevant expertise or advice.
4.11.6	Cleaning equipment shall be: • hygienically designed and fit for purpose • suitably identified for intended use (e.g. colour-coded or labelled) • cleaned and stored in a hygienic manner to prevent contamination.
Interpretation	**Cleaning equipment** Cleaning equipment, including any equipment or utensils used for cleaning activities, must be suitable for the purpose for which it is intended and capable of achieving the desired level of cleaning. For example, equipment would not be suitable if it: • had the potential to shed fibres • was not hygienically designed (to facilitate easy cleaning after use). Equipment must be clearly identified at all times (by colour-coding and/or labelling). This is necessary to ensure that different types of equipment are clearly distinguishable (e.g. floor-cleaning equipment must be distinguishable from items designated for cleaning production equipment). It must also be stored hygienically and in a manner that prevents contamination (e.g. stored in designated locations and not in contact with the floor). The operation of tray/rack washes to ensure that they operate effectively should also be considered; for example, checks could include the visual inspection of cleaned trays, monitoring water temperature or the chemical concentration of detergent, or microbiological swabbing.

4.11.7 Cleaning in place (CIP)

Interpretation

CIP is a method of cleaning the interior surfaces of pipes, vessels, process equipment, filters and associated fittings without disassembly.

There are various designs of CIP system, but they are often categorised as either of the following:

- single-use systems – where the CIP rinse solution is used and replaced with fresh solution
- re-use systems – the rinse solution is used and collected so that it can be re-used multiple times.

Additionally, the system may be fully automated or semi-automated.

CIP equipment is specialist, and therefore operator training is important. See section 7.1 for information on training.

Clause	Requirements
4.11.7.1	All CIP equipment shall be designed and constructed to ensure effective operation. This shall include: • validation confirming the correct design and operation of the system • an up-to-date schematic diagram of the layout of the CIP system • where rinse solutions are recovered and re-used, an assessment of the risk of cross-contamination (e.g. due to the re-introduction of an allergen or the existence of different production risk zones within the site). Alterations or additions to the CIP system shall be authorised by a suitably competent individual before changes are made. A record of changes shall be maintained. The system shall be revalidated at a frequency based on risk, and following any alteration or addition.

Interpretation

Effective operation, maintenance and validation of CIP systems

Effective CIP starts with the design (e.g. designed by an approved equipment supplier – see section 4.6 for information regarding new equipment) and set-up of the system. The site will therefore need validation to confirm that the design, set-up and proposed operation of the system are suitable for the intended use. For example:

- knowledge of the layout of the pipework and the position of valves, spray balls and holding tanks is essential to ensure that the system will operate consistently and effectively and that there are no dead spots or areas where cross-contamination between cleaning chemicals and product can occur
- correct design of the CIP system to ensure good coverage of cleaning solutions with suitable drainage to avoid pools of solutions; for example, the prevention of shadows caused by baffles or spray balls that have been incorrectly located
- assurance that the intended cleaning will be effective (e.g. that the food/products intended to be used on the equipment will be effectively removed during cleaning)
- consideration of the risk of potential contaminants (e.g. allergens) from previous products being re-introduced onto the equipment during the collection, recycling or re-use of solutions (e.g. rinse solutions). Where rinse solutions are recovered and re-used, there should be a specific risk assessment to prevent cross-contamination; for example, due to allergens or the existence of different production risk zones in the site. See clause 8.5.4 for the specific requirements for CIP systems operating in multiple production risk zones (e.g. high-risk and high-care areas). Confirmation of the correct design and set-up may be achieved by an inspection report (e.g. from the equipment manufacturer) or by separate documented validation.

A schematic plan or diagram should be provided by the supplier when the system is installed and must be updated whenever a change is made, including to software, equipment and operation of the system.

Clause	Requirements
Interpretation *continued*	Issues are most likely to occur where CIP systems are modified or extended. Therefore, controls must be in place to ensure that all changes (e.g. engineering modifications, changes to the programming or operation of the system, and changes to consumables such as the detergents used) are made only by a suitably trained and competent individual. This could be achieved by, for example: • having a company policy that permits modifications only by the manufacturer of the equipment • training engineering staff • password-protecting the system with different levels of access to prevent unauthorised modifications to programme parameters or software. Records of changes must be maintained. The site should use risk assessment to determine suitable intervals for revalidation of the CIP system to ensure its continuing effectiveness. The CIP system will also require revalidation following any alterations or additions to ensure it continues to operate as expected.
4.11.7.2	Limits of acceptable and unacceptable performance for key process parameters shall be defined to ensure the removal of target hazards (e.g. soil, allergens, micro-organisms, spores). At a minimum these parameters shall include: • times for each stage • detergent concentrations • flow rate and pressure • temperatures. These shall be validated and records of the validation maintained.
Interpretation	**Operation of CIP equipment** The CIP process parameters and tolerances must be identified and limits of acceptable and unacceptable performance set, e.g. detergent concentrations and limits on permitted carry-over into post-rinse solutions. The actual values of acceptable and unacceptable performance will depend on the target hazards that the CIP cleaning is intended to remove and this in turn will depend on the product types being processed. Specific hazards may include, for example, soil, allergens and/or vegetative micro-organisms. The Standard identifies minimum key parameters that need to be defined, and their limits must be validated to confirm effective removal of the identified hazards.
4.11.7.3	The CIP equipment shall be maintained by suitably trained staff to ensure effective cleaning is carried out. This shall include: • routine checking of detergent concentrations • monitoring of recovered post-rinse solutions for build-up of carry-over from the detergent tanks • cleaning and inspection of filters, where fitted, at a defined frequency • storing flexible hoses (where used) hygienically when not in use, and inspecting them at a defined frequency to ensure that they are in good condition.

Clause	Requirements
Interpretation	**Maintenance of the CIP system** A planned maintenance programme must be in place to ensure all aspects of the CIP system are in good working order. At a minimum, this should include: • monitoring detergent concentrations and post-rinse solutions • inspection, cleaning and storage of filters and flexible hoses where they are part of the CIP system. The frequency of maintaining the different aspects of the programme should be based on risk. For example, good practice normally includes ensuring detergent tanks are drained, cleaned and filled, with a log of these activities to confirm that they have been completed to schedule. Monitoring and inspection may be undertaken by trained site staff (e.g. engineers) or carried out as part of a service agreement with the supplier or with the service company maintaining the system. A report of the inspection (that includes an overview of the scope of the inspection, any recommendations for improvement, and confirmation or otherwise of the effectiveness of the system) should be kept.
4.11.7.4	CIP facilities, where used, shall be monitored at a defined frequency based on risk. This may include: • monitoring of process parameters defined in clause 4.11.7.2 • ensuring correct connections, piping and settings are in place • confirming the process is operating correctly (e.g. valves are opening/closing sequentially, spray balls are operating correctly) • ensuring effective completion of the cleaning cycle • monitoring for effective results, including draining where required. Procedures shall define the action to be taken if monitoring indicates that processing is outside the defined limits.
Interpretation	**Monitoring of CIP** To ensure the ongoing effectiveness of the CIP system, it is important to routinely monitor the operation of the system at a predefined frequency. This will include checks of connections, piping and settings prior to starting the cleaning process and a post-cleaning confirmation of effective cleaning. The frequency of monitoring should be based on risk and outlined in the procedures. This will include the actions necessary if monitoring indicates a result is outside of the defined limits. (Further details on corrective action procedures are in section 3.7).

4.11.8 Environmental monitoring

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

Interpretation

The aim of the environmental monitoring programme is to develop a proactive, preventive monitoring programme that will identify and eliminate sources of environmental micro-organisms (e.g. pathogens and spoilage organisms) in production and open product areas of the site, and facilitate timely and effective corrective action in the event of a risk being identified (i.e. prevent the environmental micro-organisms from becoming the source of product contamination which could lead to non-conforming product, a customer complaint or other incidents).

An effective programme can, for example, be used to:

- confirm the effectiveness of cleaning and hygiene activities and identify any areas that require further activity
- prevent product contamination by acting as an 'early warning' – identifying potential contamination from the site facilities before they affect products.

The design and structure of this programme will depend on the nature of the products being handled and the potential hazards associated with them.

The requirements are expected to apply to all sites with:

- open product areas
- ready-to-eat products
- products that are both processed in open product areas and ready-to-eat.

Sites are not expected to 'opt out' of this requirement by determining that they have a low-risk product or environment; completion of a risk assessment (clause 4.11.8.1) should only be used to identify relevant hazards, suitable monitoring techniques and appropriate monitoring frequencies.

There are, however, a small number of products which are inherently safe from these contaminants (e.g. because the product's intrinsic properties do not support the growth or survival of pathogens or spoilage organisms) and there is no opportunity for spoilage/pathogen contamination, and therefore an environmental monitoring programme may not be required. Where a site believes that this is not required, this belief must have a strong foundation in science and not be used to prevent good practices. Therefore it is expected that:

- all sites with high-risk, high-care or ambient high-care operations will have an environmental monitoring programme within the relevant open product areas
- environmental monitoring will be applicable to other products, as there have been a number of very high-profile food poisoning outbreaks associated with products not conventionally considered as high risk or high care (for example, cantaloupe melons, peanut butter, chocolate and milk powder), where environmental monitoring may have been effective in identifying an issue early. Similarly, shelf-life issues such as mould contamination of bakery products may be reduced by suitable monitoring.

Where a site believes environmental monitoring is not required due to the absence of risk from pathogens and spoilage organisms, the site must prove this absence of risk. As a minimum, the site will have a robust risk assessment which considers:

- both spoilage organisms and pathogens
- the complete product range at the site.

Note that this risk assessment must be more than a history of product testing – it must demonstrate an absence of risk. Suitable techniques include pathogen modelling, challenge testing and published literature from a reputable source demonstrating that pathogens cannot survive or grow.

Examples of products where risk assessment may establish that environmental monitoring is not required include:

- alcoholic beverages and vinegars with a sufficiently high level of alcohol or acid to prevent survival and growth
- salt and sugar in their dry 'pure' form
- edible oils with no added ingredients
- fully enclosed production. For example, at a specialist HPP (high-pressure processing) facility, where product is received packed, is processed in its packaging and leaves the site in the same packaging
- whole vegetables, sold unwashed.

Auditors will challenge the basis of any risk assessment to make sure this has properly considered likely issues and is demonstrably based on robust science.

The requirements for environmental monitoring indicate that the site's environmental monitoring programme must be risk-based, therefore the food safety plan/HACCP may indicate risks that should be monitored. Risks may include pathogens and/or spoilage organisms (such as yeasts or moulds), and the site should consider whether it is more suitable to monitor the risk directly or via indicator organisms. Well-known examples of pathogens and spoilage organisms that may be applicable to a site's environmental monitoring include:

- *Listeria monocytogenes* in ready-to-eat products, including those which are chilled and frozen. Alternatively, some sites monitor *Listeria* spp. and only examine the species if adverse positive results are obtained
- *Salmonella* and/or Enterobacteriaceae in dry environments where susceptible products are handled
- yeasts and/or moulds: these are widespread spoilage organisms which may be of greater relevance for some product types. For example, products such as jam are heated to a temperature that will kill many bacterial contaminants, are hot-filled, and have a low water activity and low oxygen content. Consequently, the risk of pathogen growth is limited. However, there are yeasts and moulds that can cause spoilage in these conditions, and therefore manufacturers must ensure that packaging, food contact surfaces and the environment are monitored to minimise the risk of contamination.

Clause	Requirements
4.11.8.1	The design of the environmental monitoring programme shall be based on risk, and at a minimum include: • sampling procedures • identification of sample locations • frequency of tests • target organism(s) (e.g. pathogens, spoilage organisms and/or indicator organisms) • test methods (e.g. settle plates, rapid testing and swabs) • recording and evaluation of results. The programme and its associated procedures shall be documented.
Interpretation	**Risk-based environmental monitoring programme** The programme must be based on risk assessment. At a minimum this will include: • a sampling procedure. It is important to ensure that the sampling method does not inadvertently create false positives (e.g. by allowing post-sampling contamination or growth of organisms) or false negatives (e.g. by killing organisms in the sample before the test is completed). Sampling must be appropriate for the target organisms, test

Clause	Requirements

Interpretation *continued*	methods and locations sampled; techniques may include swabs, air sampling, water/liquid samples etc. The timing and intended purpose of the sampling are also important; for example, cleaning validation, or monitoring of the spread of an organism from a potential harbourage area
	• identification of suitable test locations, taking into account:
	  • significance of the area or equipment in terms of the potential to affect food safety; for example, food contact surfaces, non-food contact areas which are in close proximity to open products, and non-food contact areas some distance away from open products (e.g. floors, walls and drains)
	  • areas or parts of equipment that are difficult to clean and could harbour pathogens
	  • areas of the site or equipment which previously tested positive
	  • areas where scientific literature has identified a specific risk (e.g. drains)
	• frequency of tests, taking into account:
	  • products that support the growth of pathogens. These require a greater frequency of testing than those that do not support growth
	  • locations with previous positive results or an upward trend towards an action level (clause 4.11.8.2). These are likely to require increased testing to confirm the effectiveness of the action taken
	• target organisms. These may include specific pathogens that present a risk to the product or environment (e.g. *Listeria* spp in wet environments or Enterobacteriaceae in dry environments), specific spoilage organisms (e.g. yeast or mould) or hygiene indicator organisms (e.g. total plate count, total coliforms)
	• test methods. Rapid on-site and laboratory tests are available, and sites should consider the requirements of section 5.6 when deciding which methods and/or laboratories to use. Where knowledge is not available on site, the site may need to obtain guidance; for example, from an accredited laboratory
	• recording and evaluation of results. The significance of the results and any actions required must be considered (clause 4.11.8.2)
	• reviews of any legal requirements in the country or region (e.g. relating to types of products, organisms of concern, or frequency or minimum number of tests). The auditor will expect to see the risk assessment and the subsequent plan along with testing protocols, procedures and evidence that the site is completing the plan to schedule.
	
	A number of organisations have published guidelines for the development of environmental monitoring programmes, including, for example, the Codex Alimentarius 'Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods' (CXG 61-2007) – Annex 1.

4.11.8.2	Appropriate control or action limits shall be defined for the environmental monitoring programme. The company shall document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate an upward trend of positive results (i.e. a trend towards a control or action limit).
Interpretation	**Control or action limits** The site will need to establish appropriate control or action limits and the actions to be taken if these are exceeded or when there is a trend towards increasingly positive results. The control limits and actions may be based on:

Clause	Requirements
Interpretation *continued*	• the organism measured, its level and the location of the positive result • when the testing was completed (e.g. was the sample taken pre- or post-cleaning?) • any legal or customer limits. In addition, many sites have found it useful to: • identify a warning limit (i.e. a limit at a level which is not an exceedance of an action or critical limit, but which allows investigation prior to any exceedance occurring) • use root cause analysis to establish preventive action (e.g. in the case of recurrence of pathogens at a set location).
4.11.8.3	The company shall review the environmental monitoring programme at least annually and whenever there are: • changes in processing conditions, process flow or equipment which could impact the environmental monitoring programme • new developments in scientific information (e.g. new pathogens of concern) • failures of the programme to identify a significant issue (e.g. regulatory authority tests identifying positive results which the site programme did not) • product failures (products with positive tests) • consistently negative results (e.g. a site with a long history of negative results should review its programme to consider whether the correct parts of the factory are being tested, whether the testing is being conducted correctly, whether the tests are for the appropriate organisms, etc.).
Interpretation	**Review of the environmental monitoring programme** The review of the programme could be accomplished as part of the HACCP review or as a separate review process. The Standard lists several points which might prompt a review, including: • changes in processing, as these could, for example, affect the ease of cleaning or susceptibility of products to contamination and therefore impact the environmental monitoring programme. For example, any changes to the cleaning procedures, including changes in cleaning frequency, cleaning chemicals or cleaning equipment used, may impact the cleanliness of equipment and facilities, and should therefore be considered as part of a review of the environmental monitoring procedures • publication of new scientific information, such as the identification of a micro-organism not previously associated with a specific product type, information relating to the survival of a pathogen in specific environmental conditions, or any new information on new and emerging pathogens • when independent testing (e.g. by a regulatory authority) identifies positives not previously identified by the site's own tests • when a positive test on a product implicates the effectiveness of the environmental monitoring programme; note that not all product failures indicate a failure in the effectiveness of the programme, but the site's root cause analysis and corrective action (see section 3.7) should identify those where the environmental monitoring programme should be reviewed.

Clause	Requirements
Interpretation *continued*	• In most situations, negative results are seen as good news and lead to an assumption that all systems are operating correctly and within permitted parameters. However, if results are continuously and consistently negative and there is a long history of negative results, this may be indicative that the site should review its programme to consider whether the correct locations are being tested, in the correct way, for the correct organisms. The aim of the programme is, after all, to identify areas of concern.

4.12 Waste and waste disposal

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

Interpretation

Waste disposal systems (for example, in production and storage areas, as well as in waste collection areas or rooms) must ensure that the risk of contamination to products is minimised through the control of cross-contamination, prevention of unnecessary waste accumulation, and control of pests. Disposal must comply with legal requirements.

Good practice should ensure that containers used for either raw material storage or handling, or for finished product storage, are not used for collecting waste. Instead, waste must be collected in appropriate, designated waste containers.

Clause	Requirements
4.12.1	Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and records of removal shall be maintained and available for audit.
Interpretation	**Licensing and legislation** Waste contractors must be appropriately licensed and/or approved where this is required by local law. Where legislation exists for specific waste streams (e.g. disposal of meat products), this must be complied with; such legislation may include requirements for segregation of waste or specific methods of disposal. Records of removal must be maintained and available for audit.
4.12.2	Internal and external waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: • clearly identified • designed for ease of use and effective cleaning • well maintained to allow cleaning and, where required, disinfection • emptied at appropriate frequencies. External waste containers shall be covered or doors kept closed as appropriate.

Clause	Requirements
Interpretation	**Waste storage** Waste collection containers and rooms housing waste facilities must be managed to minimise the risk of contamination of products. Particular consideration must be given to: • identification of waste containers and storage areas to ensure waste is collected only in designated containers/areas • ease and effectiveness of cleaning (see section 4.11) • keeping facilities well maintained • emptying at appropriate frequencies • keeping external waste containers covered or room doors closed, thus ensuring that waste cannot fall out of containers or stray out of designated rooms to cause a contamination risk • the pest control implications of external waste collection areas.
4.12.3	Waste removal from open product areas shall be managed to ensure that it does not compromise product safety.
Interpretation	**Removal of waste from open product areas** Waste should be removed from open product areas to minimise the risk of product contamination (for example, from allergens, pathogens, taint, non-compliance with claims). A number of considerations may be needed when planning waste handling, including: • risk assessment – to identify the risks associated with specific products or production areas • process flow – for example, the movement of product, waste and staff • identification of suitable equipment – for example, are lidded or sealed containers needed; are there different types of waste that need to be segregated or handled differently? • scheduling of waste removal – for example, how frequently is waste removed; is removal completed during or after the production run?
4.12.4	If unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in secure product or waste disposal and shall provide records which include the quantity of waste collected for destruction or disposal.
Interpretation	**Unsafe and trademarked waste** Requirements for the disposal of trademarked waste must be defined within a contract with the waste disposal contractor. Records of destruction or disposal must be maintained. The objective is to ensure that waste products do not re-enter the food supply chain once sent for disposal. If unsafe products are transferred to a third party for destruction, the third party must be a specialist in secure product or waste disposal and must provide records which include the quantity of waste collected.

4.13 Management of surplus food and products for animal feed

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

Interpretation

All products intended for the human food chain must not be injurious to health, and must be fit for human consumption. Therefore the site's procedures to control the handling and storage of surplus food and by-products must ensure that safety and legality are maintained.

Similarly, by-products or other materials intended for animal feed must meet the relevant requirements for safety and legality pertaining to those supply chains.

Clause	Requirements
4.13.1	Surplus customer-branded products shall be disposed of in accordance with customer-specific requirements. Customer brand names shall be removed from packed surplus products under the control of the factory before the product enters the supply chain, unless otherwise authorised by the customer.
Interpretation	**Surplus customer-branded products** This clause covers the situation where surplus product is not required by the intended customer (e.g. because of a fall in predicted orders), but is still suitable for sale to alternative customers. It does not include sales to staff or donations to charity, which are covered separately in clause 4.13.2. The release of surplus product to alternative customers must only take place in accordance with the original brand owner's specific requirements. For example, in many cases the product packaging (or associated documentation) will refer to the brand owner and these brand names will need to be removed before the product leaves the site.
4.13.2	Where customer-branded products which do not meet specifications are sold to staff or passed on to charities or other organisations, this shall be with the prior consent of the brand owner. Processes shall be in place to ensure that all products (own-branded and customer-branded) which are sold to staff or passed on to charities or other organisations are fit for consumption and meet legal requirements, and that their traceability is maintained.
Interpretation	**Staff shops and donations of products to charity** Many companies sell products to staff or donate them to charity when they are not required by the intended customer (e.g. because of a fall in predicted orders, minor cosmetic damage to packaging, or failure to meet the brand owner's specification). In many cases the product packaging (or associated documentation) will refer to the brand owner and therefore release to charity or staff must only take place with the prior consent of the brand owner. It is not necessary for the site to obtain this consent for each individual batch of product or on each occasion that the product is sent to a charity; however, the brand owner's policy or permission must be defined (e.g. in a policy document or within the company's contract).

Clause	Requirements
Interpretation *continued*	All products (customer-branded and own brand) must still be safe, be legal (e.g. meet legal requirements for labelling), maintain traceability and be fit for consumption; therefore the site should have documented procedures which detail the product assessment and release process. Staff responsibilities, including which staff have authorisation to release products for staff sale or charitable donation, should also be made clear.
4.13.3	By-products and downgraded/surplus products intended for animal feed shall be segregated from waste and protected from contamination during storage. Products for animal feed shall be managed in accordance with the relevant legislative requirements.
Interpretation	**Food for animal feed** In many parts of the world, there are specific regulations relating to the suitability of products and by-products for inclusion in animal feed (e.g. EU legislation on animal by-products and the control of transmissible spongiform encephalopathies). It is essential that, where products and by-products are supplied for animal feed, the site is aware of, and complies with, the relevant legislation. There are several recognised feed schemes and, where applicable, certification to such a scheme may be required. The animal feed contractor must also be appropriately licensed. Materials for inclusion in animal feed must be segregated from other waste streams and managed to prevent contamination, and should be labelled accordingly.

4.14 Pest management

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

Pest management programmes shall comply with all applicable legislation.

Interpretation

Management of pests must be undertaken at a level commensurate with the needs of the whole site, including temporary or seasonal facilities and all storage units, based on the:

- nature of identified potential pests, including rodents, insects and birds
- characteristics of raw materials (regarding their potential for stored insect pests)
- equipment
- finished products
- process
- site and environment (e.g. prevention of ingress and the removal of potential pest harbourage)
- potential for future pest risks
- legal requirements in the country or region where the site is located.

Where instances of pest ingress (i.e. single occasion or low numbers) occur, these need to be appropriately investigated and actioned but must not be deemed as loss of control. However, where there is pest presence (i.e. evidence of large numbers of pests breeding within the building or site over a period of time), this must be regarded as loss of control and a lack of maintenance of the pest management programme, and will lead to a major non-conformity being awarded.

Where a site uses pest management contractors or suppliers, the relevant clauses from sections 3.5.3, 4.1 and 7.1 apply.

BRCGS publishes a separate best-practice guideline on pest management, which may be purchased from the **BRCGS Store** or viewed online at **BRCGS Participate**.

Clause	Requirements
4.14.1	If pest activity is identified, it shall not present a risk of contamination to products, raw materials or packaging. The presence of any infestation on site shall be documented in pest management records and be part of an effective pest management programme to eliminate or manage the infestation so that it does not present a risk to products, raw materials or packaging.
Interpretation	**Pests present on site** Where pest activity is identified (for example, during site inspections (clauses 4.14.2 and 4.14.10) or reported by staff (clause 4.14.12)), actions must be taken to ensure the risk of contamination of products, raw materials or packaging is avoided. The site will therefore need to record and assess any reported pest activity in a timely manner to ensure appropriate action can be taken. This may include action by the site (e.g. isolation of at-risk product) or by its approved pest management contractor (clause 4.14.2). Where an infestation occurs, this must be clearly documented and effectively managed (clause 4.14.8). Any products, raw materials or packaging implicated by pest activity should be subject to the site's non-conforming product processes (see section 3.8).
4.14.2	The site shall either contract the services of a competent pest management organisation or have appropriately trained staff for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. The risk assessment shall be reviewed whenever: • there are changes to the building or production processes which could have an impact on the pest management programme • there has been a significant pest issue. Where the services of a pest management contractor are employed, the service scope shall be clearly defined and reflect the activities of the site. Service provision, regardless of the source, shall meet with all applicable regulatory requirements.
Interpretation	**Pest management system** There must be regular inspection and, where appropriate, treatment of the site to deter and eradicate infestation. The frequency of inspection and treatment of the premises must be based on the product risk, including the age, design and location of the buildings and equipment.

Clause	Requirements
Interpretation *continued*	Pest management is often contracted to external companies, which may need to be licensed or approved by local or national authorities. The contractor must demonstrate competence (evidence could, for example, include membership of a national trade association, training records, licence or CEPA certification to EN 16636 for pest management services). Section 3.5.3 also applies to the management of the pest management services. All pest management activity must be in accordance with legislative requirements. For example, in some countries you must have a licence to purchase and use certain chemicals (e.g. rodenticides in the EU). The scope of the service must be clearly defined (e.g. in a contract) and should include provision for additional treatments where required to eradicate any infestation that may occur. Where pest management is handled in-house, responsible employees must have appropriate training, as evidenced by training records (clause 4.14.3). A review of the system should be made when changes to the site or processes occur, but where no changes have been made, an annual review is also good practice. The auditor will expect to see that the frequency of inspections is appropriate to the nature of the site, and takes into account any infestation or issues with pests which have been highlighted by monitoring activity. Where automated monitoring or inspection is in place, it can affect the frequency of inspections (e.g. online monitoring devices can report to the site and contractor, allowing the contractor to advise whether a callout or other action is required). It is not a replacement for site visits but can lead to more focused visits that are not just bait-point checking. Pest management services must meet all legal and regulatory requirements of the country where the site is located. Consideration may be required if the site exports to countries with differing legislative requirements.
4.14.3	Where a site undertakes its own pest management, it shall be able to effectively demonstrate that: • pest management operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • staff undertaking pest management activities meet any legal requirements for training or registration • sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood and complied with • dedicated locked facilities are used for the storage of pesticides.
Interpretation	**In-house pest management** With regard to the need for pest management to be undertaken by trained staff, the auditor will check the appropriate training records for proof of adequate training. Suitable training would be expected to cover all relevant activities that the staff member is responsible for, including, for example, legislation, pest management techniques, correct use of monitoring and control devices, or permitted baits.

Clause	Requirements
Interpretation *continued*	Access to specialist technical knowledge can be obtained by engaging the services of an external contractor or via trade association membership. In some geographic regions legislation governing the use of pest control products is updated frequently and the appointed staff will need to keep abreast of any changes.
4.14.4	Pest management documentation and records shall be maintained. At a minimum, this shall include: • an up-to-date plan of the full site, identifying pest control devices and their locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for the site management and the contractor • details of pest control products used, including instructions for their effective use and action to be taken in the event of an emergency • any observed pest activity • details of pest control treatments undertaken. Records may be on paper (hard copy) or controlled on an electronic system (e.g. an online reporting system).
Interpretation	**Pest management documentation and records** Written procedures and inspection documentation must be maintained. These must include: • an up-to-date site plan identifying the locations of pest monitoring and control devices. This plan should be reviewed periodically, for instance annually or when there are site changes • identification (e.g. a numbered list) of the types of bait and monitoring devices on site • clearly defined responsibilities for site management and the contractor. This should include methods of communication, contact details for the nominated site and contractor personnel, and dates for when review meetings will take place • details of the pest control products used and instructions for their safe and effective use • records of any pest activity observed • details of pest control activities undertaken. All pest management inspections must be recorded, even when there are only negative findings to report. This is important for due diligence: in the event of an incident, these records can confirm when the site or area was last inspected and confirmed as satisfactory, and demonstrate this to regulatory authorities and customers. Records can be in any format as long as they are accessible by the site. For example, during an audit the auditor may review paper-based pest management records or, where records are online, ask the site to access the records and demonstrate use of the online system.
4.14.5	Bait stations or other rodent monitoring or control devices shall be appropriately located and maintained to prevent contamination risk to product. Toxic rodent baits shall not be used within production or storage areas where open product is present except when treating an active infestation. Where toxic baits are used, these shall be secured. Any missing bait stations shall be recorded, reviewed and investigated.

Clause	Requirements
Interpretation	**Bait stations** Bait stations and other rodent monitoring or control devices must be appropriately designed, located and maintained to limit the potential for contamination of products. This can be achieved by: • making them tamper-resistant • securing them in place or locating them in positions where accidental movement is unlikely • using non-spill formulations • inspecting them routinely at a frequency based on risk assessment or local legislation (this is particularly important for areas where live catch, break-back traps or spring-powered traps are permitted because of the potential for secondary pests, if the caught pests are not removed sufficiently quickly). The pest management specialist should advise on the quantity and siting of the monitoring devices; their locations might be risk-based rather than evenly distributed. When an active infestation is being treated, the location of additional monitoring or control devices should be considered. Rodent bait is generally toxic, so must be controlled to avoid contamination of product. Toxic rodent bait must not be used within production or storage areas where open product is present, except when treating an active infestation. Where this occurs, the bait must be secured to ensure product cannot be contaminated. Any missing bait stations or missing rodent control devices should be recorded and investigated. Additional action may be required depending on the reason for the absent bait station; for example, to ensure that there is no risk to product and that any pest activity has been appropriately managed.
4.14.6	Insect-killing devices, pheromone traps and/or other insect-monitoring devices shall be appropriately sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used.
Interpretation	**Insect-killing devices** Where insect-killing devices, pheromone traps or other insect-monitoring devices are used, they must be correctly sited and operational. If insects could be expelled from an insect-killing device and contaminate the product, alternative systems and equipment must be used (e.g. those based on sticky-board technology) or the devices must be moved to a more appropriate position. Equipment must be fully operational. For example, bulbs on insect-killing devices must be changed at regular intervals (in accordance with the manufacturer's instructions) to maintain optimal luminosity performance (there is no minimum frequency for changing the bulbs, as this will depend on a number of factors, including the brand of bulb used), and pheromone traps must be replenished quarterly or in accordance with the manufacturer's instructions. Documentation must provide evidence of this maintenance.
4.14.7	The site shall have adequate measures in place to prevent birds from entering buildings or roosting above loading or unloading areas.

Clause	Requirements
Interpretation	**Birds** The site (or its pest management contractor) should use a risk assessment approach to establish whether there is any potential for the ingress of birds, or for roosting and nesting at loading or unloading areas, and to assess the measures required to mitigate the risk. The expectation here is not necessarily to rebuild or reconfigure facilities; instead, the intention is to recognise any potential problems and take steps to remove or mitigate these risks from birds roosting and nesting.
4.14.8	In the event of infestation, or evidence of pest activity, immediate action shall be taken to identify at-risk products and to minimise the risk of product contamination. Any potentially affected products should be subject to the non-conforming product procedure.
Interpretation	**Infestation and evidence of pest activity** In the event of infestation (clause 4.14.1), immediate action must be taken to eliminate the hazard. This will include identifying and quarantining any potentially affected product so that it can be evaluated in accordance with the site's non-conforming product procedures. Action may also include steps to protect other products, and inspection by the pest management specialist. Any such infestation and corrective actions taken must be recorded; see section 3.8 for the non-conforming product procedure.
4.14.9	Records of pest management inspections, pest proofing and hygiene recommendations and actions taken shall be maintained. It shall be the responsibility of the site to ensure that all of the relevant recommendations made by its contractor or in-house expert are carried out in a timely manner.
Interpretation	**Records of pest management inspections** Records of pest management will include any recommendations made by the pest management specialist (e.g. changes to inspection frequency or pest proofing). It is the responsibility of the company to ensure that all relevant recommendations made by the pest management specialist are carried out within a suitable timescale and verified for effectiveness. Records of these changes must be maintained.
4.14.10	An in-depth, documented pest management assessment shall be undertaken at a frequency based on risk, but at least annually, by a pest management expert to review the pest management measures in place. The assessment shall: • include an in-depth inspection of the site, equipment and facilities for pest activity • review the existing pest management measures in place and make any recommendations for change. The assessment shall be timed to allow access to equipment for inspection where a risk of stored product insect infestation exists.

Clause	Requirements
Interpretation	**Pest management assessment** In-depth pest management assessments are in addition to the regular inspections (e.g. monthly checks of bait and traps) conducted as part of the pest management programme (clause 4.14.2). The aim of these assessments is to: • ensure an in-depth inspection of the site, equipment and facilities for evidence of pest activity and to determine the current levels of pest activity throughout the site. This should not be a matter of mere bait checking, but should include an audit of the whole of the site, especially in less accessible areas such as voids and cable runs, stores and silos (see below), where established pests are less easy to detect • review existing measures to provide a critical appraisal of the site's pest management activities to ensure they remain appropriate • where appropriate, liaise with the technician who completes the routine pest management activities, to agree changes to the pest management programme • review pest management-related records • suggest alternative approaches to resolving problems • liaise with senior site or group management. Where insects in stored product represent a potential hazard, the visits should be scheduled for a time when access to equipment for inspection purposes is available, so that the greatest value can be gained from the survey. Where pest activity is seasonal in nature, the survey may be timed to coincide with the period of greatest risk. The assessment will be completed by a pest management expert (e.g. the pest management contractor's field biologist or a senior technician with a qualification in pest management and many years of experience). Many countries have formal qualifications for those working in pest management; for example, by operating a legally backed licensing system. Anyone working as a field biologist should at least have a recognised basic pest management qualification, available in the country concerned, irrespective of whether it is a legal requirement. Few countries have formal higher-level pest management qualifications. However, a field biologist should be a senior, competent technician with a number of years of practical pest management experience. Other desirable qualifications, knowledge and skills may include: • possession of a recognised food safety qualification. Field biologists work closely with food, so should be trained to at least the same level as a food-handling employee • membership of a relevant continuing professional development (CPD) scheme, if such a scheme exists in the country of operation. At the very least, they should be able to demonstrate that they keep up to date with technical and regulatory developments in pest management • knowledge of the scope and content of the food industry standards the site is working to. For example, do they understand the requirements of the Standard and whether the site has to meet any customer-specific requirements? • knowledge and understanding of the food manufacturing processes operating at the site, particularly when commodities vulnerable to infestation by stored-product insects are being handled or processed • how to use pest monitoring data to effectively target and measure the success of control measures. For example, using monitoring data to generate trend analyses (as opposed to just counts) is key.

Clause	Requirements
Interpretation *continued*	This highlights an important difference between the in-depth audit and the practical, routine pest management service completed by the pest management technician. It is not simply a second tier of inspection, adding complexity and costs to the contract. The pest management field biologist is on hand to lead the pest management programme, and should use the in-depth audit to guide the efforts of both site personnel and the pest management technician to eliminate problems and maintain pest-free conditions. In pest management terms, the field biologist is the most important person working on behalf of the pest management contractor in any food site. It is therefore important that the site is satisfied that this expert is fully competent and has sufficient knowledge and experience to conduct the audit and produce meaningful results. Good practice is to separate the in-depth audit and routine inspections, rather than complete them at the same time. It is also often useful for the in-depth assessment to be conducted by an alternative consultant rather than the staff responsible for the regular inspections, as this has the benefit of a second expert examining the site and the current pest management programme. It is expected that the audits will be completed at least annually; however, risk assessment may indicate that a different frequency is required (e.g. where pest issues are seasonal in nature then the frequency may need to increase). The BRCGS auditor will expect to see the risk assessment that the site has used to determine the appropriate frequency. The results of the surveys should be incorporated into the company management review (clause 1.1.4). This clause applies to all sites, not just those carrying out their own pest management. BRCGS has produced a separate best-practice guideline to pest management which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.
Further guidance	**In-depth report format and content** The Standard does not prescribe the format of the report, and each pest management specialist is likely to have their own preferred format. However, it is the content and not the format that is all-important. As a minimum, the report should include: *Areas inspected* The audit report should include reference to the areas inspected, even where no problems have been found. A list of issues requiring attention without any additional detail is unlikely to provide the depth of information that the site requires to improve. If an area has been inspected and found clear, it is important that this is recorded: it is the contractor's evidence that the area has been inspected, and the food manufacturer's evidence that there are no problems there. *Any problems* Problems relating to, for example, sanitation and building fabrication should be highlighted. These observations should have as their objective either the eradication of an existing infestation, or the prevention of a new one. Where it is not immediately obvious, the reasons why the observation points to a problem should also be stated, and practical and appropriate recommendations should be made to address these matters.

Clause	Requirements
Further guidance *continued*	*Current system review* There should be a review of whether the pest management system is suitable; and, if it is found to be inadequate or inappropriate, recommendations should be made regarding alternative proactive pest management practices and strategies. Some pest contractors include useful information in addition to the on-site audit; for example, a summary of the pest inspections and trend analysis, as discussed in clause 4.14.11. This is acceptable; however, note that this information cannot form a substitute for an on-site visit, or for the audit described above.
4.14.11	Results of pest management inspections shall be assessed and analysed for trends on a regular basis. At a minimum, results of inspections shall be analysed: • annually **or** • in the event of an infestation. The analysis shall include results from trapping and monitoring devices to identify problem areas. The analysis shall be used as a basis for improving the pest management procedures.
Interpretation	**Periodic assessment and trend analysis** There must be a periodic assessment of pest management inspection results and trends. The review will consider: • pest control measures • bait takes • analysis from trapping and monitoring devices • identification of any trends • action taken • recommendations for changes or improvement. At a minimum, this periodic assessment must be conducted annually (or sooner in the event of an infestation).
4.14.12	Staff shall understand the signs of pest activity and be aware of the need to report any evidence of such activity to a designated manager.
Interpretation	**Reporting of pest activity** Any member of staff on the site should be trained to recognise pest activity in production or storage areas, and this can form part of the site's induction and refresher training programme. The content might address typical pests, different types of evidence of pest activity, and the food safety implications. Subsequently, any pest activity witnessed by any member of staff needs to be reported to the designated person. The identification of the designated person and the process by which information should be reported also need to be communicated to the staff. The designated person will need to record the evidence and assess whether additional action is required.

4.15 Storage facilities

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

Interpretation

The site's procedures for storage must be controlled to ensure they do not pose a risk to products. This includes all raw materials and packaging, intermediates and finished products. Storage facilities must be suitable for all products stored and take into consideration the requirements for specific products; for example:

- the temperature at which the product must be stored
- allergen management
- segregation, where required; for example, food and non-food storage.

Clause	Requirements
4.15.1	Procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment, understood by relevant staff and implemented accordingly. These may include, as appropriate: • managing chilled and frozen product transfer between temperature-controlled areas • segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake • storing materials off the floor and away from walls • specific handling or stacking requirements to prevent product damage.
Interpretation	**Documented storage procedures** The company must consider the potential risks to product safety and quality that may develop during storage. For example, if a product is temperature-controlled, the specified temperature must be maintained throughout the storage of the product. In addition to the points listed in the requirement, the company should also maintain the cleanliness of the storage areas (e.g. with appropriate cleaning procedures and identified frequencies, as evidenced by documented records), in accordance with the requirements in section 4.11.
4.15.2	Where appropriate, packaging shall be stored away from other raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified to maintain traceability before being returned to an appropriate storage area.
Interpretation	**Storage of packaging** In order to avoid product contamination risks from packaging (such as glass) or contamination of unused packaging by-products, packaging should be stored away from raw materials and finished product. This may be achieved by use of a dedicated packaging store or a dedicated area of a raw material store. Only packaging required for immediate use should be stored in the actual packing area (clause 6.2.1). The storage of packaging outside is acceptable only where the packaging material:

Clause	Requirements
Interpretation *continued*	• is not at risk of deterioration (e.g. rusting of cans) • is protected from contamination • is cleaned effectively before filling. Once packing has finished, controls must be in place to ensure that any leftover packaging is still suitable for use before its return to storage (e.g. it has not been contaminated or printed with code information preventing reuse). Any open containers must be appropriately resealed or rewrapped and returned to appropriate storage to minimise the potential for contamination (such as splashing during cleaning operations) or mis-packs. The traceability of packaging should be retained (i.e. the coding is retained on the outer packs on return to storage).
4.15.3	Where temperature control is required (e.g. for raw materials, semi-finished materials or final products), the storage area shall be capable of maintaining product temperature within specification and operated to ensure specified temperatures are maintained. Temperature recording equipment with suitable temperature alarms shall be fitted to all storage facilities or there shall be a system of recorded manual temperature checks, typically on at least a 4-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products.
Interpretation	**Temperature control** Where temperature control is required for the appropriate storage of products, the storage area must be capable of maintaining the required temperature. Good practice is for doors to close automatically or be alarmed to ensure they cannot be inadvertently left open. Temperature management is usually carried out through the use of automatic temperature recording systems, which raise an alarm when temperatures fall outside a set range for a defined period (to allow for the usual defrost cycles). The alarm must be capable of notifying a responsible person outside of normal working hours, either by notification to on-site security, by a home call or by ringing through to a service centre. Where such automatic systems are not in use, the same level of safeguard to product temperature control needs to be instigated through manual temperature checks. To achieve a similar level of control, manual temperature checks should be carried out on a 4-hourly basis, including during nights and weekends. The frequency of checks could be reduced where the nature of the product and the insulating capability of the unit are such that the product would remain unaffected by a refrigeration failure of longer than 4 hours (e.g. some frozen products). Ongoing temperature records must demonstrate that product temperature requirements are being met. Procedures must specify the frequency of manual checks or the use of automatic continual monitoring systems. All temperature monitoring must allow intervention before product temperatures exceed defined limits for the safety, legality or quality of products. Procedures should therefore identify the action to be taken in the event that: • temperature monitoring indicates temperatures outside of the permitted levels • there is a failure of the temperature control systems (e.g. a breakdown of the chiller or freezer).

Clause	Requirements
Interpretation *continued*	In regions where ambient temperatures may fluctuate considerably (e.g. large seasonal differences, or considerable variation from day to day), the site should be aware that this may have an adverse effect on ambient storage as well as chilled and frozen facilities. Depending on the product type, the site may need to consider emergency contingency monitoring or control to ensure product safety or quality.
4.15.4	Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions.
Interpretation	**Storage in controlled atmosphere** Where storage conditions include other parameters (e.g. modified atmosphere storage of fruit and vegetables), the mix of gases needs to be defined and monitored to ensure the quality of the product is maintained. Tests are required to ensure that the correct composition of gases is present. They are different from the tests identified in clause 4.5.3, which relate to contamination and food safety. Test results must be recorded.
4.15.5	Where storage outside is necessary, items shall be protected from contamination and deterioration. Items shall be checked for suitability before being brought into the factory.
Interpretation	**Storage outside** Where it is necessary to store product and equipment outside, they must be protected from pests and the elements. Therefore storage of products and equipment outside is normally appropriate only where the site can demonstrate that the material: • is not at risk of deterioration • is protected from contamination • is cleaned effectively before being brought into the factory. Particular attention must be paid to cleaning and inspection of the materials before they are brought into the factory and used, to prevent contamination.
4.15.6	The site shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure that materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life.
Interpretation	**Stock rotation** Stock, whether raw materials, intermediates (including rework) or finished products, must be controlled to ensure that materials are used in an appropriate order and do not exceed their shelf life. This control is generally operated on a 'first in, first out' basis. Product identification, such as labelling, and inventory systems can help to facilitate the correct order in relation to the materials' manufacturing dates and prescribed shelf life.

4.16 Dispatch and transport

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

Interpretation

The site's procedures for dispatch and transport must be controlled to ensure they do not pose a risk to final products.

Where transport or distribution is subcontracted, the requirements for suppliers of services also apply (see section 3.5.3).

Clause	Requirements
4.16.1	Procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include, as appropriate: • controlling temperature of loading dock areas and vehicles • the use of covered bays for vehicle loading or unloading • securing loads on pallets to prevent movement during transit • inspection of loads prior to dispatch.
Interpretation	**Dispatch and transport procedures** The site must consider the potential risks to product safety and quality that may develop during dispatch and transport. In addition to the points listed in the requirement, vehicles should also be inspected prior to loading and unloading (clause 4.16.2).
4.16.2	All vehicles or containers used for the transport of raw materials and the dispatch of products shall be fit for purpose. This shall ensure that they are: • in a clean condition • free from strong odours which may cause taint to products • in a suitable condition to prevent damage to products during transit • equipped to ensure any temperature requirements can be maintained throughout transportation. Records of inspections shall be maintained.
Interpretation	**Vehicle inspection** Inspection of vehicles should be a site's responsibility even where the vehicles and distribution are subcontracted. At a minimum, the inspection will cover whether vehicles have the correct levels of cleanliness and are free from evidence of pests and strong odours (which could taint a product), and have been maintained to prevent product damage during transit. The site should ensure that the correct operating temperatures are capable of being maintained throughout transportation (i.e. that the refrigeration temperature ranges remain within the permitted parameters). This may include pre-cooling trailers for temperature-sensitive products prior to loading, to maintain correct temperatures. Vehicle inspection records must be maintained.

Clause	Requirements
4.16.3	Where temperature control is required, the transport shall be capable of maintaining product temperature within specification, under minimum and maximum load. Temperature data-logging devices which can be interrogated to confirm time/temperature conditions, or a system to monitor and record at predetermined frequencies the correct operation of refrigeration equipment, shall be used and records maintained.
Interpretation	**Vehicle temperature control** Vehicles that are temperature-controlled must demonstrate the control of temperature under both minimum and maximum loads. This can be achieved through the use of temperature recorders, data loggers or manual recorded checks. Where manual checks are used, the frequency of checking must ensure that the safety and quality of the product are maintained. The use of data loggers may be considered as a monitoring method; data received should be analysed to ensure that the temperature of products transported is maintained.
4.16.4	Maintenance systems and documented cleaning procedures shall be available for all vehicles and equipment used for loading/unloading. There shall be records of the measures taken.
Interpretation	**Vehicle maintenance and hygiene** Documented hygiene and maintenance procedures for all vehicles (e.g. forklift trucks, pallet trucks) and equipment (e.g. loading hoses for silos) must be in place. They must include: • the method(s) of cleaning • the frequency at which the cleaning must be completed • records that the cleaning has been completed.
4.16.5	The company shall have procedures for the transport of products, which shall include: • any restrictions on the use of mixed loads • requirements for the security of products during transit, particularly when vehicles are parked and unattended • clear instructions in the event of vehicle breakdown, accident or failure of refrigeration systems, which ensure that the safety of the products is assessed and records maintained.
Interpretation	**Transport procedures** The site must have procedures for the transport of products. The procedures must include: • the identification of any restrictions for mixed loads (e.g. specifying where allergen-free materials are to be stored or transported) to avoid cross-contamination or taint uptake • the security of all finished products in transport to ensure that they cannot be contaminated, either accidentally or deliberately. This may include tamper-evident packing, vehicle seals or contractual handling arrangements with transport providers (such as not leaving vehicles unattended in insecure situations)

Clause	Requirements

Interpretation *continued*	• breakdown procedures for temperature-controlled vehicles (in case of, for example, vehicle breakdown or failure of the refrigeration system). These should consider:
	  • facilities for vehicle drivers to easily contact the company or haulier for assistance
	  • provision of a backup vehicle or rapid-repair facility
	  • guidelines to evaluate the acceptability of product affected by the breakdown.
	
	The appropriate staff must be trained in these procedures.

4.16.6	Where the company uses contractors, it shall have a documented supplier approval procedure to ensure risks to food quality and safety are effectively managed during dispatch and transport operations. The approval procedure shall be based on risk and include either one or a combination of: • a valid certification to the applicable BRCGS Standard (e.g. Global Standard Storage and Distribution) or GFSI-benchmarked standard **or** • a completed contract or terms and conditions. At a minimum, this shall include all the requirements of clauses 4.16.1 to 4.16.5. This shall have been reviewed and verified by a demonstrably competent person.
Interpretation	**Transport and dispatch contractors** Where the company uses third-party contractors for transport of products, it must have a documented supplier approval procedure to ensure food safety and quality of products during these activities. As a minimum, the approval procedure will include either: • certification to a BRCGS Standard (e.g. Global Standard Storage and Distribution) or standard benchmarked by GFSI **or** • a contract with terms and conditions, verified and reviewed by a competent person. As a minimum, this contract must include terms and conditions to meet all the requirements of clauses 4.16.1 to 4.16.5. The use of a contract or terms and conditions for defining the requirements may also be an option where other forms of transport are used (e.g. couriers or larger-scale carriage such as rail transport). The requirements in section 3.5.3 relating to suppliers of services also apply to dispatch and transport contractors.

5 Product control

5.1 Product design/development

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

Interpretation

Procedures must be in place to ensure that all new product development and amendments to existing products result in safe products.

New product development or the introduction of new ingredients must not compromise existing activities or products handled in the same area; for example, the introduction of an allergen or microbiological risk that does not already exist in the area would need to be risk-assessed and managed to prevent contamination of existing products.

Clause	Requirements
5.1.1	The company shall have a procedure for new product development and changes to existing product, packaging and manufacturing processes. This procedure shall include any restrictions to the scope of new product development to control the introduction of hazards which would be unacceptable to the site or customers (e.g. the introduction of allergens, glass packaging, microbiological risks or the introduction of ingredients that may affect product claims).
Interpretation	**New product development** The aim of this clause is to formalise processes for new product development, and changes to existing products, processes and packaging, to ensure the design, development and introduction into production areas does not adversely affect the safety and legality of either the existing products manufactured on site or the new products themselves. Therefore the company must have a new product development procedure which ensures that product development activities are aligned with other site policies on the types of product or hazards handled on site, to prevent the unintended introduction of these hazards – for example, where a company has an existing policy to exclude a particular allergen from the site, or where an existing product claim will be adversely affected. This requirement must operate in conjunction with the food safety plan (HACCP processes); for example, see clause 5.1.2 and section 2.12. Any such restrictions must be documented. Where no restrictions apply, this need not be documented.
5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or an authorised HACCP team member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.

Clause	Requirements
Interpretation	**Approval of HACCP for new products** It is important that the site understands the product safety rationale for all new products (i.e. the criteria that make a product safe for consumption). This may, for example, include processing conditions such as cooking or temperature control; intrinsic properties of the product such as pH or water activity; control of shelf life; or the effect of specific ingredients such as preservatives. Experience has shown that sometimes even minor changes to ingredients, packaging or processing conditions can have a significant effect on the safety of products. The sign-off of changes by the HACCP team leader or an authorised HACCP team member is designed to ensure that the consequences of any change are understood. Therefore a full description of each proposed change to a product, raw material or process must be made available to the HACCP team. This can be demonstrated by a record of the sign-off of product changes (e.g. a change authorisation form). Records should be available even where the change does not result in any modification to the existing HACCP or food safety plan. The assessment of any potential impact on product safety and subsequent sign-off must occur before the products are introduced into the factory; i.e. sign-off must be completed before production trials begin to ensure that new risks (e.g. from allergens) are not introduced into the factory without suitable controls approved by the HACCP team.
5.1.3	Trials using production equipment shall be carried out where it is necessary to validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.
Interpretation	**Production trials** Documented evidence of production trials (i.e. not kitchen-scale trials) need to be available, together with test results validating that the product formulation and manufacturing processes are capable of producing a safe product of the desired quality. Production trials may not be required where new products are very closely based on existing products. Where production trials are not undertaken, the reason must be documented.
5.1.4	Initial shelf-life trials shall be undertaken using documented protocols that reflect conditions expected during manufacture, storage, transport/distribution, use and handling to determine product shelf life. Results shall be recorded and retained and shall confirm compliance with the relevant microbiological, chemical and organoleptic criteria or sensory analysis. Where shelf-life trials prior to production are impractical, for instance for some long-life products, a documented science-based justification for the assigned shelf life shall be produced.

Clause	Requirements

Interpretation	**Initial shelf-life evaluation**
	
	Incorrect product shelf life can result in serious food safety or quality consequences, unnecessary waste and production costs. For example:
	
	• an incorrect shelf life that is too long could result in:
	  • the growth of pathogens to unacceptable levels
	  • product spoilage
	• an incorrect shelf life that is too short can result in:
	  • unnecessary waste, as unused product will be disposed of (either in the supply chain or by the consumer) before it actually needs to be
	  • increased manufacturing costs (e.g. more frequent production or smaller batch size).
	
	It is therefore important to assign shelf life in a systematic and scientific way. The company must establish a documented procedure detailing how initial shelf-life trials are undertaken for new products and changes to existing products. This procedure must consider the handling conditions throughout the supply chain (e.g. chilled products are often subject to 2 hours at an ambient temperature mid-life to mimic the conditions during retail shopping). The aim of shelf-life trials is to confirm that product safety, legality and quality are acceptable throughout the expected shelf life.
	
	Samples to determine the shelf life should be taken from the trials detailed in clause 5.1.3. Where long-shelf-life products (e.g. some canned or frozen products) are developed, it may not be possible to complete full shelf-life trials. The justification for the declared shelf life must be documented and based on experience from similar products and science-based evidence.
	
	Where rework is used or work in progress is stored, shelf life of the material should be established to ensure it is used within the correct period.
	
	Ongoing verification of shelf life is covered separately in clause 5.6.3.

5.2 Product labelling

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

Interpretation

Errors in product labelling remain a significant cause of product recalls. Site processes must therefore have robust processes, capable of consistently developing accurate and legal labels.

The labelling of products must meet all of the legal requirements for the designated country of use. The site must therefore have processes to ensure it remains up to date with labelling requirements in that country (or countries) and that these requirements are accurately transferred onto the packaging and labels.

For the purposes of the Standard, the following definitions apply:

- label – any tag, mark, picture or other descriptive matter, whether it is written, printed or otherwise marked, on or attached to the packaging of the product
- labelling – any words, picture or symbol relating to the food and placed on any packaging or label accompanying the product.

Note that activities relating to labelling and packing are located in several sections of the Standard. An effective system of label design and packing of products will therefore require these sections to interact and operate together within the company. For example:

- Section 5.1 – product design and development
- Section 5.2 – design of labelling
- Section 5.5 – design and purchase of packaging
- Section 6.2 – labelling and packing processes (i.e. packing products and applying labels to products).

Clause	Requirements
5.2.1	All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer. There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe and ingredient specifications. The company shall have a procedure for artwork approval and sign-off.
Interpretation	**Legality of labels** The site's procedures must include the completion of a legality check and sign-off of the proofs (or draft designs) of new labels to ensure their compliance; this will include verification of ingredient and allergen information, based on both the product recipe and ingredient specifications. The appropriate legislative requirements in the country (or countries) in which the products will be used must be considered. Where the company is manufacturing customer-branded products, the customer or brand owner will normally have specific policies for the completion of the final artwork; for example, the site may need to seek formal agreement of the finished product artwork. Where artwork is not formally agreed, the company shall be able to demonstrate that it has taken steps to complete the artwork in accordance with the brand owner's policies. Where the company is the brand owner, sign-off may be undertaken by an experienced and authorised manager or staff member. During the vertical audit, the auditor will assess the site's processes for ensuring the accuracy of labelling and verify that the systems are operating correctly. The auditor will not check every aspect of the labelling to confirm its legality, nor validate the label, but will select samples of on-pack information for the site to substantiate and demonstrate the robustness of procedures and compliance with this clause. For example: • for a product which claims '10% meat', the auditor may ask for the evidence that demonstrates this claim. This may include the product recipe, the mass balance exercise for the specific batch, etc. • for a product which claims to be a 'product of the UK', demonstration of the accuracy of the claim could include evidence of the origin of the materials purchased from suppliers • the auditor may compare the on-pack ingredient information with the recipe and specification.

Clause	Requirements
5.2.2	There shall be effective processes in place to ensure that labelling information is reviewed whenever changes occur to: • the product recipe • raw materials • the supplier of raw materials • the country of origin of raw materials • legislation.
Interpretation	**Label review** The accuracy of product labelling is of primary importance for the legality, consumer safety and the maintenance of product authenticity. It is therefore important that whenever a change occurs to the product, its formulation or the ingredients, there is a review of the label information to ensure it remains correct and up to date. Where it is not, this must lead to a change in the labelling. Reviews, for example, will be required when there are changes to the: • product recipe (e.g. reformulation of an existing product) • composition of the raw materials. For example, when the recipe of a bought-in compound raw material changes, good practice is for the supplier to notify the site of the proposed change before it actually occurs. This should be documented in the supplier approval process (section 3.5) • supply chain (e.g. the introduction of new suppliers of raw materials) • country of origin of the product or ingredients • legislation (in the country/ies in which the product is manufactured and sold).
5.2.3	Where the label information is the responsibility of a customer or a nominated second or third party, the company shall provide information: • to enable the label to be accurately created • whenever a change occurs which may affect the label information.
Interpretation	**Second- or third-party label design** This clause is applicable wherever the decision on pack copy is not controlled by the company but is the responsibility of the customer or a nominated second or third party. In these circumstances, the site is responsible for supplying accurate and reliable information on which to base the label creation. A system must therefore be in place to transfer all the relevant initial information to the relevant customer or nominated party and for ensuring that any changes are communicated in a timely manner. Clause 5.2.1 also applies where the customer or a nominated second or third party completes this activity, and therefore there is an expectation that artwork approval and sign-off will be completed.
5.2.4	Where cooking instructions are provided to ensure product safety, they shall be fully validated to ensure that, when the product is cooked according to the instructions, a safe, ready-to-eat product is consistently produced.

Clause	Requirements
Interpretation	**Cooking instructions** This clause is concerned with cooking instructions that are required to make a product safe to eat when cooked (e.g. products containing raw chicken), and applies to both own-brand and customer-branded products. The site must validate that the cooking instructions will result in a product that is consistently safe to eat when the instructions are followed. Sites should also consider the potential for instructions to be deviated from. Where the cooking instructions are completed by a third party, the site is still responsible for demonstrating that validation is in place. This may be done by completing the validation itself, by management of the service provider (section 3.5.3) or by having the information available (e.g. a copy of the validation report from the third party). If the site is using cooking instructions in connection with products assessed as high risk or high care, it should refer to Appendix 2 of the Standard. The Standard is not prescriptive on the cooking methods that must be used, as this will be dependent on the product type. However, the site should consider any limitations or challenges in completing the validation for the chosen cooking method(s). For example, microwave ovens provide some additional challenges for the validation of cooking instructions. To ensure validation of microwave cooking instructions (ready to heat/cook), their power and efficiency must be considered.

5.3 Management of allergens

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

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

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

Interpretation

Legislation in many countries requires that the presence of food allergens, when deliberately present in a product, must be declared on the pack.

It is important to note that the substances recognised as allergens differ from country to country, and at a minimum the company will need to consider the allergens identified as appropriate to its own business, applicable legislation (in both the country in which its products are manufactured and the intended country of sale) and customer requirements.

There are a number of organisations that provide useful information on allergens and allergen legislation; for example, the Food Allergy Research and Resource Programme (FARRP) provides a table of allergens by country, available on its **Food Allergens – International Regulatory Chart** web page. Leaving aside the deliberate use of

allergenic ingredients in a food, there are occasions when a product can be cross-contaminated (cross-contact) because of the supply chain or manufacturing environments. Where there is a genuine risk of cross-contamination (cross-contact) with an allergen, this must be managed by implementing effective allergen management procedures to prevent or minimise (to an acceptable level) both its likelihood and the levels of allergen that are likely to be present.

The specific legislative requirements in the geographic origin of the raw material, in the country of manufacture and in the country of sale must be considered. This is necessary to ensure that all the relevant allergens are managed and none is inadvertently omitted because of differences in the legislation. For example, the list of substances that are considered to be allergenic is different in Europe, the US, Australia and Japan.

Where products are both produced and sold in countries where there are no legal requirements for the labelling of allergens, the list of allergens as defined in the Codex General Standard for the Labelling of Prepackaged Foods (Codex Stan 1-1985, paragraph 4.2.1.4) should be used as the basis for assessing compliance with the Standard.

Research is continuing to be conducted in a number of countries, including the UK and Australia, to identify allergen thresholds (i.e. the minimum amount of an allergen that will cause a reaction in the majority of allergic customers). Some of this research has now outlined allergen thresholds for a number of allergens, with the aim of assisting in the more appropriate application of precautionary allergen labelling. However, this information must only be used following a meaningful risk assessment applied to a well-managed operation. The values are very low (e.g. a few milligrams), therefore factories must continue to use the full range of risk assessment, risk management and risk communication tools to ensure they produce products that are safe for allergic consumers.

BRCGS publishes a separate guideline on allergen management, which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.

Clause	Requirements
5.3.1	The site shall carry out an assessment of raw materials to establish the presence and likelihood of contamination (cross-contact) by allergens. This shall include a review of the raw material specifications and, where required, the acquisition of additional information from suppliers (e.g. through questionnaires to understand the allergen profile of the raw material, its ingredients and the factory in which it is produced).
Interpretation	**Raw material assessment** Raw materials are a potential source of allergens and of cross-contamination. Therefore, the supplier approval and raw material risk assessment procedures (section 3.5.1) must include an assessment of raw materials for the presence of allergens and the potential for cross-contamination. Raw material specifications (including flavourings, additives, carriers and processing aids) must be agreed with each raw material supplier and include the allergen status (both content and risk of cross-contamination) of the materials. Where required, additional allergen information must be obtained (e.g. through the use of supplier questionnaires or audits). Where a compound raw material (i.e. one manufactured from a number of ingredients) is purchased, the risk assessment must consider the risks associated with the raw material, its ingredients and the manufacturing sites of the ingredients. The assessment process and the outcome of the assessment must be documented.

Clause	Requirements
Interpretation *continued*	It is good practice for allergen risk assessments to be reviewed, as part of the review processes for the food safety plan (e.g. see clause 2.12.3); for example, when there is a change in raw materials or the supply chain.
5.3.2	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products, and any new product development ingredients or products.
Interpretation	**List of allergenic materials** The aim of this clause is to ensure that the site maintains up-to-date knowledge of the allergens that are handled on the site. It is therefore important that the allergen statuses of all raw materials, additives, processing aids, intermediates and final products are known, in terms of both the deliberate presence of allergens and the potential for cross-contamination. All materials that contain allergenic substances (ingredients, processing aids, intermediates and finished products) must be listed in a single reference document or database. It is not a requirement for this list to be a separate document just for allergen information. Provided that all the relevant information is available in a timely fashion (for example, if an allergen list can be pulled from the company's raw material database and clearly identifies which allergens are used on site, in which raw materials or finished product), this list or database would fulfil the requirements of this clause. This might also include non-food materials used in production areas (e.g. pest control baits that are wheat-based). The need to maintain an up-to-date list should be communicated to all areas of the company that can introduce new allergens onto the site or is responsible for allergen risk assessment (e.g. the HACCP team, new product development or engineering).
5.3.3	A documented risk assessment shall be carried out to identify routes of contamination (cross-contact) and establish documented policies, and procedures for handling raw materials and intermediate and finished products, to ensure cross-contamination (cross-contact) is avoided. This assessment shall include: • consideration of the physical state of the allergenic material (e.g. powder, liquid, particulate) • identification of potential points of cross-contamination (cross-contact) through the process flow • assessment of the risk of allergen cross-contamination (cross-contact) at each process step • identification of suitable controls to reduce or eliminate the risk of cross-contamination (cross-contact).

Interpretation	**Risk assessment for cross-contamination (cross-contact)**
	
	A risk assessment process must be completed to identify potential routes of cross-contamination (cross-contact). Consideration must be given to
	
	• the physical state of the allergen. For example:
	  • powdered ingredients represent a greater risk of aerial cross-contamination than those in liquid form
	  • sticky or fatty ingredients are likely to adhere to surfaces should cleaning be ineffective

Clause	Requirements
Interpretation *continued*	• particulates (such as pieces of nut) may result in significant heterogeneous contamination • the identification of potential points of cross-contamination (cross-contact). An 'allergen process flow diagram' or 'allergen map' can be useful in understanding where allergenic ingredients and foods exist in the plant and where they are introduced into the process. This usually takes the form of a site plan on which are highlighted all the routes each allergenic material can take. This map can subsequently be used to identify areas where cross-contamination between allergenic and non-allergenic materials (ingredients, intermediates or products) can occur. (The map should consider process flow, environmental factors, production activities, shared equipment and people.) • an assessment of the risk at each stage identified in the previous step • the identification and implementation of all reasonable controls to reduce or eliminate cross-contamination (e.g. segregation, the use of dedicated lines or equipment, enhanced cleaning schedules). The risk assessment process, the assessments and any resulting procedures and/or factory controls must be documented.
5.3.4	Procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination (cross-contact) of products not containing the allergen. These shall include, as appropriate: • physical or time segregation while allergen-containing materials are being stored, processed or packed • the use of separate or additional protective overclothing when handling allergenic materials • use of identified, dedicated equipment and utensils for processing • scheduling of production to reduce changes between products containing an allergen and products not containing the allergen • systems to restrict the movement of airborne dust containing allergenic material • waste handling and spillage controls • restrictions on food brought onto site by staff, visitors and contractors and for catering purposes.
Interpretation	**Cross-contamination (cross-contact) procedures** The risk assessment (clause 5.3.3) must be used to develop the factory controls and procedures for handling raw materials, intermediates and finished products to reduce (and, where possible, remove) the risk of allergen cross-contact. All allergens present on site must be considered so that procedures can be designed to prevent allergen cross-contact with each specific allergen. For example, contaminating an allergen-containing product with another allergen-containing product (such as contaminating a nut-containing product with a milk-containing product) is just as significant as contaminating a product with no allergens with that allergen. Effective allergen management procedures must be implemented even where on-pack warning labels (clause 5.3.6) are used. Particular attention should be given to: • physical segregation. Ideally, allergenic ingredients and products will be totally segregated from non-allergenic ingredients and products. This could involve, for example, dedicated storage areas, dedicated (and colour-coded) production equipment, and the use of dedicated production lines

Clause	Requirements
Interpretation *continued*	• time segregation. Where products must be handled in the same factory areas or on the same production lines, consideration should be given to the use of time segregation. For example, all non-allergenic products could be produced first and allergenic materials introduced subsequently, or the use of allergenic materials could be confined to the end of a day/shift and only before a full clean. Production scheduling could also be used to minimise the frequency of changeovers between allergen-containing and non-allergen-containing products. For example, in some factories it is possible to limit the use of nuts to a defined period or shift, rather than producing nut-containing products throughout the week • the potential for protective clothing to be a source of allergen contamination. The use of separate clothing or overalls for handling allergenic materials should be considered. It is normally useful to colour-code protective clothing to prevent confusion • the use of dedicated equipment or utensils. These should be clearly identifiable (e.g. by colour-coding) • allergens that can form fine powders (e.g. flour, milk powder and soya isolates). The movement of airborne dust should be minimised by, for example, using physical barriers (such as shrouds, lids or segregated areas) for dispensing and mixing operations. The location of air-conditioning outlets or the use of fans should also be considered to ensure these do not distribute airborne allergens • waste handling and spillage controls. Allergens should be removed efficiently, ensuring that the removal process does not become the source of allergen contamination in other areas of the factory • the allergens that may be handled in non-production areas of the site (e.g. in canteens or in new product development). A policy for food brought on site by staff, or used in vending machines or catering facilities, should be developed. The policy may ban certain allergens or restrict them to certain areas of the site. Where colour-coding is used, consideration must be given to the choice of colours to ensure that colour-blind staff are able to identify the correct items.
5.3.5	Where rework is used, or reworking operations are carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.
Interpretation	**Rework** Specific documented procedures must operate to prevent rework containing allergens from being used in products or processes that do not contain those allergens. Best practice is for rework to be used on a 'like-for-like' basis (i.e. it is used only in exactly the same product). The use of rework must be documented.
5.3.6	Where a justified, risk-based assessment demonstrates that the nature of the production process is such that cross-contamination (cross-contact) from an allergen cannot be prevented, a warning should be included on the label. Legislation, national guidelines or codes of practice shall be used when making such a warning statement.

Clause	Requirements
Interpretation	**On-pack warning labels** Where well-implemented and managed allergen management controls cannot prevent cross-contamination (cross-contact) and there is a significant and genuine risk of the presence of an allergen that would not otherwise be present and is therefore not mentioned elsewhere on the product (e.g. in the ingredients list), the use of on-pack advisory warning labels should be considered – i.e. an on-pack, advisory, consumer-facing warning label stating that there is a risk of cross-contact from an allergen, which cannot be prevented. While different wording may be used in different countries (see below), such warnings are often referred to as 'may contain' labels, as they refer to unpreventable cross-contact rather than to the deliberate inclusion of the allergen in the product. The use of a warning label should be justifiable on the basis of the risk assessment and procedure (clauses 5.3.3 and 5.3.4) and should not be a substitute for effective implementation of good manufacturing practices. Reference must be made to national legislation, guidelines or codes of practice when making such a statement to ensure that best practice is followed. For example, consideration should be given to: • the location of the warning (preferably in close proximity to the ingredients list) • the visibility of the statement – colour, highlighting, location and font size can all aid consumers • the choice of the warning phrase used, so that the meaning is clear to consumers. The site should consider: • the allergens identified as important by the company, i.e. from the risk assessments and controls described above • legislation in the country of intended sale (relating to both which allergens need to be labelled and the permitted warnings) • customer requirements.
5.3.7	Where a claim is made regarding the suitability of a food for individuals with a food allergy or food sensitivity (sometimes referred to as a 'food hyper-sensitivity'), the site shall ensure that the production process is fully validated to meet the stated claim and the effectiveness of the process is routinely verified. This shall be documented.
Interpretation	**Allergen claims** Allergic, food-intolerant and other food-hypersensitive individuals are likely to actively seek and choose products that claim to be suitable for them to consume (e.g. 'gluten-free' products). It is therefore essential that any allergen claim is based on rigorous controls to ensure its validity and continuous implementation to prevent adverse health consequences. Where a claim is made regarding the suitability of a food, full validation and verification activities will be required to ensure that the claim is consistently met. Typically, this will include: • reference to legislation or national guidelines on the permitted claims and the manufacturing requirements to make the claim. For example, some countries have been discussing tolerances or acceptable limits for allergen labelling • demonstration that production processes are in place to ensure the product does not contain unacceptable traces of the allergen

Clause	Requirements
Interpretation *continued*	• analysis of the final product • assessment of the adequacy of cleaning, as detailed in clause 5.3.8 (where the site also produces products containing the allergen about which the claim is made, additional verification controls will be required) • raw material controls. In addition to the normal requirements listed in clause 5.3.1, additional validation/verification requirements are likely to be needed (e.g. raw material testing, additional supplier questionnaires, site audits). The validation and verification activities must be recorded.
5.3.8	Equipment or area-cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination (cross-contact) by allergens. The cleaning methods shall be validated to ensure that they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be: • identifiable and specific for allergen use • single use • effectively cleaned after use.
Interpretation	**Allergen cleaning regimes** Some standard cleaning regimes will be insufficient to ensure the removal of all allergenic material. Therefore, specific cleaning procedures must be present on site where allergen-containing materials require control. Cleaning procedures must be designed to remove or reduce to acceptable levels any allergenic material. They must consider: • cleaning schedules (i.e. when cleaning will be completed) • scheduling sufficient time to fully complete the clean to the required standard • ensuring that cleaning instructions contain all the information required • the order in which cleaning must be performed (to ensure that cleaning does not move an allergen into a previously cleaned area) • the cleaning equipment used for cleaning allergenic materials, which must not be a source of contamination and must therefore be either dedicated for the removal of that allergen, single use or effectively cleaned after use. There is no internationally recognised definition of acceptable allergen levels; this would be dependent on the intended country of sale. For example, reference doses are being discussed in the EU (**further information** can be found on the German Federal Institute for Risk Assessment's website). Where multiple allergens are handled on site, consider whether all allergens could be managed by the same cleaning/validation/verification activities. For example, peanuts, milk and sesame seeds may need different controls because of their different physical characteristics. They may also be used on different equipment and production lines, again requiring separate consideration. The effectiveness of the procedures must be validated. The validation must be documented and evidence will typically include: • worst-case production/cleaning trials, where all equipment, processes and allergens need to be considered

Clause	Requirements
Interpretation *continued*	• targeted test locations, such as food contact surfaces, difficult-to-clean areas, deadlegs etc. • targeted samples, where worst-case samples are identified for laboratory testing using suitably sensitive test methods. (Validation tests should be accredited methods and, wherever possible, quantifiable. Rapid tests, ATP and lateral flow devices are good for verification activities but are not suitable for validation.) Possible samples include the first product manufactured in the next production run, rinse water from cleaning systems, swabs etc. • assessment of new equipment for ease of cleaning prior to purchase • positive testing of the test method used, to confirm that it will detect the allergen if it is present in a real sample (i.e. confirmation that product matrix will not interfere with the test). It is likely that validation data will need to be collected from several production runs to ensure it is representative and complete. A number of best-practice guidelines have been published on the validation of cleaning (e.g. **Campden BRI Guideline 59 – Validation of Cleaning to Remove Food Allergens**). The cleaning procedures must be routinely verified by, for example: • visual inspections and documented sign-off • inclusion in internal audits • the use of swabs or testing (e.g. rapid tests, ATP, lateral flow devices or laboratory tests). Records must be maintained of validation and verification tests and activities. Any corrective actions must also be recorded and completed. BRCGS has a training course on validation and verification. **Further information** is available on the BRCGS website.

5.4 Product authenticity, claims and chain of custody

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

Interpretation

The objectives of this section of the Standard are to ensure:

- the site has assessed its raw materials and supply chain for vulnerability to food fraud activities such as the dilution, substitution or misrepresentation of ingredients prior to delivery to the site, all of which could lead to the sale of unfit, illegal or potentially harmful products
- the site has appropriate controls in place (based on the assessment) to minimise the risk of purchasing fraudulent or adulterated raw materials
- all claims relating to raw materials used in products can be substantiated and that the audit provides a suitable evaluation of the site's management of the chain of custody, where claims are made relating to primary agricultural schemes such as GLOBALG.A.P.

Note that the security of products, while under the management control of the company, is also an important aspect of fraud prevention. Security of products is covered in section 4.1 and food defence in section 4.2; this section focuses on the sourcing of raw materials and their vulnerability within the supply chain.

Section 1 of the Standard deals with senior management commitment in relation to product authenticity; for example, operating processes and objectives that facilitate product authenticity, and the importance of keeping up to date with emerging issues and relevant legislation. These activities complement this section; for example, knowledge of an emerging risk (clause 1.1.8) could be added to the information relating to potential fraud (clause 5.4.2), instigating a review of the vulnerability assessment (clause 5.4.3).

This section applies to food raw materials and ingredients; therefore packaging does not need to be considered under this section.

Product claims are also covered in this section in clauses 5.4.5 (raw material status), 5.4.6 (certification and methods of production) and 5.4.7 (validation of claims, formulation, and methods of production).

Clause	Requirements
5.4.1	Where personnel are engaged in vulnerability assessments, the individual or team responsible shall understand potential food fraud risks. This shall include knowledge of raw materials used by the site and the principles of vulnerability assessment.
Interpretation	**Competency of the vulnerability assessment and food fraud team** It is important that personnel completing vulnerability assessments for food fraud are competent to develop the plan; they need to understand the risk they are trying to prevent. Therefore, it is expected that within the team there will be knowledge of: • the principles of food fraud (e.g. what food fraud is, why its management is important) • risk assessment or vulnerability assessment techniques • the risks associated with the raw material, product, supply chain or process being assessed. The Standard is not prescriptive regarding how this knowledge is demonstrated and may, for example, include: • formal training (e.g. a training course in food fraud, vulnerability assessment or VACCP) • internal training, development and experience (e.g. demonstrable knowledge of the site) • other competency (e.g. the completeness and effectiveness of the vulnerability assessment and its implementation). Risk assessments may be completed either by responsible individuals or by a team. The advantage of a team is that every company has several departments that are likely to possess useful information; for example: • technical or QA staff are often subject matter experts • supplier approval will see information relating to specific raw materials, suppliers and supply chains • purchasing departments are usually well informed about availability or pricing concerns • goods receipt and production teams see the materials actually delivered to the site. Where a team is used to complete assessments, it is important to consider the overall capability of the team. If the site does not have the appropriate in-house knowledge, external expertise (e.g. food safety consultants) may be used; however, reference should be made to clause 1.2.4 and section 3.5.3.

Clause	Requirements
5.4.2	The company shall have processes in place to access information on historical and developing threats to the supply chain which may present a risk of adulteration or substitution of raw materials (i.e. fraudulent raw materials). Such information may come from, for example: • trade associations • government sources • private resource centres • activities completed for clause 1.1.8.
Interpretation	**Provision of knowledge and information** Information relating to the adulteration or substitution of raw materials constantly changes as new risks are identified and existing ones are managed. The objective of this clause is therefore to ensure that sites remain up to date with emerging issues and are able to adapt their systems to protect their products against new and existing risks to the authenticity of their products. The company must be able to demonstrate that it maintains up-to-date knowledge of relevant scientific and technical developments, emerging issues and known risks relating to the authenticity of the raw materials it purchases and the potential for food fraud in the supply chain. The company's systems therefore must ensure that information is reliably obtained and reviewed in a timely manner. Ideally the company should be proactive, looking for and reviewing information, rather than reacting to situations that have already occurred. Mechanisms to achieve this may include: • membership of a trade association which provides this service • help from government officials or local enforcement offices • subscription to a service provider supplying updates on food fraud • regular review of reputable, quality information sources such as websites covering food fraud. The auditor will look for evidence of systematic checking and a process for ensuring the information is transferred into action as necessary (clause 5.4.3). Information may be obtained and collated as part of the provision of technical knowledge (clause 1.1.8) or as a separate exercise, providing it is clear that relevant information is being obtained. Good practice is to reference data sources, as this allows later reference; for example, if further details are required or an update occurs. There are many different types of information that may indicate fraud and are useful when completing or updating a vulnerability assessment; examples are listed in clause 5.4.3 and its interpretation. A number of organisations provide information and updates on food fraud risks; for example: • European Commission Knowledge Centre for Food Fraud and Quality • Reports from Operation OPSON.

Clause	Requirements
5.4.3	A documented vulnerability assessment shall be carried out on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution. This shall take into account: • historical evidence of substitution or adulteration • economic factors which may make adulteration or substitution more attractive • ease of access to raw materials through the supply chain • sophistication of routine testing to identify adulterants • the nature of the raw material. The output from this assessment shall be a documented vulnerability assessment plan. This plan shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risks. It shall be reviewed annually and whenever there is: • a change in raw materials or a supplier of raw materials • emergence of a new risk (e.g. known adulteration of an ingredient or developments in scientific information associated with authenticity of the site's products or raw materials, for example, information obtained as part of clause 1.1.8) • following a significant product safety incident (e.g. a product recall) where the authenticity of the site's products or raw materials is implicated.

Interpretation

Vulnerability assessment

A vulnerability assessment is a search for potential weaknesses in the supply chain in order to prevent food fraud (i.e. to prevent the adulteration or substitution of raw materials before they arrive at the site). It is a specialised form of risk assessment, and needs a systematic and structured approach to ensure data gathering, identification of significant food fraud hazards, assessment of likelihood of occurrence, and identification and implementation of controls to mitigate genuine risks. The aim of the assessment is not to assess the potential for fraud at the site, but to examine the supply chain for potential concerns or weaknesses, thereby identifying those raw materials that are at particular risk of adulteration or substitution, so that appropriate controls can be put in place (clause 5.4.4).

The vulnerability assessment will consider information relating to each ingredient in order to assess whether there is a potential for food fraud. Where a site purchases a number of similar raw materials, it may be possible to consider these as a group rather than each raw material individually, providing the risks are similar. The company will need to ensure that all food materials are subject to a vulnerability assessment.

Typical information to incorporate into the assessment includes:

- any emerging issues and information identified in clause 5.4.2
- historical evidence of substitution or adulteration of the ingredient
- cost/value of the material
- availability (e.g. a poor harvest may restrict availability and may increase the potential for adulteration)
- sophistication of routine testing to identify adulterants. If testing within the supply chain is comprehensive and specifically focused on potential fraud issues, then the likelihood of adulteration is reduced (e.g. fruit juice is often tested for a comprehensive range of parameters, including DNA, isotopic analysis, added sugars and added water to prevent potential fraud)

Clause	Requirements
Interpretation *continued*	• country of origin • length and complexity of the supply chain • supply chain model • controls that are already in the supply chain. For example, if the raw material supplier is certificated to the Standard, then as part of that certification the supplier must have completed its own vulnerability assessment, and there is no requirement in the Standard for the site to duplicate its supplier's vulnerability assessment. The nature of the raw material may change the potential for food fraud. For example, if a slaughterhouse is purchasing cattle, horses and pigs for slaughter, it will be obvious if there is an issue with the live animals; however, if the slaughterhouse intends to make a claim such as organic, Aberdeen Angus or specified country of origin, then greater controls of raw materials will be required to ensure only those which meet the claim are purchased. Similarly, prepared ingredients such as beef mince or ground spices are likely to have a greater risk than the whole ingredient. The Standard does not define the exact process that the site must follow when completing the vulnerability assessment; however, it is likely to incorporate the following steps: • draw up a list of raw materials (or groups of raw materials) and the controls (e.g. product testing, traceability systems or supply chain audits) that are already in operation • consider the information obtained from clause 5.4.2 for each ingredient • complete a risk assessment on the vulnerability of each ingredient. Note that the Standard does not require full supply chain mapping for all raw materials, although this may be a useful tool where a risk assessment indicates that a genuine risk exists and there is a need to identify the point in the supply chain where an effective control can be applied. The output of the vulnerability assessment must include a documented vulnerability assessment plan which should rank or score the materials to identify those which need additional controls. The ranking and actions required could, for example, be as follows: • **Very high** A high-profile raw material with recent reports of adulteration published by regulatory authorities. Action or monitoring is required to ensure only genuine materials are purchased • **High** A high-profile material that provides an attractive target for potential adulteration. Some action and/or monitoring is required to ensure only genuine materials are purchased • **Low** This material is unlikely to be a target for substitution or adulteration; however a re-assessment may be necessary if new information becomes available • **Negligible** No further action required as the material is extremely unlikely to be a target for food fraud. As mentioned earlier in this interpretation, situations relating to food fraud change, and it is therefore important that the company has a dynamic system that can react to and assess new information as it becomes available, thereby ensuring the vulnerability assessment remains up to date. At a minimum, the vulnerability assessment must be reviewed at least annually and when there is a significant change to the ingredient. As a guide, a review may be triggered by the following, although this is not an exhaustive list:

Clause	Requirements
Interpretation *continued*	• a change in the country of origin or the supplier of raw materials • a change in the financial situation of raw material suppliers or countries of origin • a change in cost of raw materials, either upwards or downwards • a change in the supply chain, logistics and delivery of materials • a change in material availability (e.g. because of seasonal shortages) • emergence of a new risk (e.g. known adulteration of an ingredient) • developments in scientific information associated with ingredients, process or product • information received as part of a supplier approval or raw material risk assessment (e.g. clause 3.5.1.1) which highlights new or evolving risks. A number of risk assessment tools have been published. These include some specialist vulnerability assessment tools such as CARVER + Shock and TACCP (threat assessment and critical control points), which may be used to achieve a structured approach to the assessment process. BRCGS has published a number of items to assist with vulnerability assessments. These include a specific vulnerability assessment guideline that can be obtained from the **BRCGS Store** or viewed online at **BRCGS Participate**, and a training course available through BRCGS Performance Enhancement and its global network of approved training providers. A number of organisations have produced tools to assist with food fraud and vulnerability assessments, including, for example, the **Food Fraud Resilience Self-Assessment Tool** available on the UK FSA website.
5.4.4	Where raw materials are identified as being at particular risk of adulteration or substitution, the vulnerability assessment plan shall include appropriate assurance and/or testing processes to mitigate the identified risks.
Interpretation	**Output from the vulnerability assessment** Where raw materials are identified as being of particular risk of adulteration or substitution, appropriate assurance controls need to be in place to ensure that only genuine materials are purchased. Depending on the perceived risk, assurance controls may include: • certificates of analysis from raw material suppliers • raw material testing • supply chain audits • use of tamper evidence or seals on incoming raw materials • enhanced supplier approval checks • mass balance exercises at the raw material supplier • changes to the supply chain (e.g. a change of supplier or a move to a shorter supply chain). It is worth noting that the best controls are proactive and continuous as these are the most likely to prevent an incident from occurring. For example, product testing is a useful tool but it is reactive (i.e. it can only tell you if something has happened; it cannot prevent it from occurring or recurring in future).

Clause	Requirements
5.4.5	Where products are labelled or claims are made on finished packs which are dependent on the status of a raw material, the status of each batch of the raw material shall be verified. These claims include: • specific provenance or origin • breed/varietal claims • assured status (e.g. GLOBALG.A.P.) • genetically modified organism (GMO) status • identity preserved • named specific trademarked ingredients. The facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The site shall undertake documented mass balance tests at a frequency to meet the particular requirements of any scheme it is certificated to, or in the absence of a scheme-specific requirement, at least one mass balance test every 6 months.

Interpretation

Status verification of raw materials

The types of claim covered by this clause relate to the provenance of ingredients used in a product that differentiates those ingredients or product from the norm. Such a claim may be made either on the product label for the consumer or in business-to-business communication. The types of claim include:

- varietal claims (e.g. basmati rice, Aberdeen Angus beef, Bramley apples and cod fish cakes)
- origin claims (e.g. Madagascan vanilla and Florida grapefruit)
- assurance claims (e.g. GLOBALG.A.P., Red Tractor, Marine Stewardship, dolphin-friendly tuna and sustainable palm oil)
- identity-preserved claims (e.g. GMO-free).

Claims which relate to the composition of the product (e.g. nutritional claims, fat-free, reduced sugar, free-from) are covered in clauses 5.3.7 and 5.4.7.

It is the responsibility of the site to make reasonable checks to ensure that the raw materials supplied are genuine and that claims made about ingredients are proven.

For many assurance schemes, such as GLOBALG.A.P., it is possible to check the assurance status and the scope of products of the supplier on a database. Reliance solely on a declaration from a supplier will not be sufficient. Where claims relate to variety or species (e.g. varieties of fruit), examination of visual characteristics may suffice. However, for claims where visual analysis is not possible (e.g. block frozen fish), certificates of analysis and periodic sample analysis will be required.

Full traceability records must be maintained, as required in section 3.9. The records must also include details of the quantities purchased and amounts used at each step to enable a mass balance exercise to be undertaken.

In the absence of more frequent requirements relating to a particular scheme, the site must undertake a mass balance traceability exercise on typical products for which a claim is made at least every 6 months. This must ensure that the system of records maintained enables all finished product batches to be identified for a particular batch of raw materials and that, for a given finished product, the batch(es) of raw materials used for its production can be identified. The test must be carried out in both directions.

Clause	Requirements
Interpretation *continued*	The ingredients selected for the mass balance exercise must include the ingredient for which a claim is made. The objective is to test the systems and, where necessary, make improvements to information recording to allow claims to be substantiated should they be challenged by a customer or legal authority. It follows that, where very different traceability systems are used within, for example, a complex or multi-product site, more than one mass balance traceability exercise may be required every 6 months to ensure that all systems are working effectively. However, where a site has multiple claims, it is not intended that every claim be mass balance tested every 6 months but that a representative selection of claims are chosen. In this situation, good practice would be to choose different claims or products each time the test is conducted. The use of a third-party mass balance exercise (e.g. by an organic certifier or by the Fairtrade Foundation) would be acceptable evidence of a test, providing that records of the test, the results and evidence of any necessary improvements made as a result of the test are maintained. Where the third-party scheme measures the mass balance over a period (e.g. 1 month) rather than for a single batch code this is considered acceptable providing the requirements discussed above are met. If, as part of the requirements for a particular scheme or to use a logo, there is a requirement for more frequent mass balance traceability exercises, then that scheme's requirements must be met.
5.4.6	Where claims are made about the methods of production (e.g. organic, halal, kosher), the site shall maintain the necessary certification status in order to make such a claim.
Interpretation	**Certificated third-party standards** Where a site wishes to make claims relating to specific production methods, such as organic, Halal or Kosher, the site is responsible for maintaining the appropriate certification to those standards. While the accuracy of the production methods relating to these third-party certification standards will not be assessed during a BRCGS audit, the auditor will require evidence that the appropriate certification is in place (e.g. by reviewing the certificate or an online database of certificated sites).
5.4.7	Where a product is designed to enable a claim to be made, the company shall ensure that all claims are substantiated, and product formulation and the production process are fully validated to meet the stated claim and any legal requirements (in the country of intended sale) relating to the claim. The process flow (see clause 2.5.1) for the production of products where claims are made shall be documented and potential areas for contamination or loss of identity identified. Appropriate controls shall be established to ensure the integrity of the product claims.

Clause	Requirements
Interpretation	**Claims and loss of identity** Where a particular claim about the formulation of a product has been made, procedures must be in place to: • validate that the claim is correct (this should include all steps in the process including, for example, label design, raw material sourcing and production) • ensure legal requirements relating to the claim in the country of intended sale are met; for example, in the EU, nutritional claims are defined • identify and prevent potential sources of contamination, loss of identity or variation which adversely affects the claim; for example, by using the process flow diagram to identify steps in the manufacturing process where product may be located in shared production areas or on shared lines. For example, an on-pack claim that a product is plant-based or vegetarian would need to be validated, and this may include: • inclusion of the claim in raw material risk assessment, supplier approval and specifications • inclusion of the claim in the food safety plan, e.g. use of the process flow (see below) leading to specific controls such as segregation and dedicated equipment, or validated cleaning regimes • review of the production processes, equipment segregation etc. Good practice is to ensure that a programme of ongoing verification and monitoring is in place to demonstrate that claims are consistently met. Claims such as 'free from allergen' and 'allergen-free' need particular care to ensure that cross-contamination cannot occur during processing. This is covered separately in clause 5.3.7. The process flow diagram used within the food safety plan (or HACCP process) may be used as the basis for demonstrating compliance with this clause (the requirement may already be covered within the HACCP or food safety plan). The site must identify (e.g. as a list or on the process flow) potential areas where mixing of products or loss of identity may occur. Procedures of working or changes in process flow must be introduced to reduce the risk of mistakes and false claims being made. For example, in a large packhouse packing both farm-assured and non-farm-assured fruit, the farm-assured fruit is always stored separately within dedicated cold stores. Grading and packing operations are organised so that the packing of farm-assured product occurs first or on particular packing lines.

5.5 Product packaging

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

Interpretation

Consideration of packaging and the process for the purchase of product packaging is crucial for ensuring the ongoing integrity of the product (i.e. ensuring it is clean, is of the appropriate quality and minimises product deterioration), and in maintaining product safety and legality (e.g. preventing product contamination).

Clause	Requirements
5.5.1	When purchasing or specifying primary packaging, the supplier of packaging materials shall be made aware of any particular characteristics of the food or existing packaging (e.g. high fat content, pH, usage conditions such as microwaving, other packaging used on the product, use of recyclable or reusable packaging materials) which may affect packaging suitability. Certificates of conformity or other evidence shall be available for primary packaging to confirm it complies with applicable food safety legislation and is suitable for its intended use.

Interpretation

Compliance with legislative requirements

There have been incidences of product recalls which have resulted from a lack of communication between the supplier of the packaging materials and the food manufacturer, typically where a packaging material has been used in extreme product conditions or where packaging not designed for direct food contact has been used (e.g. a plastic liner of a carton is removed or changed to reduce costs).

The company must be able to demonstrate that each item of product packaging meets legal requirements for its use (e.g. compliance with food contact regulations in the country of sale). This may be in the form of specifications, migration data or a certificate of conformity. Where a declaration of conformity is used, any limitations on usage must be stated (e.g. the food types or storage conditions: ambient, chilled or frozen).

The supplier of the packaging must be made aware of the conditions under which the packaging is going to be used, so that the suitability of the packaging materials can be confirmed. This may take the form of a specification provided to the packaging supplier and would include, as appropriate:

- contact with food – direct food contact or, where not used for direct food contact, the nature of the barrier layer
- characteristics of the food – any adverse characteristics of the food which may increase migration of chemicals from the packaging (e.g. high fat content, or low or high product pH)
- conditions of processing (e.g. high-temperature fill, thermal processing in pack, or freezing)
- expected customer usage (e.g. microwave in pack, cooking in pack, or freezing)
- use of recyclable or reusable packaging materials
- other packaging, especially where the components will be supplied by different companies and there is a need for compatibility between the component parts (e.g. a bottle and cap manufactured and supplied by different suppliers).

Direct food contact materials are of most concern as these have the greatest potential for harm and many geographical regions have specific legislation around direct contact packaging. However, there may be risk associated with the additional layers of packaging, particularly labelling which often comprises the primary pack (consumer unit) and also secondary packaging such as corrugated cases. Physical or chemical contamination can occur from these packaging components.

Discussions with the provider of packaging materials are imperative to ensure that the right materials in the right configurations are used (e.g. it may be necessary to use lower levels of recycled content in a corrugated case for products that are susceptible to chemical migration). Extensive work at the start of the process is incredibly valuable and can prevent costly errors from being made in specifications.

Clause	Requirements
Interpretation *continued*	It is also vital to consider the product supply chain to establish the most appropriate packaging, given the storage and distribution conditions that the product will be subjected to. The requirement allows some flexibility in the approach used; for example, a site could use risk assessment to identify the appropriate controls, and establish the level of evidence that is satisfactory for the level of risk (although the site would need to ensure that any legal requirements were addressed). For example, in the EU the site may decide that it needs to review an EU Declaration of Compliance (DoC) for Food Contact Materials due to a perceived risk of migration. The site would need to demonstrate that the evidence available is appropriate for the level of risk associated with the packaging – it would not be acceptable to list the clause as 'not applicable', as there should also be evidence that the matter has been adequately communicated/discussed with the packaging supplier. BRCGS has published a guideline on migration from packaging materials into food, which may be purchased from the BRCGS Store or viewed online at BRCGS Participate.
5.5.2	Product liners and bags purchased by the company for use in direct contact with ingredients, or work in process, shall be appropriately coloured (e.g. contrasting colour to the product) and resistant to tearing to prevent accidental contamination.
Interpretation	**Product contact liners** Materials used as liners for containers, as covers for work in progress or as bags for prepared ingredients may themselves be a source of contamination. Such packaging materials must be visually distinct from the product (e.g. blue or red) and of a sufficient thickness to reduce the potential for ripping or being damaged. Good practice is to ensure that bag and film gauges are documented and communicated to suppliers to ensure that only suitable materials are purchased. The requirement applies only to materials purchased by the site and used on site; it does not apply to finished product packing. However, suppliers of raw materials should be strongly encouraged to supply ingredients in accordance with this requirement to reduce the risk of packaging contaminating products. Where companies are producing products for further processing, clear liners should not be used as they present a potential hazard for the next manufacturer. This clause does not apply to packaging used for sale to the final consumer.
5.5.3	The company shall have a procedure to manage obsolete packaging (including labels). This shall include: • mechanisms to prevent accidental use of obsolete packaging • control and disposal of obsolete packaging • appropriate procedures for the disposal of obsolete printed materials (e.g. rendering trademarked materials unusable).

Clause	Requirements
Interpretation	**Obsolete packaging** Mis-labelling and mis-packing of product is a common cause of product recall. This is of particular concern when, for example, allergens are introduced which are not accurately reflected on the labelling. Effective management of packaging materials, particularly those that are printed, can minimise the risk of these incidents. One of the key aspects of this management is the effective control of obsolete packaging (i.e. items that are no longer required) such as those that are out of date because of a change in the ingredients used in the product. At a minimum sites should have: • mechanisms to prevent the accidental use of obsolete packaging (e.g. physical segregation in storage areas, clear 'do not use' labelling, blocks in electronic inventory systems) • controls for the disposal of obsolete packaging (e.g. timescales for the disposal of materials; how accidental use will be prevented while waiting for disposal; and how materials will be disposed of) • appropriate procedures for the disposal of obsolete printed materials (e.g. rendering trademarked materials such as out-of-date labels unusable).

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

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

Interpretation

The company needs to identify and schedule the inspection and analyses which are critical for the products it produces. For example, critical analyses may include:

- known product safety risks associated with the product type or identified during the HACCP risk assessment
- legal requirements, particularly those associated with the country of intended sale (where this is known)
- product authenticity (e.g. where a genuine risk of adulteration, substitution or fraud has been identified during the vulnerability assessment described in section 5.4)
- quality attributes (e.g. where these form part of a specification agreed with the customer).

The frequency and type of inspection and tests are not prescribed by the Standard as these should be risk-based and specific to the type of products (see clause 5.6.1).

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

Clause	Requirements

Interpretation	**Product test schedules**
	
	The company needs to have a documented schedule of tests which are carried out on the products. The objective of these tests is to ensure that products are manufactured to specification and in compliance with safety and legislative requirements. The HACCP or food safety plan is likely to identify some of the tests required and their frequency. However, other tests which ensure the quality of the product and which may not have been included in assessments of product safety must be considered. For example, tests may be identified to:
	
	• monitor for a potential contaminant (e.g. pesticides, heavy metals or microbiological contamination)
	• test for conformity to a specification or claim (e.g. nutritional content)
	• monitor trends (e.g. environmental monitoring of the site environment – see section 4.11.8 for full details)
	• confirm compliance with a customer's quality requirements
	• monitor potential food fraud or food defence concerns (e.g. as an output from food defence or food fraud assessments – see sections 4.2 and 5.4).
	
	The processes for obtaining product samples, including, where necessary, their delivery to a laboratory, must be considered and will be dependent on the production process, the type of product, and whether the test is completed on site or at an external laboratory. For example:
	
	• how the sample is removed from the production flow – identifying the correct product, preventing contamination of the rest of the production, confirming the correct quantity is taken
	• sample integrity – to ensure that the sample is fit for analysis; for example, protecting it from contamination or adverse treatment (e.g. maintaining appropriate product temperature and respecting any time limitations for chilled or frozen products prior to microbiological testing)
	• clear labelling of samples with relevant information, including traceability
	• where required, procedures for:
	  • storage of samples before testing
	  • delivery to a laboratory
	  • clear communication with the laboratory.
	
	The frequency and type of product tests should be based on risk and on any particular customer requirements. The site is expected to be able to explain and justify the basis for the frequency of tests with reference to historical or scientific information as appropriate.
	
	The test method and specifications for each test must be documented. Where the results of a test include subjective criteria (e.g. bake colour, texture or organoleptic tests), colour standards or reference samples must be used to provide a reference point for the test results (i.e. to define pass/fail criteria).
	
	Where tests are completed on site, the location of the testing should be considered; for example, laboratory facilities will need appropriate siting and controls (clause 5.6.5) and organoleptic tests should be completed in a designated area and not on the production line.

Clause	Requirements
5.6.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. The significance of on-site and laboratory results shall be understood and acted upon accordingly. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends. Where legal limits apply, these shall be understood and appropriate action taken promptly to address any exceedance of these limits. Where applicable, the measurement uncertainty associated with laboratory test results shall be considered.
Interpretation	**Reviewing test results** Systems of recording and review must be formalised and must include evidence of actions taken on identified trends, or where unsatisfactory results have been recorded. The use of graphs or charts of test results provides a good method of identifying trends and anomalous results. Wherever testing is carried out, criteria (e.g. acceptable limits, action limits or legal limits) shall be established and documented, so results can be interpreted. It is important that the receiving site understands the test results and the content of any test report and can interpret their significance. Where test results are found to be outside established limits, there must be clear protocols on the actions to be taken (e.g. product hold, additional testing, customer notification, product withdrawal or recall). Appropriate actions should be implemented promptly to address unsatisfactory results or trends and thus protect consumer safety, product quality, legality and brand reputation. Records of the results, review and any actions taken should be maintained. The site must agree with the laboratory on how the measurement uncertainty shall be applied to results (for some tests, in some countries, this may be defined by legislation).
Measurement uncertainty	Measurement uncertainty (sometimes simply referred to as 'uncertainty') is a parameter associated with the result of a quantitative measurement. It is defined as the range of the values that could reasonably be expected for the attribute (e.g. the micro-organism, allergen or chemical) being measured. It is sometimes known as the 'margin of doubt' of the result. Measurement uncertainty is important when making conformity decisions (i.e. assessing whether a test result is within legal, safety or acceptable limits), as the range of probable values may cross one of these limits. No matter what method is used, it will be subject to challenges inherent in taking the measurements accurately, day-to-day variations (e.g. in equipment, reagents, personnel or environmental conditions), and any systematic errors, random errors or corrections associated with the test; therefore the result obtained is the best estimate of the value. Random errors are errors that fluctuate due to the unpredictability or uncertainty inherent in the measuring process, or the variation in the quantity being measured (i.e. variation throughout the sample or product being tested, and this is often demonstrated by the normal variation seen in replicate measurements of the same material). A systematic error is one that originates from a persistent issue and leads to a consistent error in the measurements; for example, recovery.

Clause	Requirements
Measurement uncertainty *continued*	Product testing is often completed to establish compliance with limits; i.e. to demonstrate that a product meets the requirements defined in its specification, by regulations and by customers. Knowing the measurement uncertainty is important when making these conformity decisions. For illustrative purposes only, in Figure 20, the horizontal line represents the target value or limit; values above this fall outside the permitted range, and values below it are within the permitted range.

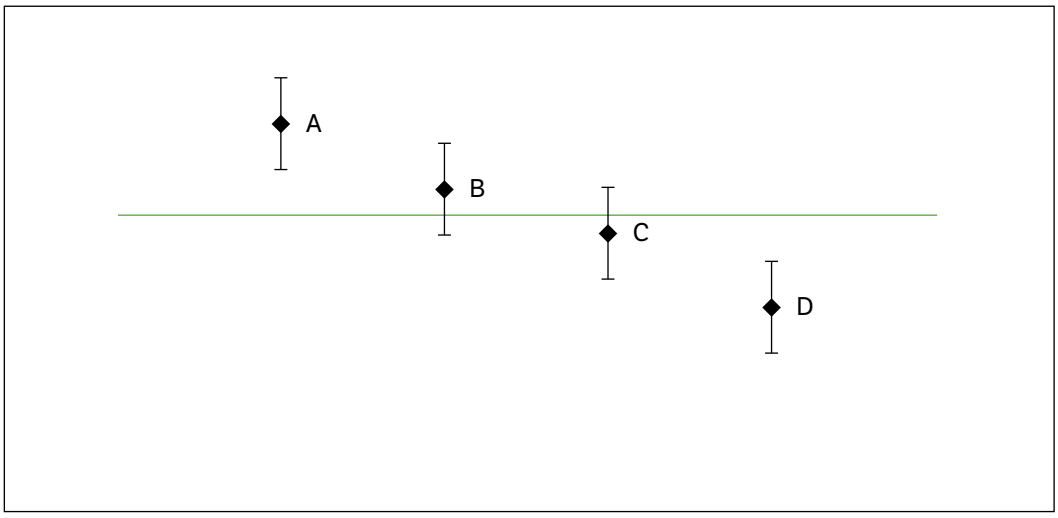

Figure 20 Example of the possible effects of measurement uncertainty

Results A and D are well above or well below the limit, and thus applying the measurement uncertainty value will not change the conformity statement made (e.g. A is still outside the limit and D is still in specification). It is in results B and C where measurement uncertainty would impact on the conformity.

The value obtained for C is within the limit. However, if the result and measurement uncertainty are combined, the value represented by C may fall above the limit and thus be out of specification.

The value obtained for B is above the limit and therefore would be out of specification, but taking measurement uncertainty into consideration, there is a potential that B could fall below the threshold (i.e. be within specification).

Applying measurement uncertainty in this manner needs careful consideration and justification depending on the risk, applicable legislation or customer requirements. Where the test is of a critical parameter (e.g. product safety or legality), measurement uncertainty must not be used to prevent taking the correct action to protect consumers and/or maintain legality.

5.6.3	The site shall ensure that a system of validation and ongoing verification of the shelf life is in place. This shall be based on risk and shall include sensory analysis and, as applicable, microbiological testing and relevant chemical factors such as pH and a_w. Records and results from shelf-life tests shall verify the shelf-life period indicated on the product.

Clause	Requirements
Interpretation	**Shelf-life verification** Shelf-life testing may be critical to product safety; for example, where the product is susceptible to the growth of pathogens. Therefore, after the initial shelf life is determined (see clause 5.1.4), the site is expected to have a programme of ongoing shelf-life validation and verification across its range of products or product types. To achieve this, samples should be retained from some or all production runs. Records must be available supporting the declared shelf life for each product or group of similar products. These may include microbiological and sensory analyses, as well as relevant chemical factors such as pH and a_w. Shelf-life trials extending beyond the stated life of the product, to ensure a margin of safety, may be required for some product types.
5.6.4	Pathogen testing (including pathogens tested as part of the site's environmental monitoring programme) shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be fully segregated from the production and storage areas and have operating procedures to prevent any risk of contamination of products or production areas.
Interpretation	**Pathogen-testing facilities** The requirements apply specifically to the testing of pathogens, and not to general microbiological tests such as those for yeasts and moulds, total viable count (TVC), coliforms or Enterobacteriaceae (while these need to be carefully controlled, they present a lower level of risk). If pathogen-testing facilities are not carefully managed, they could present a risk to products. Pathogen testing also tends to be a specialised activity requiring specific facilities, and consequently it is usually outsourced to a specialist laboratory. Where pathogen testing is carried out on the production site, the laboratory facility must be physically segregated (ideally in a separate building) from production, food-handling and storage areas. The company must have documented procedures to prevent product contamination and must be able to justify the controls in place. Consideration of the design of the laboratory is covered in clause 5.6.5. Facilities for testing pathogens, their location (in relation to production and food-storage/handling operations) and containment arrangements may be subject to legislation and/or guidelines, which the site will need to comply with. Allergens and other contaminant tests, for example, will also require suitable facilities, with procedures for the delivery and removal of samples from the laboratory (i.e. this should not be done via production or food-handling areas). For environmental monitoring testing methods and use of rapid testing kits and ATP swabbing, see section 4.11.8.

Clause	Requirements
5.6.5	Where testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented and implemented, and include consideration of: • operating procedures to contain laboratory activities, including the design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • hygiene and protective clothing arrangements • movement of materials that may pose a risk to products, raw materials or the production area, into and out of the laboratory, including the disposal of laboratory waste • the management and monitoring of laboratory equipment. Where testing activities are performed in production or storage areas (e.g. at the line tests or rapid tests), these shall be located, designed and operated to prevent product contamination.
Interpretation	**Design of laboratory facilities** If a laboratory is present within the site, documented control procedures are required to eliminate potential risks to product safety. These include: • appropriate containment of the work, i.e. design and operating procedures that ensure that product and production areas cannot be contaminated by laboratory samples or laboratory activities • drainage and ventilation systems; for example, by ensuring the drainage does not flow through the production areas • restricted or controlled access for authorised personnel only • procedures which ensure that protective clothing arrangements are suitable (e.g. not wearing laboratory clothing in other areas of the site, especially in production and storage areas) and coat change procedures • movement of materials to and from the laboratory (e.g. laboratory consumables, chemicals, reference materials, equipment and laboratory waste) • hygiene procedures such as hand-washing on entry to the area. Where at-line testing is undertaken, measures shall be in place to protect the integrity of testing and production activities (e.g. by locating them in designated areas away from the production line, and allowing them to be completed only by trained and authorised staff). Accreditation to ISO/IEC 17025, or a similar recognised national standard with equivalent requirements, will demonstrate that the laboratory meets these requirements.
5.6.6	Where the company undertakes or subcontracts analyses which are critical to product safety, authenticity or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025, including proficiency testing where applicable. Documented justification shall be available where accredited methods are not undertaken.

Clause	Requirements
Interpretation	**Analyses critical to safety and legality** This clause applies to tests which are critical to product safety or legality. Results from such tests must be credible and may be called upon in a court of law. The company needs to identify which tests are critical to product safety, authenticity or legality, such as compliance with label claims or declarations (e.g. nutritional claims, alcohol content) and tests for contamination (e.g. pesticides, aflatoxins), and verify that they are fit for purpose; for example, by confirming that the laboratory and method is covered by the laboratory's accreditation to ISO/IEC 17025 for the product/material in question. Note that while the laboratory itself may have accreditation, the actual test methods must also be accredited, as laboratory accreditation will relate to specific testing activities, and may not cover all of the services that the laboratory provides. The specific tests should be defined within the laboratory's schedule of accreditation. Any method of analysis that is not accredited needs justification as to why it was used (e.g. it may be a method for which no accreditation is yet available). Where critical tests are carried out by non-accredited laboratories or with non-accredited methods (either contracted or on-site laboratories), there must be suitable documented evidence that the laboratory is working to the requirements and principles of ISO/IEC 17025. This must include confirmation of the laboratory's procedures to meet the following general principles: • document control • defined responsibilities and authority • staff competency and documented training • documented test methodology based on accepted standards • equipment that is fit for purpose and appropriately calibrated • a documented quality assurance programme, including proficiency testing (this is interlaboratory analysis, where multiple laboratories test the same material to allow a comparison of the results. A site or laboratory can therefore demonstrate that the test procedures used are working effectively and equivalent to those used in other laboratories) • completion of internal audits of the laboratory's operation. Other good practices include: • equipment control (e.g. maintenance, calibration, traceability to recognised standards, monitoring and result appraisal) • validation of methods and materials to confirm fitness for purpose (e.g. test methods, equipment, test kits, reagents, chemicals) • quality-monitoring processes (e.g. proficiency tests, reference materials) • appropriate monitoring of environmental conditions • communication systems between the site and laboratory • completeness of record-keeping • management of non-conforming laboratory work • review of laboratory performance and operations.

Clause	Requirements
5.6.7	Procedures shall be in place to ensure reliability of laboratory results, other than those critical to safety and legality specified in clause 5.6.6. These shall include: • use of recognised test methods, where available • documented testing procedures • ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required • use of a system to verify the accuracy of test results (e.g. proficiency testing where applicable) • use of appropriately calibrated and maintained equipment.
Interpretation	**Management of tests not critical to safety and legality** This requirement applies to non-critical product testing. While such tests need not be carried out by a laboratory accredited to ISO/IEC 17025, it is nonetheless important that the results can be relied upon. The clause sets out the documented procedures which must be in place to provide confidence in reliability. In accordance with good laboratory practice, all laboratory testing should be suitability-controlled irrespective of the nature of the tests. Clause 5.6.6 clarifies the requirements for tests relating to product safety, authenticity and legality.

5.7 Product release

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

Interpretation

The site must have a process to ensure that finished product is not released from its control until all production checks have been completed and reviewed. Completion of end-product testing may not be applicable prior to the release of all products. (An example would be microbiological checks on short-shelf-life products such as sandwiches.) However, there must be appropriate checks on the CCPs to ensure that the process was within specification before product is released from the company's control. This allows product to be held when a review of the process checks identifies a potential problem.

Clause	Requirements
5.7.1	Where products require positive release, procedures shall be in place to ensure that release does not occur until all release criteria have been completed and the release has been authorised.
Interpretation	**Management of positive release** Where products are held either on or off site awaiting positive release, there need to be documented procedures describing the process for release and who authorises it. The procedures need to be sufficiently robust so that accidental release cannot occur; for example, having password control on a computerised system to prevent unauthorised picking of held product, or using the physical identification of pallets in the warehouse.

5.8 Pet food and animal feed

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

Interpretation

For example, pet food and animal feed need to be considered as part of the food safety plan (HACCP), as detailed within section 2 of the Standard.

Where a site produces by-products of the food manufacturing process or sells downgraded/surplus products for animal feed, the requirements for this process are detailed in section 4.13, especially clause 4.13.3.

Where a site does not manufacture pet food/animal feed, this section can be marked as not applicable (n/a).

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

Interpretation

Pet food and/or animal feed is manufactured in the same type of environment as food for human consumption, but there are some specific additional requirements that reflect the nature of pet food and animal feed manufacture.

Clause	Requirements
5.8.1	The site shall ensure that pet food and animal feed is formulated/designed for the intended use (e.g. where products are designed for complete diet or as a complementary product).
Interpretation	**Pet food and animal feed product development** Pet food and animal feed are unique in that a product can be designed for complete diet (i.e. a pet may eat the same product at every meal, often without other additions to the diet) or as a complementary product (e.g. as an addition to certain meals or as an occasional treat). The formulation and design (e.g. nutritional composition, portion size etc.) is therefore likely to be different depending on the intended frequency of consumption (complete or complementary). Auditors will expect to see documented evidence that this formulation requirement has been considered (e.g. in new product development processes, recipe design and/or specifications).
5.8.2	Where a site's product range includes pet food or animal feed products for different animal species, the site shall have specific procedures for the management of any ingredients, raw materials, products or rework that could be harmful to unintended recipients.
Interpretation	**Pet foods and animal feeds for different species** Sites that produce pet food and/or animal feed for many different animal species (e.g. cats, dogs, fish) must be aware that some ingredients cannot be safely eaten by all species without deleterious effect. For example, there are foods that can be fed to cats but not dogs because of their different dietary requirements. Therefore, sites should consider: • a system to identify materials that could potentially be harmful to unintended recipients (i.e. to other species of pets). This shall include raw materials, processing aids, intermediate and finished products, and any new product development ingredients or products

Clause	Requirements
Interpretation *continued*	• a system to ensure incorrect ingredients cannot be used • procedures (e.g. cleaning procedures) to prevent cross-contamination from the production of one type of pet food into the subsequent pet food for a different species • specific procedures to ensure correct labelling of intended animal species and any limitations on use.
5.8.3	Where the site manufactures, processes or packs pet food or animal feed products that contain medicinal substances, the site shall have specific procedures for the management of the medicated raw materials and finished products. At a minimum, these procedures shall include: • identification of medication-containing materials handled on site. These can be raw materials, processing aids, intermediate and finished products, rework or any new product or product development ingredients • supplier approval equivalent to section 3.5.1 for all medicated raw materials • specific staff training on the correct handling of medicated materials • mechanisms to ensure the correct concentrations of medicinal substances in finished products • procedures (e.g. cleaning procedures) to prevent contamination of non-medicated pet food or animal feed with materials containing medicinal substances • specific procedures to ensure the correct labelling of medicated pet food or animal feed • waste disposal mechanisms (see section 4.12) that include the safe and legal disposal of medicated raw materials and products.
Interpretation	**Medicated products** If a site manufactures pet food and/or animal feed which contains medicinal substances, it is vital that these materials (both the raw materials and the finished products) are controlled to ensure correct doses and prevent cross-contamination. At a minimum, procedures must: • ensure clear identification of medicated materials (raw materials, processing aids, intermediate products, rework and finished products) throughout the receipt, storage and manufacturing processes, so that all staff are aware that the material is medicated and of the nature of the medication. This is important where multiple medicated substances are handled on site • include supplier approval in accordance with section 3.5.1 for all medicated raw materials (in addition to the other feed ingredients which are already covered in section 3.5.1); for example, raw material risk assessments, supplier approval and monitoring procedures • ensure relevant product safety training, as required by section 7.1 of the Standard. If the site handles medicated materials, training must provide specific information on the handling of these materials and any relevant procedures specifically related to the medicated substances • include processes to evaluate the correct doses of medicated substances for new product development, recipes and specifications • ensure that only the correct amounts of medicated substances are added to the batch during manufacture. Any features of the manufacturing process that could affect these concentrations (e.g. uneven distribution through the batch or a production process that effectively concentrates the medication such as a cooking process that causes water loss) must be considered

Clause	Requirements
Interpretation *continued*	• prevent cross-contamination from the production of medicated pet food into subsequent pet food which should not contain the medication. This applies principally to cleaning procedures. Medicated substances and products containing them are likely to be subject to additional procedures and legal requirements; for example: • specific storage requirements • segregation between medicated and non-medicated materials and products (both in storage and during production) • handling of waste materials in a way that is legal and prevents product contamination (as already highlighted in section 4.12). Medicated substances, and products containing them, are likely to require specific procedures to ensure safe and legal waste disposal; for example, controlled disposal, licensed contractors, prevention of environmental contamination.
5.8.4	Site procedures shall be designed and implemented to meet the relevant pet food and animal feed product safety legislation (both in the country of production and in the country of sale).
Interpretation	**Legislation** Different parts of the world have different legislative requirements relating to pet food and animal feed. For example, in the UK, the production of pet food using materials of animal origin and animal by-products needs to be registered with the Animal and Plant Health Agency (APHA), and the EU Animal Feed Regulations apply, such as the regulation regarding the placing of animal feed on the market. Clause 1.1.8 requires sites to have systems in place to ensure that they remain up to date with product safety legislation (as well as other aspects of good practice). Clause 5.8.4 requires that legislation is converted into practice, such that site procedures are designed and implemented to meet the legislative requirements in both the country of manufacture and the country where the product is sold.

5.9 Animal primary conversion

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

Interpretation

Animal primary conversion is defined as completing the slaughter and/or evisceration of animals (including red meat, poultry and game) or the slaughter and/or gutting of fish. Applicable sites will therefore fall within BRCGS product categories 1, 2 or 4.

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

Interpretation

Specific controls are required to ensure that food remains safe, authentic and legal during animal primary conversion.

The clauses in this section are closely linked to clauses in other sections of the Standard and the interpretation provided with them.

Clause	Requirements
5.9.1	The company shall undertake a risk assessment for potential prohibited substances (i.e. those prohibited by legislation in the country of operation or intended country of sale). Example substances include pharmaceuticals, veterinary medicines (e.g. growth hormones), heavy metals and pesticides. The risk assessment may be completed as part of clause 3.5.1.1 or as a separate activity. The results of the risk assessment shall be included in raw material acceptance and testing procedures and in the processes adopted for supplier approval and monitoring (see clauses 3.5.1.2–3.5.2.2).
Interpretation	**Prohibited substances risk assessment** Many countries have legislation relating to substances that are prohibited in food, and specifically meat and products of animal origin. A risk assessment is therefore required to assess the risk of raw materials containing these substances. The Standard does not provide a definitive list of prohibited substances, as this will depend on the location of the site and the countries where the products will be sold; however, examples include pharmaceuticals, veterinary medicines (such as growth hormones), specific heavy metals and pesticides. This activity may form part of the larger risk assessment completed on all raw materials (see clause 3.5.1.1), be completed as part of the HACCP process (see clause 2.7.1) or be completed as a separate activity. Section 3.5.1 requires the company to have supplier approval and monitoring processes, and the output from this risk assessment must be included in those activities.
5.9.2	Where the site is in receipt of live animals, there shall be an inspection by a suitably competent individual at lairage and post-mortem to ensure that the animals are fit for human consumption.
Interpretation	**Live animal inspection** This requirement relates only to sites that are in receipt of live animals, such as slaughterhouses and sites receiving live fish. The purpose of the inspection is to ensure that the animals are not diseased and are fit for slaughter for human consumption. The inspection must be carried out both before and after slaughter. It should also identify any live animals that may present an increased risk of cross-contamination in the plant; for example, excessively dirty or salmonella-positive flocks. Such animals require extra actions, such as cleaning or slaughter at the end of production, to prevent cross-contamination of unaffected animals or products. In most countries, official veterinary inspections occur before and after slaughter. This fulfils the primary requirements of the clause. In the absence of an official veterinary inspection, the checks must be carried out by site staff who understand the signs of disease that present a risk to human consumption and any legislative requirements, and who have the authority to reject animals or organs.

Clause	Requirements
Interpretation *continued*	Where an animal is found to be unfit for human consumption, the site would be expected to have procedures in place for the segregation of unfit meat or animals to prevent them from entering the human food chain. Records should be kept of the inspections.
5.9.3	The site shall operate procedures to ensure that the traceability of all edible parts of the carcass (i.e. all parts that are intended for the human food supply chain) is maintained.
Interpretation	**Traceability of all edible parts of the carcasses** The site must operate appropriate procedures to ensure that the traceability of all edible parts of the carcass (i.e. those intended for the human food chain) is maintained, including blood or other by-products for human consumption. Similarly to clause 3.9.1, the Standard is not prescriptive on the traceability system used. However, the site must be aware of any limitations of the traceability systems used. If a carcass is deemed unfit for consumption, all edible parts associated with that carcass need to be removed from the product flow. If traceability is to the day or batch rather than to specific carcasses, in the event of a product withdrawal or recall, the whole day of production or batch may need to be recalled for each edible part. The site must document its traceability procedure, and ensure relevant personnel are trained in it and it is fully implemented. Note that for the purposes of this clause, edible parts include any part of the carcass which enters the human food chain (including offal, animal by-products for human food chain, and blood for human consumption; e.g. in the UK, blood is incorporated into the manufacture of black pudding). The site should be aware that in addition to a documented procedure, traceability requires a number of activities including identification of raw materials, intermediate/semi-processed products, part-used materials, and finished products in accordance with clause 3.9.2.
5.9.4	The site shall establish defined time and temperature requirements for all post-slaughter processes (for example, post-slaughter cooling, processing, storage and distribution). These requirements shall be defined for all chilled or frozen, edible parts of the carcass.
Interpretation	**Post-slaughter time and temperature** Clause 6.1.1 requires the site to have documented process specifications and work instructions for all key processes that may adversely affect product safety, legality and quality. This requirement specifically focuses on the need for post-slaughter times and temperatures to ensure product safety. These must be available for: • all edible parts intended for the human food chain • all parts of the post-slaughter process including, for example, initial cooling (and time to reach intended carcass temperature), any processing stage, storage and distribution.

6 Process control

6.1 Control of operations

Fundamental

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

Interpretation

The principle of these requirements is to ensure that the documented HACCP or food safety plan is put into operation on a day-to-day basis, together with effective procedures to ensure that the product can be produced:

- to food safety and legality requirements
- consistently to the specified quality.

Note that this section of the Standard covers production facilities. In conjunction with these requirements, sites may find it useful to consider sections 4.15 (product storage) and 4.16 (management of transportation/distribution of the product).

Clause	Requirements
6.1.1	Documented process specifications and work instructions/procedures shall be available for the key processes in the production of products to ensure product safety, legality and quality. The process specifications and work instructions/procedures (as appropriate) shall include: • recipes – including identification of any allergens • mixing instructions, speed, time • equipment process settings • cooking times and temperatures • cooling times and temperatures • labelling instructions • coding and shelf-life marking • storage conditions (e.g. storage temperatures) • any additional critical control points identified in the HACCP or food safety plan. Process specifications shall be in accordance with the agreed finished product specification. The site shall review the process specifications and work instructions/procedures prior to any changes which may affect food safety, legality and quality.

Interpretation

Manufacturing instructions and process specifications

Documented process specifications, procedures or work instructions must be available for all key stages of the operation. These documents must be readily available to staff in the area in which the activity is undertaken. The documents must be sufficient to ensure that all key process parameters are specified and controlled, thereby ensuring that manufactured product consistently meets safety, legality and quality specifications.

Clause	Requirements

Interpretation *continued*	Note that while some of these key processes are likely to be CCPs or equivalent, they are unlikely to be limited to just CCPs, and sites may need to consider other control points and prerequisites to ensure all relevant parameters are captured. The Standard lists some examples including (although this is not an exhaustive list):
	• recipes – including identification of any allergens
	• mixing instructions such as speed and time
	• equipment process settings; for example, line speed, which may in turn affect other online food safety and quality activities such as:
	  • the performance of metal detectors, check weighers and automated packaging accuracy checks
	  • manual inspection for quality
	  • cooking, chilling and freezing where this is completed using a continuous production line
	• cooking times and temperatures
	• cooling times and temperatures
	• labelling instructions
	• coding and shelf-life marking – it is worth noting that product recalls have occurred when date codes are incorrectly calculated and incorrect information printed on the pack
	• storage conditions (e.g. storage temperatures) for raw materials, intermediates and final products
	• any additional critical control points identified in the HACCP or food safety plan.
	
	Staff must be trained in the work instructions relevant to their role (section 7.1). Manufacturing instructions and process specifications must correctly reflect customer requirements, such as final product specifications. The equipment settings must be checked to ensure that the equipment is set up correctly for the specific product in production, and labelling instructions (such as particular requirements for label positioning on the pack) must be followed.
	
	Specifications for work in progress are not applicable to all products. For example, when a product is manufactured in several stages and combined to form the final product, or when a product is partially processed and retained for future processing, a separate specification for that product may be required. It must detail the important criteria that affect the finished product quality or safety parameters (e.g. brix, weight, colour, shelf life or storage conditions) and must include the acceptable range of each parameter.
	
	Simple photographic specifications, including minimum, target and maximum grading levels for parameters such as size and colour, may be appropriate for production staff.
	
	The site must ensure that process specifications and work instructions remain up to date, and therefore needs a review process that ensures that documents are updated prior to any changes.

6.1.2	Where equipment settings are critical to the safety or legality of the product, changes to the equipment settings shall only be completed by trained and authorised staff. Where applicable, controls shall be password-protected or otherwise restricted.

Clause	Requirements
Interpretation	**Equipment settings** As with any electronically stored data or records, equipment settings for product safety and/or legality should be adjusted only by trained and competent members of staff, and controls should be in place to ensure that this remains the case. Where equipment has the capacity for password protection or other restrictions such as locked controls, these should be used to ensure that only trained and authorised staff can make the amendments. Where equipment does not include these functions, the site will need to identify alternative mechanisms of control.
6.1.3	Process monitoring, such as temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification.
Interpretation	**Process monitoring** Processes must be adequately controlled and monitored to ensure that product is produced within specification. These processes may include CCPs or prerequisite programmes addressing issues such as temperature, time, pressure and chemical properties. Monitoring must be carried out at suitable frequencies based on experience of the reliability of equipment, frequency of process changes, and risk to product safety and quality. The frequency of checks should be included on recording forms and/or in procedure documentation. A record of all monitoring must be maintained. Where processes are shown to have exceeded defined limits, corrective actions must be taken and this action must be recorded (clause 6.1.6).
6.1.4	In circumstances where process parameters or product quality are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.
Interpretation	**In-line monitoring devices** Where process parameters or product quality are controlled by in-line monitoring devices (e.g. automatic temperature or pH loggers), they must be linked to a suitable failure alert system (e.g. audible/visual alarm, machine stop function or product divert system) which is activated when defined parameters are exceeded. This alarm must be tested routinely to ensure that it functions properly, and records must be maintained.
6.1.5	Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated and verified at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores).
Interpretation	**Critical safety or quality parameters** The objective is to ensure that products can be consistently produced and stored within clearly defined parameters (e.g. within defined temperatures). It is recognised that process conditions are often not uniform throughout a chill store or an oven. It is important,

Clause	Requirements
Interpretation *continued*	therefore, to identify hot or cold spots, both to try to improve uniformity and to identify worst-case scenarios to ensure that all products meet at least the minimum process conditions. The Standard includes some common examples of equipment parameters such as: • heat distribution in retorts, ovens and processing vessels – the Standard expects heat-distribution studies to be carried out on cooking equipment wherever small variations in process temperature may affect the safety of the products. Heat-distribution studies of a static oven may identify cold spots. If it is not possible to make adjustments to eliminate these cold spots, the areas should be used as the worst-case scenarios when completing heat-distribution studies • temperature distribution in freezers and cold stores – when assessing whether to undertake temperature distribution studies on chill or freezer facilities, the level of risk will depend on the product, the time spent in store and any margin allowed by the temperature settings (e.g. setting the temperature at −20°C to ensure achievement of −18°C). Temperature distribution studies would not normally be necessary for small chill or cold stores where product is stored only for short periods. However, this is not a prescriptive list, and the site should consider all situations where variations in processing conditions may occur in equipment critical to the safety or quality of products. For example, if pH is identified as critical, it may be necessary to validate the pH distribution in a mixing vessel, and consider the thoroughness of the mixing process to achieve the desired pH throughout the batch. When testing equipment, any seasonal variations in performance must be considered, especially when trying to assess worst-case scenarios. For example, a chiller evaluated in winter may not give the same results in summer, especially if there are large seasonal differences in the ambient temperatures. Some refrigeration equipment may be at the limit of their performance on especially hot days if temperature parameters have not been properly specified.
6.1.6	In the event of equipment failure or deviation of the process from specification, procedures shall be in place to establish the safety status and quality of the product to determine the action to be taken.
Interpretation	**Equipment failure and results outside defined limits** In cases of equipment failure or deviation from process or specification (e.g. outside the critical limit), the company must have defined procedures in place to ensure that the product is safe prior to its release. At a minimum, this should include: • identification of all products at risk (i.e. product produced since the last satisfactory check) • how the affected product will be assessed for suitability/safety (this may include sensory testing, microbiological sampling, reference to thermal process data or the use of mathematical modelling techniques, depending on the product and issue) • who is authorised to undertake action and make a final decision on the affected product. Where product safety, authenticity, legality or quality is implicated, the site may need to apply its non-conforming product procedures (see section 3.8). Records must be kept of any deviation and the action taken.

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

Interpretation

Exclusions from audit scope

This aim of this requirement is to ensure that the site has considered and managed any potential product safety, authenticity and legality risks associated with products or materials that are outside of the scope of the BRCGS audit.

During the audit, the auditor may request information or watch the process, to ensure procedures are in place and completed appropriately, and therefore do not represent a risk to the products within scope.

Examples of products outside of scope include, but are not limited to:

- by-products of the manufacturing process, which are not permitted to be included in the scope of the Standard (e.g. materials taken for non-food use)
- exclusions from scope (in accordance with section 1.6.2 of the audit protocol).

6.2 Labelling and pack control

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

Interpretation

One of the common causes of withdrawals and recalls is incorrectly packed products and labelling (e.g. allergen labelling) that does not reflect the actual content of the product. Therefore the aim of this section is to ensure that the site has effective procedures to manage packing operations and to pack products in the correct packaging.

Packaging controls must be in place which ensure the whole packing process is documented and working effectively. These controls must be managed by nominated staff who have received specific labelling and packing process training (see clause 7.1.5).

Sites may find it beneficial to consider this section in conjunction with sections 5.2 (product labelling) and 5.5 (product packaging), which detail requirements on the design and purchase of packaging and labels.

Clause	Requirements
6.2.1	There shall be a formal process for the allocation of packaging materials to packing lines and control in the packing area which ensures that only the packaging for immediate use is available to the packing machines. Where offline coding or printing of packaging materials occurs: • setting and amendments to the printer parameters (e.g. the input of, or changes to, date codes) shall only be completed by an authorised member of staff • controls shall be in place to ensure that only correctly printed material is available at the packing machines. Processes shall be in place to check label use is reconciled with expected use and the cause of any inconsistencies investigated.

Interpretation

Allocation of packaging materials

Packaging for each production run must be brought to the line in a formal and controlled manner following a documented process.

Only the packaging required for immediate use should be available to the packing line at any one time. Ideally, this will be achieved by only releasing new packaging from the store when all packaging from the previous run has been removed from the area. Where this is not possible (e.g. because of off-site packaging stores), a mechanism must be in place to ensure that only the relevant packaging can be released to the packing line (e.g. by storing packaging in a designated, secure location with authorised access).

Where multiple component packaging is used (e.g. pots with separate lids, multi-packs or packaging with separate labels), then the controls will need to apply to all the individual parts, to ensure they all match the product being produced.

The integrity of date codes is vital to ensure product safety is maintained. Where date codes (or other information) are applied to packaging or product on site (e.g. on the trays, sleeves or flow wraps), this must be controlled so that only authorised (and competent) personnel can set or make the changes to printers (e.g. inputting the required date code).

Processes must be in place to ensure that, after the product run, any unused labels are removed from the packaging line.

Checks must be in place to monitor that actual label use matches expected label use (i.e. the actual and expected uses are reconciled). The aim is to confirm correct usage, and therefore provide an opportunity for any inconsistencies or unexpected results to be investigated. The Standard is not prescriptive on how this is completed; however, the site may find it useful to consider:

- the typical waste tolerance, i.e. how many labels are typically wasted or destroyed during a production run (this allows normal waste figures to be included in the reconciliation)
- the number of labels received, issued, used or restocked, along with any obsolete, misprinted or destroyed labels that need to be accounted for
- systems for recording packing information; for example, when new reels or new batches of labels are added to the line
- the frequency of the checks – for most sites, this is likely to be at the end of each production run, as this allows investigation of any inconsistences while the product is still within the site's control. However, there may be situations, for example, with very long production runs, where an alternative frequency is justified

Clause	Requirements
Interpretation *continued*	• the system to be used to complete the check; for example, an automated label check and accounting system or a manual check system could be used, either of which might take the form of a formal mass balance at the end of each production run, or of a stock take. Any inconsistencies or unexpected results must be investigated to ensure correct label use. Where appropriate, non-conforming product procedures (see section 3.8), corrective action, root cause analysis and preventive actions may be required (see section 3.7).
6.2.2	Documented checks of the production line shall be carried out before commencing production and following changes of product. These shall ensure that lines have been suitably cleared and are ready for production. Documented checks shall be carried out at product changes to ensure that all products and printed packaging and labels from the previous production have been removed from the line before changing to the next production.

Interpretation	**Production line checks**
	
	Sites are required to manage product changeovers and line start-ups to ensure the line is ready and correctly set for the next production run. If changeover is completed incorrectly, this represents a weakness at a key point in the production process, which could result in the production of non-conforming products; for example:
	
	• incorrect products being packed
	• incorrect labels being used (a major cause of product withdrawals and recalls in several parts of the world)
	• insufficient cleaning between products, resulting in:
	  • the potential for microbiological or allergen cross-contamination
	  • quality issues related to the product being contaminated or tainted with previous products
	• incorrect process parameters being used, e.g. cooking times and temperatures, or incorrect date coding.
	
	Documented checks carried out on the production line before production commences must therefore ensure that systems are correctly set and running. Checks must include confirmation that:
	
	• lines have been suitably cleaned
	• lines have been cleared of any packaging from previous production runs
	• lines are ready for production, with CCPs and quality parameters correctly set (e.g. metal detector checks completed satisfactorily, cookers set to the correct temperature programme, correct packaging selected).
	
	If the line is set up with equipment that has not been used for some time, there may be a need to re-disinfect food contact surfaces immediately prior to use, or undertake additional line checks, to ensure appropriate set-up (for example, that condition monitoring has been completed and the correct operating settings selected).

Clause	Requirements
Interpretation *continued*	Checks are also required following changes of product to ensure that all product, packaging and labels from the previous production have been removed and, where appropriate, to ensure that both cleaning and line set-up have been completed correctly for the new product. Line checks are usually the responsibility of the line manager or supervisor. Evidence that checks have been carried out (e.g. line check sheets) and guidelines on the checks to complete should be available. During the audit, the auditor will normally expect to witness at least one product changeover, and wherever practical at least one line start-up. There may be exceptional circumstances where a site has very long production runs, or situations where there are no scheduled product changeovers during the audit (as when the length of the production run is longer than the number of days that the auditor is on site), and therefore the inclusion of a product changeover or a line start-up is not possible; however, this must be considered exceptional, and any exceptions or omissions will be detailed in the audit report.
6.2.3	Procedures shall be in place to ensure that all products are packed into the correct packaging and correctly labelled. These shall include checks: • at the start of packing • during the packing run (e.g. at predefined intervals and when printed packaging or labels are brought to the line during the production run) • when changing batches of packaging materials at the end of each production run. The checks shall also include verification of any printing carried out at the packing stage including, as appropriate: • date coding • batch coding • quantity indication • pricing information • bar coding • country of origin • allergen information.
Interpretation	**Packaging controls** A high proportion of product withdrawals/recalls are because of products being packed into incorrect packaging or incorrectly labelled. Therefore, specific documented packaging controls must be in place. Particular care is required where: • a number of similar-looking products are manufactured • a standard product may be packed into different types of packaging • there is a family of very similar labels for a product range, each containing different information (e.g. the presence of different allergens or different use-by/best-before dates). Procedures must be in place to verify that adequate checks have been carried out to minimise potential errors. The frequency of checks must be predefined, based on risk assessment, but at a minimum those checks specified in the requirement must be included: • at the start of packing – this is especially useful to confirm the correct packaging and labels are being used, and that line changeover procedures (clause 6.2.2) have effectively removed all labels from the previous run

Clause	Requirements
Interpretation *continued*	• during the packing run (i.e. at predefined intervals); for example, the risk assessment may have identified a maximum frequency based on previous experience, or a maximum amount of product based on the site's ability to recover and check product in the event of a failure • when changing batches of packaging materials; for example, when each new reel of labels or new batch of packaging is added to the line • at the end of each production run. The packing run can be defined as a batch or lot (e.g. each time a new reel is used), or another distinct period. The intention is to ensure that the site is maintaining control over pre-printed packaging materials and their packing. The procedures must also include verification of any code information or other printing carried out at the packing stage (i.e. applied by the site). This verification shall include those checks as specified in the requirement. Packaging and label checks should be recorded.
6.2.4	Where online verification equipment (e.g. bar code scanners) is used to check product labels and printing, the site shall establish and implement procedures for the operation and testing of the equipment to ensure that the system is correctly set up and capable of alerting or rejecting product when packaging information is out of specification. At a minimum, testing of the equipment shall be completed at: • the start of the packing run • the end of the packing run • a frequency based on the site's ability to identify, hold and prevent the release of any implicated materials should the equipment fail (e.g. during the packing run or when changing batches of packaging materials). The site shall establish and implement procedures in the event of a failure in the online verification equipment (e.g. a documented and trained manual checking procedure).
Interpretation	**Online vision equipment** Some sites have found that the use of automated online vision equipment (e.g. bar code scanners or cameras) provides a beneficial check of the accuracy of the packing operation. This equipment is able to check that the correct packaging has been consistently used throughout the packing run and that the correct date code has been applied. Any out-of-specification information (as when the wrong packaging is used) is identified by this equipment, and staff are either alerted or the product is rejected out of the product flow. Where a company chooses to use this type of equipment, it is important that procedures are in place to ensure that it is correctly set up and operates effectively throughout the packing run. At a minimum this will include checks: • at the beginning of the packing run, so that the equipment is confirmed to be set up correctly before packing commences • at the end of the packing run, to confirm that the equipment is still operating effectively when packing is completed

Clause	Requirements
Interpretation *continued*	• during the packing run, at a frequency based on risk (i.e. based on the site's ability to take appropriate action in the event of an adverse test result, before the implicated materials are released from the site). Depending on the function of the vision system, incorrect packaging might include the wrong packaging, an incorrect date code or an obscured label. Due to the variations in the different types of online vision equipment, the testing procedures are not prescribed in the Standard. However, where the verification equipment exists as a separate item of equipment (situated, for example, towards the end of a production line, similar to the common placement of metal detectors), good practice is to test the system using incorrect packs to ensure that the equipment identifies and rejects those packs. It is important that these test packs are clearly marked so that they cannot inadvertently enter the process flow. The method can be used to check each function of the equipment (e.g. detection system, rejection mechanism or line stop, authorised restart and mis-read/non-read alarm). However, where the verification equipment is integral to another piece of equipment on the packing line (e.g. based on cameras or scanners built into the printer, or printed film roll dispensers), or is situated where packaging is constructed (e.g. where cardboard boxes are glued immediately prior to the camera), it may not be possible, or practical, to insert incorrect packaging as a means of testing. In these situations, the site may devise alternative testing solutions. For example, before the packing run begins, a test programme could check each function of the verification equipment by causing the instrument to reject the existing/correct packaging. The site must consider the procedures it would follow in the event of an equipment failure (e.g. a backup plan).

6.3 Quantity – weight, volume and number control

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

Interpretation

The site must ensure that products meet the requirements of customers and the legislation of the country, state or territory where the product is sold.

Clause	Requirements
6.3.1	The frequency and methodology of quantity checking shall meet the requirements of the appropriate legislation governing quantity verification, and records of checks shall be retained.
Interpretation	**Quantity control – legislative requirements** The type of quantity control used (e.g. average weights, catch weight, minimum weight or count) may be determined by the company in conjunction with the requirements of the customer.

Clause	Requirements
Interpretation *continued*	The system used must operate to the legal requirements in the country, state or territory in which the product is sold. Potential changes during transport and shelf life (e.g. weight loss during transport or water loss (desiccation) during storage) may need to be factored in, so that the weight at the end of shelf life continues to meet statutory and customer requirements. Adequate records must be kept or, where automatic check-weighing equipment is used, this must be properly set up and the rejection system tested according to industry-sector guidelines. Checks of automatic reject systems must be carried out using representative packs of the product being produced. The colour-coding of the clause indicates that it should be audited during on-site audits of production areas where the equipment is located, as the auditor will normally expect to see the process in operation, and not just a review of records.
6.3.2	Where the quantity of the product is not governed by legislative requirements (e.g. bulk quantity), the product shall conform to customer requirements and records shall be maintained.
Interpretation	**Quantity control – customer requirements** Where there are no legislative requirements (e.g. where bulk quantities are supplied to the customer), procedures must be in place to ensure that customer requirements are met (e.g. monitoring by flow meter or calibrated weighbridge for tanker loads). Good practice is to ensure that the customer requirements are clearly defined; for example, in a specification or buying contract. Records must be maintained.
6.3.3	Where used, the site shall establish procedures for the operation and testing of online check weighers. At a minimum, this shall include: • consideration of any legal requirements • responsibilities for testing the equipment • operating effectiveness and any variations for particular products • methods and frequency of testing the check weighers • processes for handling rejected packs • records of the test results.
Interpretation	**Online check weighers** A check weigher is defined as automated equipment for checking that the weight of products is correct and within relevant limits (e.g. it meets legislative and customer limits). The equipment must be sufficiently rigorous for the intended purpose. For example, a check weigher that is simply used to provide a rough check during production is likely to be less critical to product legality than one used to verify legal compliance of a final product. The effective operation of a check weigher must be verified within the context of legal requirements (e.g. minimum fill weights against declaration), and its function must be assured through testing and operation.

Clause	Requirements
Interpretation *continued*	The Standard lists the minimum items that the site procedures will need to include: • consideration of any legal requirements – depending on the product and the legislation in the country of sale, this might include minimum weight, average weight, maximum weight (for example, if large portion size affects minimum cooking times for food safety) etc. • methods, frequency and responsibilities for testing the equipment – the method of testing the check weigher; the actions to take if it fails the test; how frequently the tests are completed and the staff responsible for completing them. In accordance with section 7.1, staff will need to be trained in the correct procedures • operating effectiveness and any variations for particular products (e.g. any known and permitted variations) • processes for handling rejected packs; for example, ensuring underweight packs are removed and do not re-enter the product flow, procedures indicating whether packs can be opened and the content returned to the product flow, any investigation needed as a result of rejected packs • records of the test results. Clause 6.4.1 details the requirement for calibration of measuring equipment, which includes check weighers. The methodology of testing should be documented, and the operator or person with responsibility for the check weigher should understand the expected output and frequency. Particular consideration should be given to the location of the check weigher to ensure that results accurately reflect the batch of product leaving the site. For example, if the site locates metal detectors, or sampling points after the check weigher, it may need to consider the implications of the removal of product by those systems on, for example, average weight calculations.

6.4 Calibration and control of measuring and monitoring devices

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

Interpretation

The site must ensure that key pieces of equipment that control and monitor processes are themselves confirmed as operating effectively and accurately. This is routinely confirmed by measurement against recognised standards. Where national or international standards do not exist, the company needs to demonstrate how the equipment is adequately monitored.

Clause	Requirements
6.4.1	The site shall identify and control measuring equipment used to monitor critical control points and product safety, legality and quality. This shall include, at a minimum: • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration or misuse.

Clause	Requirements
Interpretation	**Identification and control of measuring equipment** The site needs to identify the measuring equipment (e.g. scales, thermometers and pH meters) that is used to monitor CCPs, product safety, legality and quality. At a minimum, this equipment must be: • documented in a list which details the location of each item of equipment • marked in accordance with its calibration requirements; for example, with an identification code and the calibration due date. This may be achieved by engraving the piece of equipment with a number that cross-references to the documented list, or labelling the equipment with its calibration due date. Where equipment (e.g. a pH meter) is calibrated daily or more frequently, this could be addressed by a procedure that clearly states the frequency of calibration and a record of the daily calibration activities • protected against unauthorised adjustment (e.g. through the use of programme ID codes or locking keys) • protected from damage or misuse through good design or the training of staff.
6.4.2	All identified measuring devices, including new equipment, shall be checked and, where necessary, adjusted: • at a predetermined frequency, based on risk assessment • to a defined method traceable to a recognised national or international standard where possible. Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform.
Interpretation	**Calibration checks** The site needs to establish the method by which the precision and accuracy of equipment is verified. This must include: • a predefined check frequency, based on a risk assessment (e.g. historical reliability, nature of use, manufacturer's recommendations) • who is authorised to complete the checks (e.g. trained staff) • the method to be used (which must, where possible, be traceable to a recognised standard, e.g. use of a master calibration thermometer that has a certified test certificate traceable to a national standard). Equipment must be of a suitable accuracy for the measurements it is required to perform. For example, where temperature is critical to the safety of a product (as in pasteurisation or the canning process), the measuring thermometer requires an accuracy of ±0.5°C, whereas a thermometer used to check vehicle temperatures may only need an accuracy of ±1°C.
6.4.3	Reference measuring equipment shall be calibrated and traceable to a recognised national or international standard and records maintained. The uncertainty of calibration shall be considered when equipment is used to assess critical limits.

Clause	Requirements
Interpretation	**Reference equipment** All reference equipment (e.g. a master thermometer) must be calibrated and traceable to a national or international standard. Where equipment is used to measure or monitor a critical limit, it is important that the tolerance (or uncertainty) of the calibration is considered. For example, if a thermometer is required to measure a critical limit of 72°C, but the calibration shows an uncertainty of 0.5°C, then a thermometer reading of exactly 72°C could in fact represent a true temperature of anywhere between 71.5 and 72.5°C (i.e. the temperature could be lower or higher than the critical limit). In this situation, to guarantee a minimum temperature of 72°C, it would be necessary for the reading on the thermometer to always be 72.5°C or higher. Records must be kept.
6.4.4	Procedures shall be in place to record actions to be taken when the prescribed measuring devices are found not to be operating within specified limits. Where the safety or legality of products is based on equipment found to be inaccurate, action shall be taken to ensure at-risk product is not offered for sale.
Interpretation	**Equipment outside specified limits** Documented procedures must detail the action to be taken when equipment is found to be outside specified limits. The documentation must specify what will be done and by whom, and must include what will happen to products that have been monitored by this equipment since the last successful check (to prevent at-risk products from being offered for sale). Records must be kept of the actions taken.

7 Personnel

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

Fundamental
The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.

Interpretation

Training is a fundamental requirement of the Standard, as without properly trained and competent staff, it is unlikely that product safety, authenticity, legality or quality procedures can be completed in a rigorous and consistent manner. Staff must therefore have the knowledge and skills to undertake their role, and must understand the impact their actions will make.

Companies must ensure that all training is up to date, covering relevant product safety, legality and quality requirements.

Seasonal/temporary personnel and contractors must be included. Where employment agencies are used for the provision of staff, all the requirements in this section need to be adequately met and evidenced. This may include:

- specifying company policies within any supply contract
- obtaining evidence of staff training records from the agency prior to a staff member commencing work
- using a risk-based system to challenge staff understanding and ensure competence in carrying out roles.

Employment agencies are subcontracted service providers whose business is to assist companies in filling vacant positions. Agency staff are often used to fill temporary positions, such as those caused by seasonal variations in production.

Clause	Requirements
7.1.1	All personnel, including agency-supplied staff, temporary staff and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.

Interpretation

Initial training and supervision

The company must ensure that all staff, including temporary staff, agency-supplied staff (see statement of intent) and contractors, receive training.

All staff will need some level of training; this should be proportional to their responsibility and the type of work or activity they perform. The company is responsible for defining the training requirements appropriate for each specific role (see clause 7.1.3).

For example, the following training options may be considered:

- induction training for all staff, covering company policies on hygiene, allergen awareness (see clause 7.1.4), quality requirements, entry and exit procedures, pest control, a basic introduction to HACCP, etc.
- obtaining a qualification in 'basic food hygiene' for food handlers

Clause	Requirements
Interpretation *continued*	• training in areas that impact food safety, such as cleaning, machine operation, quality inspections and sampling • CCP monitoring (see clause 7.1.2). All personnel must be adequately supervised throughout the working period. Particular attention should be paid to identifying the needs of temporary/seasonal workers and contractors. Good practice is for new starters to have additional supervision for a defined period. This additional supervision can be reduced or removed at the end of the period following a review of the employee's competency to complete the role (see clause 7.1.7).
7.1.2	Where personnel are engaged in activities relating to control measures and critical control points, relevant training and competency assessment shall be in place.
Interpretation	**Critical control point training** To ensure that activities identified as either control measures or critical control points (CCPs) within the food safety plan or HACCP are managed correctly, personnel involved in these areas must be appropriately trained in the relevant procedure. This includes the operation of the control and monitoring activities and the implementation of corrective action. Clear, documented instructions must be available, detailing: • how to carry out the tasks • when the tasks are to be completed • records to be maintained • action to be taken in the event of a non-conforming result. A competency assessment must take place on completion of the training and at predefined intervals (see clause 7.1.7) (e.g. during internal audits of CCPs). The assessment needs to confirm that the procedure is being followed correctly, test knowledge of the corrective actions, and check for the completion of any relevant training.
7.1.3	The site shall put in place documented programmes covering the training needs of personnel. These shall include, at a minimum: • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training • delivery of training in the appropriate language for trainees.
Interpretation	**Documented training programme** The site must have a documented training programme showing what job role competencies are required, including activities related to food safety, authenticity, legality and quality; the actions taken to ensure that staff obtain these competencies; and a review of the effectiveness of these actions. For example, a job training matrix could list all of the site roles, with details of which procedures and work instructions are required for each role. Training must be delivered in an appropriate language for the trainee (e.g. by providing either written or oral translation where it is required). It is not a requirement for all documentation to be translated into every language of the workforce, but all staff must be able to understand the instructions necessary for their job. For example, hygiene rules may be provided in written translations or in pictorial format, while CCP monitoring instructions may be translated into the languages spoken by the staff involved in these areas.

Clause		Requirements
Interpretation *continued*		The Standard is not prescriptive on the format of the training, and may, for example, include: • internal training provided by the site • one-to-one training • on-the-job training • external training courses • computer-based training (CBT) • training provided by employment agencies, prior to the agency-supplied staff commencing roles at the site. (In this situation, the site will need to ensure that the agency has the necessary knowledge and training in order to subsequently train staff supplied to the site.) Training may be delivered internally or externally, but the company needs to ensure that the training has been effective. This can be achieved through assessment of the staff's ability to undertake the tasks they need to perform, by testing their knowledge or by on-the-job assessment. A review of training and assessment of its effectiveness is an important part of the process, to ensure that it has achieved the level of learning, understanding or competency required. Where tests of knowledge are used, good practice is to follow these with a review of any areas that were not answered correctly, to ensure that the trainee understands these areas. This is particularly important where product safety or legality could be implicated if the activity was completed incorrectly.
7.1.4		All personnel, including engineers, agency-supplied staff, temporary staff and contractors, shall have received general allergen awareness training and be trained in the site's allergen-handling procedures.
Interpretation		**Allergen training** All personnel, including all agency-supplied staff, temporary staff and contractors, involved in handling materials (ingredients, equipment, utensils, packaging and products), must have received training to raise awareness of food allergens and the specific allergen measures used by the company. The level of training should be appropriate to the individual's role. For example: • Personnel who do not actively handle allergens may require only a general understanding of the importance of allergens (for example, simple allergen awareness training, which could be included as part of the induction process). • Those involved in tasks critical to the safety of the product need additional training on specific procedures in which they are involved. • The management team responsible for incidents require a more in-depth knowledge. • Personnel who develop the allergen management system, and therefore are the site's subject matter experts, require the highest level of training. All training records must be kept.
7.1.5		All relevant personnel (including relevant agency-supplied staff, temporary staff and contractors) shall have received training on the site's labelling and packing processes which are designed to ensure the correct labelling and packing of products.

Clause	Requirements
Interpretation	**Packing and labelling training** Mis-packed and mis-labelled goods are the leading cause of product recalls across the world. This clause requires any personnel linked to the packing or labelling of raw materials, intermediates or finished product to be trained in, and kept up to date with, proper procedures. It is also useful for these staff to understand the implications of mis-packed or mis-labelled product.
7.1.6	Records of all training shall be available. These shall include, at a minimum: • the name of the trainee and confirmation of attendance • the date and duration of the training • the title or course contents, as appropriate • the training provider • for internal courses, a reference to the material, work instruction or procedure that is used in the training. Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
Interpretation	**Training records** Evidence of all training needs to be kept and must include all the details as listed in the requirement. These details may be included in the certificate of attendance provided at an external or internal course, or the course contents may be included in a personnel induction booklet that is cross-referenced with a record of the training completed (with trainee name, date and name of trainer, together with the name of any translator). Where training is internal, the site should retain reference to the material used (e.g. to the company procedure and its version number). Where the site has used 'on-the-job' or informal training methods (e.g. toolbox talks), a summary of the content could be used and made available for reference. Training records for any temporary agency-supplied staff and/or external consultants must also be available.
7.1.7	The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.
Interpretation	**Competency review** The company must ensure there is ongoing assessment of staff competencies in their roles (e.g. through one-to-one appraisals, team performance monitoring by line managers, review of the results of internal audits, or review of records). Where the need is identified (e.g. when a job role changes; following performance issues; or when there are changes in operating procedures such as a change in the requirements for a CCP), there must be appropriate refresher training (supplied internally or externally), coaching, mentoring or on-the-job experience to improve skills and understanding.

Clause	Requirements
Interpretation *continued*	The site should determine the appropriate frequency for reviews of competency and training needs. There are likely to be several different scenarios; for example: • a routine review process (e.g. linked to annual performance reviews) • change management (e.g. when a procedure is amended or updated) • whenever there is evidence that an update would be beneficial.

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

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

Interpretation

The site must have documented personal hygiene rules designed to prevent product contamination from personnel. These should be based on risk and may take into account different requirements for different production risk zones, and any national or regional legislation.

All personnel, including agency-supplied staff, contractors and visitors entering production areas (including raw material storage, preparation, processing, packing and storage areas), must adhere to the company's documented personal hygiene rules, including those regarding personal belongings, hand-washing, injuries, illness and medication.

Clause	Requirements
7.2.1	The requirements for personal hygiene shall be documented and communicated to all personnel. These shall include, at a minimum, the following: • watches and similar wearable devices shall not be worn • jewellery shall not be worn, with the exception of a single, plain wedding ring, wedding wristband or medical alert jewellery • rings and studs in exposed parts of the body, such as ears, noses and eyebrows, shall not be worn • fingernails shall be kept short, clean and unvarnished • false fingernails and nail art shall not be permitted • excessive perfume or aftershave shall not be worn. Compliance with the requirements shall be checked routinely.
Interpretation	**Documented personal hygiene policy** This clause is designed to ensure that personal items are not a source of product contamination; for example, small parts that may fall off and become foreign-body hazards, or a source of microbiological or allergen contamination (e.g. if the items were previously worn in an area that was contaminated and the contaminant was transferred into the production area). The site must document its personal hygiene requirements. At a minimum, these must include: • Watches are not permitted in open product areas (including devices used for fitness monitoring and tracking). It is good practice to include details for all portable personal

Clause	Requirements
Interpretation *continued*	items within site policies; for example, mobile phones and tablet devices (e.g. the site might exclude all individuals' personal mobile phones, but have specific rules relating to company-issued equipment, which could, for example, include instructions for cleaning on entry to production areas). • Jewellery must not be worn apart from plain, smooth rings or wristbands (i.e. without stones that may fall out), such as wedding rings. Exceptions must be minimal and must not constitute a risk to product (e.g. wristbands identifying a particular medical condition, such as epilepsy or an allergy, may be worn where product is not at risk of contamination). Where religious reasons prevent the removal of an item of jewellery, it must be covered and the site must complete a risk assessment to determine how this will be achieved (e.g. by totally covering the item with the wearer's clothing, or by wearing overalls that are buttoned up to cover the item). • The potential for broken, damaged or lost glasses and contact lenses to become a foreign-body risk should be considered. • Rings and studs must not be worn in exposed parts of the body such as ears, noses, eyebrows and tongues. • Long fingernails are not permitted, as they are a contamination hazard since they may break off; nor are nail varnish, nail art or false nails. Fingernails must be kept clean, commensurate with the level of hygiene expected within a food manufacturing environment. Where visitors cannot comply with these rules, other controls (such as limiting where visitors may enter and what they may touch, and the obligatory use of gloves) must be implemented to minimise the risk of contamination. • Excessive perfume or aftershave must not be worn, as this has the potential to taint foods. These requirements are applicable to raw-material handling, preparation, processing, packing and storage areas. The requirements for staff working solely in enclosed product areas may be relaxed where no risk is presented to the products. The requirements must be communicated to all personnel (e.g. through induction training and sign-in procedures for visitors and contractors). Consideration must be given to the language in which the training is completed; for example, where employees will be working in their second or third language. Appropriate methods of training (e.g. use of translators) must be provided for them. Compliance with requirements must be checked regularly; for example, by incorporating checks into daily or weekly good manufacturing practice audits (see clause 3.4.4), or through the questioning of personnel at regular intervals.
7.2.2	Hand-washing shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.
Interpretation	**Hand-washing** Hand-washing must be conducted at a frequency appropriate to the level of risk to the product being produced and in line with good industry practice. At a minimum, hands must be washed before staff enter the production area and whenever an activity is undertaken that could potentially be a risk to products (e.g. after going to the toilet, eating, smoking, blowing noses, sneezing or handling shoes). Appropriate instructions for hand-washing, considering the language needs of staff (e.g. including pictorial instructions), must be provided (clause 4.8.4).

Clause	Requirements
Further guidance	**Introduction to hand-washing techniques** Hand-washing is recognised as an effective way to reduce the risk of contaminating food with micro-organisms such as *E. coli, Salmonella* and *Staphylococcus aureus.* However, a number of studies have shown that people either do not wash their hands or fail to clean them effectively. So it is vital that food companies not only provide staff with appropriate facilities to wash their hands but also ensure staff are aware of the correct procedure to follow. **What makes a good hand-washing procedure?** *Frequency* Hand-washing should be carried out as often as is appropriate for the level of risk to the product. At a minimum hands should be washed: • before entering production areas • after any break which involves leaving the production area • after going to the toilet • after eating or smoking • after blowing your nose. See also clause 8.4.1 for hand-washing facilities and procedures in high-risk and high-care zones. *Method* There are a number of steps in an effective hand-washing procedure: • wet hands with water • apply soap • rub the hands so that all the parts of the hands are cleaned, including palms, backs of hands, between fingers, backs of fingers, thumbs and fingertips • rinse hands to remove soap • dry hands thoroughly, as careful drying is a vital step in preventing the contamination of food products. For a pictorial example of best practice for hand-washing, visit the World Health Organization's 'How to Handwash?' page. In addition to the above routine, good practice is to apply a sanitiser such as an anti-bacterial hand gel after the hands have been washed and dried. An effective hand-washing routine should take approximately 40–60 seconds to complete. *Training* It is important that a good hygiene culture operates within the site so that an effective hand-washing routine becomes normal, everyday behaviour. This means that all new staff should be trained (e.g. during induction training) in the site's hand-cleaning procedures and understand the importance of them. Regular updates can help ensure the information remains fresh in people's minds. *Facilities* For a description of hand-washing facilities, see the guidance for clause 4.8.4.

Clause	Requirements
7.2.3	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue) and contains a metal detectable strip. These shall be site-issued and monitored. Where appropriate, in addition to the plaster, a glove shall be worn.
Interpretation	**Cuts and grazes** Cuts and grazes on exposed areas of skin must be covered to prevent contamination of product. To minimise the potential for plasters or band-aids to contaminate product, they must be controlled by the site (e.g. through the use of an issue procedure, where numbered plasters or band-aids are documented in a log, stating when and to whom they were issued). The site may consider the need for an audit of plasters at the end of the shift, and for staff to immediately inform supervisors of any loss. Plasters or band-aids must be visually distinct (preferably blue) and include a metal detectable strip. This applies even where the site does not use metal detectors, as many products are sold for further processing and the plaster or band-aid could therefore be detected at a later stage in the supply chain. Where appropriate, in addition to the plaster or band-aid, a glove must be worn.
7.2.4	Where metal detection equipment is used, a sample from each batch of plasters shall be successfully tested through the equipment and records shall be kept.
Interpretation	**Metal detectable plasters** To ensure that each batch of plasters purchased fulfils the metal detectable requirement, a sample from each batch must be tested to confirm that it is successfully rejected by the metal detector in use. If multiple metal detectors are used on site, it is good practice to use a risk assessment to identify the least sensitive detector, as using this will ensure that a lost plaster can be detected by all of the detectors on site. Records must be kept. Where the site does not use metal detectors, this requirement (for keeping a sample of the batch of plasters) will not apply.
7.2.5	Processes and written instructions for staff shall be in place to control the use and storage of personal medicines, so as to minimise the risk of product contamination.
Interpretation	**Personal medicines** Personal medicines need to be controlled to ensure they do not constitute a risk to product. The site must have a documented procedure on the control and storage of medicines. Wherever possible, medicines should not be taken into production areas (e.g. they could be stored in lockers along with other personal items). However, where staff have a medical need to keep personal medicines with them (e.g. they have asthma or diabetes), procedures must be in place to control these medicines (such as a requirement to notify the company of the defined medical need). Consideration should be given to the format and packaging of the medicines (e.g. glass bottles) to minimise the potential risk of product contamination.

7.3 Medical screening

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

Interpretation

To ensure that all persons who will come into contact with food production and storage areas are not the source of a hazard, the company must have procedures in place by which staff and visitors are fully informed of the health conditions and symptoms which prevent them from working in food production and storage areas.

Clause	Requirements
7.3.1	The site shall make staff aware of the symptoms of infection, disease or condition which would prevent a person working with open food. The site shall have a procedure which enables notification by staff (including temporary employees), contractors and visitors to the site, of any relevant symptoms, infection, disease or condition which they may have been in contact with or may be suffering from.
Interpretation	**Illness notification procedures** Personnel need to receive, as part of their training, clear instructions on the potential risks of food-borne disease and the site's procedures for illness notification. Staff who are suffering from symptoms which may place products at risk must be prevented from working with open food. The site must be expected to define the symptoms, infections or conditions of concern, as advised by local legislation (e.g. a list of communicable diseases). These policies must be documented. This requirement covers all personnel on site, including temporary staff and those employed via an employment agency. The site may consider the use of a pre-employment and/or return-to-work medical questionnaire or medical examination (e.g. stool testing), as appropriate to the risk. The use of suitably trained and competent persons and external medical experts may be required, particularly where privacy laws exist. Some countries have legislation relating to fitness to work with food or the handling of personal information. Sites are therefore expected to operate in accordance with these legislative requirements. For example, in the UK, guidance can be found in the FSA guide '**Food Handlers: Fitness to Work – Regulatory Guidance and Best Practice Advice For Food Business Operators**'.
7.3.2	Where there may be a risk to product safety, visitors and contractors shall be made aware of the types of symptoms, infection, disease or condition which would prevent a person visiting areas with open food. Where permitted by law, visitors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to entering the raw material, preparation, processing, packing and storage areas.

Clause	Requirements
Interpretation	**Illness notification procedures for visitors to the site** The site must ensure that visitors and contractors who enter areas where there may be a risk to product safety, or who undertake work that may constitute a risk to product, are informed of the site's policies and the medical conditions (e.g. the symptoms) that would prevent entry into production, storage or open product areas. Where permitted by legislation, visitors must be screened by use of a health questionnaire. The site must ensure that regular visitors and contractors, such as external company staff or pest control providers, are included. Where questionnaires are used, these must be reviewed by a competent person. A site with live animals (see clause 5.9.2) may need to include the prevention of transmission of animal diseases; for example, by establishing whether the visitor has been to an area within the last 48 hours, where there has been a known outbreak or other risk to the animals that are on site. The procedure must be documented.
7.3.3	There shall be procedures for staff (including temporary employees), contractors and visitors relating to action to be taken where they may be suffering from or have been in contact with an infectious disease. Expert medical advice shall be sought where required.
Interpretation	**Documented infectious disease procedure** Where staff, visitors or contractors declare they are suffering from, or have been in contact with, the identified diseases, infections etc., they must be subject to, and informed of, the procedures to prevent product contamination. This will usually include relocation to a role where they are not in contact with open products.

7.4 Protective clothing: staff or visitors to production areas

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

Interpretation

The purpose of protective clothing is to protect the products from contamination. Therefore protective clothing includes uniforms, overalls, head coverings (such as hats and hairnets), shoes and boots, aprons and gloves (whether disposable or washable). A suitable design of protective clothing must be provided to all staff, visitors and contractors working in or visiting production areas.

Clause	Requirements
7.4.1	The company shall document and communicate to all staff (including agency and temporary personnel), contractors and visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. production areas, storage areas). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, and use of canteen and smoking areas).

Clause	Requirements
Interpretation	**Documented protective clothing policy** The company is required to determine and document the procedures for application and use of protective clothing based on a risk assessment. The risk assessment must consider foreign-body, microbiological and allergen risks as appropriate, as well as general good-practice principles. It must document: • what must be worn (e.g. footwear, overalls and hair covering) and the design of each • where clothing must be put on and taken off, including designated area(s) for changing • the order in which clothing is applied (e.g. hairnet, footwear, wash hands and then overall or coat) • where protective clothing will be stored when not in use • special requirements for specific areas • instructions for the removal of protective clothing when moving away from the production area. Good practice is to include details on what should happen to protective clothing after removal; for example, the correct disposal of disposable clothing, correct storage of reusable clothing or where to put clothing that requires laundering • removal of protective clothing before entering toilets • procedures for the removal of protective clothes in canteens and smoking areas • areas where the product is fully enclosed and has no or very little risk of contamination from the factory environment during normal production. The wearing of full company-issued protective clothing is not an absolute requirement if all of the following criteria apply: • all products are fully enclosed • the product would, if it were not fully enclosed, be classed as a low-risk product • the area is separate from areas containing open product • staff do not need to pass through open product areas to access the area. The wearing of a company uniform is preferred. Where personal clothing is allowed, sites must provide guidance on the standards of clothing which are acceptable. Wherever product lines are entered (e.g. adjustments at the filler), protective clothing and hair coverings must be worn.
7.4.2	Protective clothing shall be available that: • is provided in sufficient numbers for each employee • is of suitable design to prevent contamination of the product (at a minimum containing no external pockets above the waist or sewn-on buttons) • fully contains all scalp hair to prevent product contamination • includes snoods for beards and moustaches, where required, to prevent product contamination.
Interpretation	**Availability and design of protective clothing** Clothing must be available for all staff working in production and storage areas (including employment agency staff, temporary staff and contractors). Items must be provided in sufficient numbers so that they may be maintained in an acceptable condition during working (e.g. to allow for washing).

Clause	Requirements
Interpretation *continued*	The company needs to consider the design of protective clothing and ensure that it is suitable for the production processes. At a minimum: • the clothing must not include external pockets above the waist (e.g. no pockets in coats) and must not have sewn-on buttons • the company must consider the design of protective footwear for production areas and must provide footwear that can be kept clean • staff and visitors must wear headwear (such as mob caps or hairnets) that completely covers head hair to minimise potential contamination • snoods must be provided for staff or visitors who have beards or moustaches where protection is needed to prevent product contamination. Clear rules must be in place and understood by staff, based on an assessment by the company.
7.4.3	Protective clothing shall be laundered by an approved contracted or in-house laundry using defined criteria to validate the effectiveness of the laundering process. The laundry must operate procedures which ensure: • adequate segregation between dirty and cleaned clothes • effective cleaning of the protective clothing • cleaned clothes are supplied protected from contamination until use (e.g. by the use of covers or bags). Washing of protective clothing by the employee is exceptional but shall be acceptable where: • the protective clothing is not used for product safety purposes; for example, it is used to protect the employee from the products handled **and** • the protective clothing is worn in enclosed product or low-risk areas only.
Interpretation	**Laundry** Protective clothing may be cleaned by contracting the services of a specialised laundry, by laundering in-house or, in exceptional circumstances, by employees laundering their own clothes. External contracted services must be incorporated within the company's purchasing supplier approval programme (clause 3.5.3.1) and have systems of approval and continual assessment to ensure that the process is under control. This should be based on risk assessment and may include self-audit questionnaires where low-risk products are manufactured. The monitoring of the effectiveness of cleaning is likely to consist of visual assessment and the monitoring of complaints. In-house laundering carried out on the company premises must be controlled. This is likely to be via HACCP-style principles, controls and validation data, such as monitoring of the temperature and detergent, specifying items not to be washed together, overseeing drying processes and visual inspection. The laundry will also be included in the programme of internal audits (clause 3.4.1). Laundries (both in-house and contracted) must ensure that: • dirty and clean clothing is adequately segregated to ensure that recently laundered items are not re-contaminated

Clause	Requirements
Interpretation *continued*	• the protective clothing is effectively cleaned (e.g. by the completion of microbiological validation and verification tests) • cleaned clothes are protected from contamination until delivered to the site (e.g. through the use of covers or bags). The Standard allows home laundering of protective clothing by employees, but only in exceptional circumstances, where both of the following conditions are met: • protective clothing is not used for product safety purposes, but is instead used to protect the employee from the products handled; for example, in the produce industry, raw vegetables arriving from the fields may be covered in mud or dirt, and employees wear overalls to protect their personal clothing **and** • it is used only in low-risk or enclosed product areas (these are both defined in Appendix 2 of the Standard). It is important that where a site wishes to approve home laundering, both of these requirements are satisfied. For example, home laundering would not be permitted in bakeries because although the protective clothing is being used in a low-risk area, it is an open product area where the clothing is needed to protect the product, not the employee. Home laundering still requires appropriate care and attention to ensure that potential pathogens are removed or killed. Therefore, where approved, home laundering needs to be controlled by written instructions, including, for example: • how garments are to be washed (temperature, detergent, specifying items not to be washed together, and drying instructions such as the use of a hot iron to further heat-disinfect the clothes) • procedures for transporting clean protective clothing to the workplace; for example, provision of sealable plastic bags or similar, which allow washed garments to be transported from home to the workplace without becoming contaminated • on-site procedures; for example, defined responsibility within the company for monitoring the effectiveness of the system (typically achieved by visual inspection). There must also be a procedure and system for effectively dealing with any case where employees are unable to perform self-laundry, either through lack of diligence or through lack of facilities. This system must be capable of being brought into immediate effect once a problem has been identified.
7.4.4	Protective clothing shall be changed at an appropriate frequency, based on risk.
Interpretation	**Changing protective clothing** Protective clothing needs to be changed at an appropriate frequency to ensure that clothing cannot become a source of product contamination. The frequency of changes must be based on risk (e.g. using visual inspections, swabbing or contact plates). For example, hairnets are changed daily or whenever they are removed.
7.4.5	If gloves are used, they shall be replaced regularly. Where appropriate, gloves shall be suitable for food use, of a disposable type, of a distinctive colour (blue where possible) and intact, and shall not shed loose fibres.

Clause	Requirements
Interpretation	**Gloves** Gloves are a potential source of foreign bodies; therefore, sufficient control procedures (such as regular inspection and replacement) need to be put in place to ensure they are intact and do not shed loose fibres. The company needs to consider the design of gloves and whether they need to be disposable, of food grade and of a visually distinct colour from the product (preferably blue).
7.4.6	Where items of protective clothing that are not suitable for laundering are provided (such as chain mail, gloves and aprons), these shall be cleaned and disinfected at a frequency based on risk.
Interpretation	**Protective clothing that cannot be laundered** A documented procedure must be developed for protective items that cannot be laundered, such as shoes, chain mail (cut-resistant, metallic PPE), gloves and aprons. The frequency of cleaning and disinfection must be defined based on risk.

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

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

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

Interpretation

Prevention of potential contamination with pathogens is of paramount importance in the production of safe food. One of the key ways of achieving this is to ensure the correct design (e.g. segregation) and control (e.g. restricted access) of areas of the site where open products, susceptible to contamination, are handled. The Standard defines these areas as production risk zones.

The main principle of the production risk zones in the Standard is to ensure that the environmental conditions and controls in open product areas are appropriate for the products being handled. Therefore the expectations for factory hygiene, finish of buildings, equipment, protective clothing and staff hygiene should reflect the potential risks to the product.

Where a site produces products that require handling in high-risk, high-care and/or ambient high-care production facilities (see Appendix 2 of the Standard for the definition of products that require these facilities), equivalent controls are expected for any subsequent handling or re-packing operation where the product is open to the factory environment (i.e. the re-packing site is expected to have equivalent facilities).

BRCGS has produced a specific guideline on high risk, high care and ambient high care, which explains the requirements and provides details of good practice. It may be purchased from the BRCGS Store or viewed online at BRCGS Participate.

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

Interpretation

The requirements in this section are in addition to those in section 4.3. Sites are therefore recommended to review the two sections together, rather than separately.

Clause	Requirements
8.1.1	The map of the site (see clause 4.3.2) shall include the location of the pathogen control step(s).

Interpretation

Production risk zones on the site map

Clause 4.3.2 of the Standard requires the site to construct a site map, and this will include reference to the production risk zones appropriate to the site.

Clause	Requirements
Interpretation *continued*	It is important to note that the high-care, high-risk and ambient high-care production zones usually apply to only part of a factory's production processes; they typically follow a microbiological kill step or pathogen control step, where any pathogens are removed or reduced to an acceptable level. For example, this could be a microbiological kill step such as heat treatment or cooking, or a process to reduce the pathogen levels such as a chlorine wash of fruit or vegetables. The production risk zone needs to be maintained until the products are enclosed in packaging. For high-risk, high-care and ambient high-care areas, the location of the site's pathogen control step(s) must be included on the site map. As explained in the interpretation for clause 4.3.2, the site map must also include an indication of any areas where time segregation is used; for example, which areas apply time segregation between high care and low risk. The boundaries of this segregation must be clearly detailed. The Standard is not prescriptive on the format of the site plan; however, good practice is to include all the information in an easy-to-use form. Examples include: • use of schematic diagrams • overlaying several maps to form a complete picture, which allows both an overview of the site and a focus into the specific features detailed on individual layers.
8.1.2	Where high-risk areas are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, the nature of the materials (including packaging), the equipment, the personnel, the chemicals, the disposal of waste, the flow of air, the air quality and the provision of utilities (including drains). The location of transfer points shall not compromise the segregation between high-risk areas and other areas of the factory. Practices shall be in place to minimise the risk of product contamination (e.g. the disinfection of materials on entry).
Interpretation	**High-risk areas** High-risk areas require the highest levels of hygiene, working practices, and design and fabrication of facilities and equipment, to prevent product contamination from microbiological hazards. High-risk areas must be fully separated areas, with physical segregation in place between them and other parts of the facility. The purpose of the physical segregation is to provide a self-contained area where uncovered (i.e. unprotected) high-risk products are handled after the microbiological kill step (e.g. heat treatment or cooking) until they are fully protected, usually by means of final packaging. The segregating barrier must be capable of minimising the risk of cross-contamination from: • pathogens which may be present in a low-risk environment or on products or ingredients that have not received a full cook • all people moving between the high-risk area and other areas, except through designated changing areas • the movement of all equipment, cleaning chemicals, utensils or materials into the high-risk area, except through designated ports with sanitising controls in place • water or other liquids (e.g. cleaning chemicals) on the floor, washing into the high-risk area • airborne contaminants (e.g. dust particles or water droplets).

Clause	Requirements
Interpretation *continued*	The ideal barrier is a full wall (e.g. a separate room) separating the high-risk area from other areas. In assessing the suitability of a segregating barrier, a risk assessment should be carried out and documented. Time segregation is not an acceptable alternative for high-risk areas, except for the transfer areas noted below. The location and operation of all transfer points must not compromise high-risk and low-risk segregation. For example, where raw materials or staff move into a high-risk area, consideration must be given to whether this introduces a contamination hazard; it may therefore require measures that involve: • use of disinfection • removal of outer packaging • double-door ovens, blast chillers or freezers (i.e. those with a separate entrance and exit) • controlled air flow (clause 8.2.2) • changing the design of entrances and exits (e.g. roller lifting doors may represent a risk when raised, due to the fact they have been in contact with the floor and the difficulty in cleaning them effectively). High-risk areas are expected to be self-contained and fully segregated. Best practice is that, where there is a cook step in the production of high-risk products, the cooker becomes the transfer point into the high-risk area via a double-door system (i.e. the cooker is loaded in the low-risk area and unloaded directly into the high-risk area). While new cooker installations and new-build sites must incorporate double-door cooking systems, many existing plants are equipped with single-door cookers and have established risk-based procedures for the loading and unloading of the cookers to prevent cross-contamination of cooked products. The Standard will, therefore, accept the use of single-door cooking systems where a thorough risk assessment has been completed as an interim measure prior to the eventual upgrading. Operating practices must be consistently achievable and effective, and prevent cross-contamination of cooked products. The risk assessment must consider, and control potential risk, from: • crossover between cooked and raw products in the unloading area • operators and their clothing (e.g. handling of cooked products by operators who have previously worked with raw products) • hand-contamination resulting from touching surfaces such as common equipment, cooker control panels and cooker door handles • equipment used for transferring product into and out of cookers • airborne contamination from low-risk processes (e.g. the loading and unloading area should be separate from the main low-risk processing area) • the floor (e.g. contamination of the wheels of trolleys transferring cooked products to the high-risk area). When cooked products are unloaded from the cooker, they must be moved immediately to a designated high-risk area to meet the requirements of the Standard. The auditor will assess the procedures in operation where single-door cookers are in use to ensure they are adequate, effective and understood by operators. The audit report will describe the procedures in place to protect the cooked products from contamination. High-risk areas contain only components and foods which have undergone a cook or similar process to achieve, typically, a 6-log reduction for *Listeria*. Where a single area includes, by necessity, some components which have received a lesser kill, together with fully cooked components (e.g. in a sandwich preparation area), this will be classed as high care.

Clause	Requirements
Example	**Cooked crustacea – a product requiring a high-risk production zone** Where crustacea are cooked as part of the production process, or were cooked at an earlier step in the production process (including at another site), the site will need to ensure the correct production risk zones are used. According to the definitions in Appendix 2 of the Standard, cooked crustacea fit into the definition of a product requiring a high-risk production zone because: • finished product is chilled or frozen to preserve food safety • all components have received a full cook (equivalent to a 6 log reduction in *Listeria monocytogenes*) • finished product is vulnerable to growth of pathogens or survival of pathogens that could subsequently grow during normal storage and use • finished product is ready to eat or ready to heat or, on the basis of known consumer use, is likely to be eaten without adequate cooking. Although the Standard recognises that some food products can be effectively managed using consumer cooking instructions, these instructions are not considered a valid justification for using a different production zone for cooked crustacea, as known consumer use in many countries is to eat the product cold without any heating, and therefore without a full cook by the consumer. Furthermore, the product appearance could lead consumers to believe the product is already fully cooked, and that no additional cooking is required. Where a site is partially heating a crustacean (i.e. less than a 6-log reduction in *Listeria monocytogenes*), a high-care area will be appropriate.
8.1.3	Where high-care areas are part of the manufacturing site, there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, the nature of materials (including packaging), the equipment, the personnel, the chemicals, the disposal of waste, the flow of air, the air quality and the provision of utilities (including drains). Where physical barriers are not in place, the site shall have undertaken a documented risk assessment of the potential for cross-contamination, and effective, validated processes shall be in place to protect products from contamination, including the procedures for changeover from low-risk to high-care.
Interpretation	**High-care areas** This clause is applicable to high-care areas (i.e. areas designed to a high standard, where practices are in place to minimise product contamination by pathogenic micro-organisms; see Appendix 2 of the Standard). Vulnerable products and ingredients have, before entry to the high-care area, undergone a process to reduce any contamination by pathogenic bacteria (e.g. a chlorine wash of salad materials, or an early cook step as in the pasteurisation of cream). It is important that the high-care area is effectively protected from contamination by low-risk zones. This is most effectively achieved through full physical segregation by means of walls which separate the high-care area from other factory areas. Where a separate, fully walled-off area is not available, alternative procedures must be in place to segregate the high-care area. The segregating barrier must be capable of preventing the risk of cross-contamination from:

Clause	Requirements
Interpretation *continued*	• unauthorised access and movement between high-care and other areas of the factory, except through designated changing areas • transfer of materials, cleaning chemicals, utensils or equipment, except through designated ports with sanitising controls in place • microbiological contamination which may be present in a low-risk environment • airborne contaminants (e.g. dust particles or water droplets). The segregating barrier may include time or space separation, control of movement or other restrictions. In assessing its suitability, a risk assessment must be carried out and documented. The method employed must be validated to demonstrate that the controls are effective in preventing cross-contamination. The auditor will critically examine the arrangements to ensure that potential risks for contamination have been addressed, and that the alternative controls are consistently workable before the solution is considered acceptable. (This will be recorded in the audit report.) Where the solution is time segregation (i.e. a time separation between low-risk and high-care products being produced in the same area, to allow the area to be converted from a low-risk zone to a high-care zone (e.g. by cleaning, changes of protective clothing, or environmental monitoring)): • The changeover between low-risk and high-care operations should be as infrequent as possible, as it is unlikely that a sufficient standard of cleaning could be reached if changes occur frequently during the day. • Fully validated procedures to change the area from low risk to high care are required. These activities need to be taken into account when scheduling production, to ensure effective transformation of the area, including personnel. If the same personnel are responsible for the area during low-risk and high-care operations, they must undergo a complete change of protective clothing. • The shared area must be designed to meet the requirements of the high-care zone. Therefore all the facilities must be appropriate for a high-care production zone; for example, drainage is appropriate and meets the requirements of clause 8.2.1. Where product characteristics meet the description of high care but the systems are fully enclosed (e.g. dairies filling cartons with milk), the production area is considered an enclosed product area. However, additional precautions are required when breaking into the lines or entering filler equipment (e.g. for maintenance, to free product blockage or for cleaning). Wherever equipment is entered, the necessary hygiene requirements must be completed before operations can recommence. It is expected that newly built factories will employ full wall segregation where high-care facilities are required.

Clause	Requirements
8.1.4	Where ambient high-care areas are required, a documented risk assessment shall be completed to determine the risk of cross-contamination with pathogens. The risk assessment shall take into account the potential sources of microbiological contamination and include: • the raw materials and products • the flow of raw materials, packaging, products, equipment, personnel and waste • air flow and quality • the provision and location of utilities (including drains). Effective processes shall be in place to protect the final product from microbiological contamination. These processes may include segregation, management of process flow or other controls.

Interpretation

Ambient high-care areas

This clause is applicable to ambient high-care areas (i.e. areas designed to a high standard, where practices are in place to minimise product contamination by pathogenic micro-organisms).

Ambient products that are handled in these areas are vulnerable, as vegetative pathogens are known to survive adverse conditions and may subsequently represent a potential food poisoning risk.

Products which require handling in ambient high-care areas are those which meet all of the following criteria:

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

Where products fall into the ambient high care category, the site should conduct a risk assessment to identify the potential risks of cross-contamination (e.g. locations where cross-contamination could occur) and introduce procedures and processes to manage these potential risks.

The procedures required will be dependent on the level of risk, but could, for example, include:

- segregation – normally this would be physical separation; however, time segregation would be permitted where the site can demonstrate that processes effectively minimise the risk of contamination
- cleaning and disinfection processes which ensure that areas where at-risk materials are located are maintained at a suitably high level of cleanliness

Clause	Requirements
Interpretation *continued*	• management of the process flow – ensuring a logical (and usually linear process) so that implicated raw materials are not in the same area/zone as final product (or intermediates that have been through the process to remove or reduce micro-organisms) • enhanced environmental monitoring. Additional information on ambient high-care areas can be found in Appendix 2 of the Standard.

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

Interpretation

The requirements in this section are in addition to those in section 4.4. Sites are therefore recommended to review the two sections together, rather than separately.

Clause	Requirements
8.2.1	Where sites include high-risk or high-care facilities, there shall be a map of the drains for these areas which shows the direction of flow and the location of any equipment fitted to prevent the backup of waste water. The flow from drains shall not present a risk of contamination to the high-risk/care area.
Interpretation	**Drainage for high-risk and high-care areas** The flow of drains must not present a risk of contamination of the high-risk or high-care areas. There must be a plan of the drains for these areas which shows the direction of flow and location of any equipment fitted to prevent the backing-up of waste water. For example, drains should flow from high-risk to low-risk areas and include suitable barriers, such as separate drains that are not connected to other areas of the site. They should also feature non-return or anti-syphon valves, and one-way traps or a sufficient drop to ensure flow in the correct direction. The map of the drains does not need to be a separate document – it can be incorporated into the site map (see clauses 8.1.1 and 4.3.2) if this is more convenient. The direction of flow of the drains must be included on the map. Good practice is for the site to have procedures in place for the action to be taken in the event of a failure of the drain traps or if water backs up into the high-risk or high-care areas. This should be more than just mopping up and then continuing production, as the clause requires that drains must not become a risk of contamination. A full clean, microbiological swabbing etc. may be required to reinstate and confirm the status of the high-risk area.
8.2.2	High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented, based on a risk assessment that takes into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.

Clause	Requirements
Interpretation	**Ventilation for high-risk areas** High-risk areas must be supplied with sufficient changes of filtered air. Therefore a risk assessment must be completed, with the aim of ensuring that the air introduced will not contain micro-organisms of concern and will not be a source of additional contamination (e.g. through the formation of airborne water droplets). The following criteria should be considered: • the source of air. The air inlet needs to be located to minimise intake of contaminated air (at a minimum, it should be upwind of potential contaminants such as dust and chemical vapours) • the frequency of air changes • the specification of filter used. There is no absolute global standard for the filters used in specific food industry applications; the grade required will depend on the source of the air and the length of time of exposure of high-risk products/ingredients • the frequency of replacement of filters • the need to maintain positive pressure compared with adjacent areas, particularly where there is an interface with low-risk areas. The effectiveness of the system employed should be checked using periodic sampling of air microbiological quality. While there is no specific requirement for an over-pressure of air in high-risk areas, good practice is for the ventilation system to be in balance, so that there is no large movement of air from low-risk into high-risk areas. Where air socks are used for high-risk areas, they should be identifiable and kept separate from those for other areas.
8.2.3	Where sites include removable walls as part of the design of the high-risk or high-care area (e.g. to allow occasional movement of large items or specialist maintenance equipment), procedures shall be in place to ensure: • removable walls are tight fitting • their use is managed • movement of the walls is authorised and is completed only by trained and authorised staff • cleaning and reconditioning procedures are in place and completed prior to production.
Interpretation	**Removable walls** Production risk zones may have removable walls or removable wall panels, to allow the movement of large items or specialist equipment between areas. Sites must have documented procedures for the use of removable walls. As a minimum, the Standard expects: • these walls are tight fitting (e.g. to ensure pathogen contamination cannot occur through any gaps; for example, if air or water movement occurs between the two areas) • use of the removable wall is managed correctly and in a controlled manner (e.g. its removal must be authorised and is only completed by trained and authorised personnel, at approved times when there is no production, and in accordance with documented procedures)

Clause	Requirements
Interpretation *continued*	• cleaning and reconditioning are completed prior to the next production (i.e. to ensure that any contamination that has occurred has been removed, and that the area is reliably returned to its high-risk or high-care status). Good practice is to update the site map to show the walls which can be moved.

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

Interpretation

The requirements in this section are in addition to those in sections 4.6 and 4.7. Sites are therefore recommended to review these sections together, rather than separately.

Clause	Requirements
8.3.1	Maintenance activities undertaken in high-risk and high-care areas shall respect the segregation requirements of the area. Wherever possible, tools and equipment shall be dedicated for use in that area and retained there.
Interpretation	**Maintenance in high-risk and high-care areas** It is important that maintenance activities do not result in microbiological contamination of high-risk or high-care areas. Tools that are frequently needed in the area (e.g. spanners) should be dedicated to the area and not removed from there. Where specialist tools or equipment need to be brought into an area for a specific task, then mechanisms should be in place to ensure that this does not result in contamination (e.g. cleaning equipment before entry and post-maintenance cleaning of the high-risk or high-care area).
8.3.2	Where equipment is removed from the high-risk or high-care area, the site shall have a procedure to ensure the cleanliness and removal of contamination hazards before the equipment is accepted back into the area. Records of acceptance back into the area shall be maintained.
Interpretation	**Movement of equipment** Some equipment is moved from place to place in order to be used in different areas. Where this occurs, the site must take steps to ensure that re-introduction to those areas does not compromise the conditions (i.e. the equipment is suitably clean and will not be a source of contamination). The auditor will expect to see a procedure that addresses the re-introduction of equipment to a high-risk or high-care area, as well as evidence of adherence to this procedure where equipment has been moved.
8.3.3	Where portable equipment (e.g. handheld devices) and battery-charging equipment is used in high-risk or high-care areas, these items shall either: • be visually distinctive and dedicated for use in that area, or • have specific procedures (e.g. a full clean) to ensure that their use does not result in contamination.

Clause	Requirements
Interpretation	**Portable equipment (including battery-charging equipment)** Systems must ensure that the use or transportation of small portable equipment, such as handheld devices (e.g. pH meter, temperature probe) and battery-charging, cannot become the source of pathogen contamination. Good practice is for these items to be dedicated to the designated area. Where this is not practical, then specific procedures must be in place to prevent contamination (e.g. movement only through designated routes with associated cleaning or sanitising controls).

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

Interpretation

The requirements in this section are in addition to those in section 4.8. Sites are therefore recommended to review both of these sections together, rather than separately.

Clause	Requirements

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

Interpretation	**High-risk and high-care area changing facilities** The objective of this clause is to ensure that protective clothing, once applied, is not contaminated before entry into the high-risk or high-care area. In facilities with high-risk or high-care areas, personnel must enter these areas via a specific, designated changing facility (i.e. separate from other, lower-risk changing areas) and must follow documented instructions to:

Clause	Requirements

Interpretation *continued*	• apply specific dedicated protective clothing which is visually distinct (e.g. a different colour or style), including clean overalls, headwear and footwear
	• apply clothing in a given order; for example:
	  • put on hair covering
	  • remove shoes
	  • step over barrier (see below)
	  • put on dedicated footwear
	  • wash hands
	  • put on coat or overalls
	  • wash and sanitise hands
	• wash hands during the changing procedure.
	
	When personnel leave the high-risk or high-care area, there must be clear instructions for changing out of protective clothing to ensure that they remove their overalls before handling shoes or a hair covering. (This is particularly important where the clothing is to be reused; for example, if someone is temporarily leaving the area for lunch or a break.)
	
	The footwear worn in these areas must be dedicated to the factory (i.e. factory-issued and not worn outside the factory) and captive to the area (i.e. worn only in the high-risk area). The changing area must be laid out with an effective system to differentiate areas for wearing high-risk footwear (e.g. by the use of a barrier or bench system).
	
	By exception, boot-wash facilities may be used instead of changing into captive footwear dedicated to the area; these must be located at the entrance to an area. Boot-wash facilities must be effectively controlled, managed and validated to prevent the introduction of pathogens. The site must have undertaken a risk assessment to identify the suitability of the boot-wash facilities, and have established controls to manage the effective sanitation of footwear. The controls must have been validated by microbiological swabbing of footwear, floors and drains in the high-risk or high-care area to demonstrate the absence of pathogens (e.g. *Listeria* species).
	
	For controls to be effective, they should include the following criteria:
	
	• The footwear must be company-issued and of a design which is easily cleaned (i.e. smooth upper surfaces, and cleats on soles sufficiently spaced so as not to trap dirt which may not be easily removed by boot-wash equipment).
	• The potential for cross-contamination of boots prior to boot-washing must be considered.
	• Permitted areas where footwear may be worn prior to entry to an area must be clearly defined. For example, the same footwear must not be worn outside the facility or in low-risk processing areas prior to entering the area.
	• The boot-wash equipment must be suitably designed, well maintained and demonstrably effective in cleaning and sanitising the footwear.
	• The minimum cleaning time and concentrations of detergent and sanitiser must be determined, monitored, documented and controlled to ensure effective cleaning of footwear.
	• A schedule for the cleaning of the boot-wash facility and equipment should be in place to ensure that the boot-wash does not become a source or vector of microbiological contamination.
	• Records of the detergent/sanitiser checks and of the effectiveness of the boot-wash facilities are to be kept.

Clause	Requirements
Interpretation *continued*	Environmental monitoring programmes must include specific reference to high-risk and high-care areas (e.g. footwear, floors and drains) to demonstrate the continued effectiveness of the footwear control. All visitors and contractors entering the area will need dedicated footwear; shoe covers are not satisfactory for high-risk or high-care areas, as they rarely cover the whole shoe and often tear or fragment during use, resulting in a lack of protection and the potential to become foreign-body risks. The objective of the use of dedicated clothing is to prevent the potential contamination of products. If members of the cleaning team (or indeed anyone else, such as engineers or visitors) enter an area while production is in progress or open products are present, they must follow the same clothing rules as production staff. If cleaning occurs outside production time, the absolute rules on protective clothing may be adapted but must ensure that the production area is left in a condition, after cleaning, such that no microbiological risks have been introduced by the cleaners or the equipment used. The same principles apply to engineers undertaking maintenance work (which should be followed by cleaning to restore the microbiological security of the area). Wherever practical, auditors will be expected to observe the cleaning in high-risk areas to ensure that the practices used are effective and that controls are in place to prevent this activity introducing new risks. Further details are available in the BRCGS guideline on Understanding High Risk, High Care and Ambient High Care, available on **BRCGS Participate**.

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

Interpretation

The requirements in this section are in addition to those in section 4.11. Sites are therefore recommended to review both of these sections together, rather than separately.

Clause	Requirements
8.5.1	Environmental cleaning procedures in high-care/high-risk areas shall consider the different microbiological risks associated with each production risk zone. At a minimum, cleaning procedures in high-risk and high-care areas shall include all of the requirements in clause 4.11.2. The frequency and methods of cleaning shall be based on risk, and the procedures shall be implemented to ensure that appropriate standards of cleaning are achieved.
Interpretation	**Documented cleaning procedures** In addition to clause 4.11.2, the site must consider the different microbiological risks associated with each high-risk and high-care area. Documented cleaning procedures must be in place to ensure consistent and effective cleaning. These procedures should be specific to the area being cleaned, i.e. for the high-risk or high-care area, as the risks may be different. Cleaning procedures for these areas need to include information on the:

Clause	Requirements
Interpretation *continued*	• staff responsible • equipment, building and plant to be cleaned • frequency of cleaning • methods to be used • materials to be used (e.g. required chemicals and concentrations – good practice is to follow the cleaning chemical manufacturer's instructions relating to concentration, temperature and contact time) • equipment to be used, such as hoses or brushes • instructions on the correct and safe dismantling of equipment where this is required for cleaning purposes • records to be kept • responsibility for verification of cleaning • methods of verification (e.g. visual inspection, ATP monitoring, microbiological swabs or allergen swabs) • procedures to prevent contamination; for example, if the cleaning team moves from one production risk zone to another during the cleaning operations, good practice is to move from the higher-risk area to the lower-risk area. Where equipment requires different levels of cleaning (e.g. between products, or between daily and weekly cleans), each requirement should be clearly detailed. It may be useful to include photographs in the instructions. The procedures need to be reviewed and updated when changes occur to the areas to be cleaned.
8.5.2	Microbiological limits for acceptable and unacceptable cleaning performance shall be defined for high-risk/high-care production risk zones. These limits shall be based on the potential hazards relevant to the product or processing area. Therefore, acceptable levels of cleaning shall be defined, for example, by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing or chemical testing as appropriate. The site shall define the corrective action to be taken when monitored results are outside of the acceptable limits. Where cleaning and disinfection procedures are part of a defined prerequisite plan to control the risk of a specific hazard, the procedures and frequencies shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.
Interpretation	**Cleaning performance limits** At a minimum, limits of acceptable and unacceptable cleaning performance must be defined for environmental cleaning (i.e. the factory environment) in high-risk and high-care areas. The limits need to be based on the risk, and this should be used for assessing whether the cleaning undertaken is of an acceptable standard. Acceptable limits may be based on visual inspection, ATP monitoring or specific analysis such as microbiological testing. Where the cleaning procedure forms part of a defined prerequisite (clause 2.2.1), designed to manage a specific hazard, the procedure must be validated to confirm that the specified cleaning method, chemicals and concentrations are capable of consistently achieving the level of performance required. Records of validation must be maintained.

Clause	Requirements
8.5.3	Equipment used for cleaning in high-care and high-risk areas shall be: • visually distinctive and dedicated for use in that area • hygienically designed and fit for purpose • cleaned and stored in a hygienic manner to prevent contamination (for example, storing equipment in designated locations, off the floor, when not in use).
Interpretation	**Cleaning equipment** Equipment used for cleaning high-risk or high-care areas must be dedicated for use in that area, and therefore retained in the area (i.e. it should not be removed from the area for cleaning or any other purpose). It should also be visually distinct (e.g. colour-coded) from cleaning equipment used in other areas. Where it is not possible to effectively clean equipment in the high-risk or high-care area, a suitable transfer control should be in operation (e.g. heating or disinfection prior to transfer back into the high-risk or high-care area). The cleaning equipment used in high-risk and high-care areas should also be: • hygienically designed and fit for purpose; for example, high-pressure hoses are not normally used in high-risk areas because of the potential to create aerosols and move debris • cleaned and stored to prevent contamination; for example, many items of equipment should be stored off of the floors (the obvious exception being equipment designed for cleaning the floors), and in designated storage areas.
8.5.4	Where the site uses CIP equipment, either this shall be for a specific area only (i.e. separate equipment for high-risk, high-care and other production areas) or the CIP system shall be designed and controlled so that it does not present a risk of contamination to the high-risk/high-care area (i.e. controlling direction of flow from high-risk/high-care to low-risk areas, preventing the recycling or re-use of rinse solutions from one area to another).
Interpretation	**CIP equipment** It is important that cleaning equipment cannot be a source of product contamination. This includes the use of CIP systems. Therefore, in addition to the requirements for CIP identified in section 4.11.7, the site must ensure that specific risks to the high-risk and high-care areas are managed appropriately. As a minimum, the CIP system for high-risk or high-care areas must be either: • a dedicated system, with separate CIP from the systems used in other parts of the facility, or • controlled so that contamination cannot occur, including controlled direction of flow from higher-risk to lower-risk areas, and not reusing or recycling cleaning chemicals, cleaning solutions or rinse solutions from one area to another.

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

Interpretation

The requirements in this section are in addition to those in section 4.12. Sites are therefore recommended to review both of these sections together, rather than separately.

Clause	Requirements
8.6.1	Waste disposal systems shall ensure that the risk of contamination of products is minimised through the control of potential cross-contamination. Risk assessment shall consider the movement and flow of waste and waste containers. For example, waste bins should be dedicated to either high-risk or high-care areas and not be moved between different production risk zones.
Interpretation	**Waste disposal in high-risk or high-care areas** It is important that waste disposal systems are not a source of contamination in high-risk or high-care areas. Therefore risk assessment must consider the movement and flow of waste and waste containers. For example, bins must be dedicated to either high-risk or low-risk areas and must not move between the two. Waste from high-risk and high-care areas should be transferred to other containers at the transfer point. The risk assessment for waste in high-risk and high-care areas may be included in the previous documented risk assessment on waste disposal (see clause 4.12.3) or as a separate document.

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

Interpretation

The requirements in this section are in addition to those in section 7.4. Sites are therefore recommended to review both of these sections together, rather than separately.

Clause	Requirements
8.7.1	Laundering of protective clothing for high-risk and high-care areas shall be done by an approved contracted or in-house laundry using defined criteria to validate the effectiveness of the laundering process. The laundry must operate procedures which ensure: • adequate segregation between dirty and cleaned clothes • adequate segregation between clothes for high-risk, high-care and low-risk areas etc. • effective cleaning of the protective clothing • commercial sterilisation of the protective clothing following the washing and drying process • protection of the cleaned clothes from contamination until use.
Interpretation	**Laundry** Protective clothing may be cleaned by contracting the services of a specialised laundry, or by laundering in-house. External contracted services must be incorporated within the company's purchasing supplier approval programme (clause 3.5.3.1) and have systems of approval and continual assessment to ensure that the process is under control.

Clause	Requirements
Interpretation *continued*	In-house laundering carried out on the company premises must be controlled. This is likely to be done via HACCP-style principles, controls and validation data, such as monitoring of the temperature and detergent, specifying items not to be washed together, overseeing drying processes, and visual inspection. The laundry will also be included in the programme of internal audits (clause 3.4.1). The aim of the clause is to ensure management of the laundry process for high-risk and high-care protective clothing, including segregation of clean and dirty protective clothing and of clean clothing used in different risk production zones. Therefore laundries (both in-house and contracted) must ensure that: • dirty and clean clothing is adequately segregated to ensure that recently laundered items are not re-contaminated • high-risk, high-care and low-risk clothing is adequately segregated throughout the laundry process • the protective clothing is effectively cleaned (e.g. by the completion of microbiological validation and verification tests) • clothing is commercially sterile following the washing and drying process. This means that any vegetative forms of micro-organisms associated with food poisoning and/or spoilage must have been removed. To achieve this, a garment should be laundered at a temperature no lower than 65°C for a minimum of 10 minutes, or laundered at a temperature no lower than 71°C for a minimum of 3 minutes, or in accordance with local regulatory requirements • cleaned clothes are protected from contamination until delivered to the appropriate area of the site (e.g. specific storage for clean protective clothing in the high-risk changing facility). Home laundering is not considered suitable for protective clothing used in high-risk or high-care areas.
8.7.2	Where protective clothing for high-care or high-risk areas is cleaned by a contracted or in-house laundry, the laundry shall be audited either directly or by a third party. The frequency of these audits shall be based on risk.
Interpretation	**Protective clothing for high-risk and high-care areas** The company will need to assess and monitor the laundry (e.g. through visual inspection, regular audits and a complaints procedure) to ensure that the processes in place for the cleaning of high-risk and high-care clothing are maintained and kept consistently under control. The audits of the laundry can be completed either directly (i.e. by the site) or by a suitable third party. The frequency of the audits should be based on risk.
8.7.3	Protective clothing for use in high-risk and high-care areas shall be changed at an appropriate frequency based on risk, and at a minimum daily.

Clause	Requirements
Interpretation	**Changing protective clothing** Protective clothing needs to be changed at an appropriate frequency to ensure that clothing cannot become a source of product contamination. Protective clothing worn in high-risk or high-care areas must be changed at least daily and hairnets changed daily or whenever removed (e.g. when leaving the area). Where risk assessment determines that more frequent changing is appropriate, the site must ensure this occurs. The auditor will expect to see the risk assessment, documented protective clothing procedures, and application of the procedures in practice. Spare protective clothing should be available on demand should currently used items become soiled.

9 Requirements for traded products

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

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

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

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

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

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

Interpretation

Traded products include food final products, food raw materials and food ingredients that are:

- purchased and sold (but not manufactured, processed, reworked, packed or labelled on site)
- stored for another site, e.g. another site in the same company (but are not manufactured, processed, reworked, packed or labelled on site).

Traded products do not include:

- non-food products, non-food ingredients or non-food raw materials
- any material that is manufactured, processed, reworked, packed or labelled on site (for example, where a product is subject to an outsourced process, but subsequently returns to the site for further processing, packing or labelling, it is not considered a traded product).

The auditor will require some additional time to complete the audit of traded products. Full information on audit duration, including the additional time required for auditing traded products, can be found in the audit duration calculator.

9.1 The food safety plan – HACCP

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

Interpretation

It is important that traded products are managed correctly to ensure that:

- product safety, legality and traceability are maintained
- the traded products do not represent a food safety risk to the products manufactured, processed, reworked, packed or labelled on site.

The first step in the management of the traded products is therefore to complete a HACCP or food safety plan which specifically includes these products.

Clause	Requirements
9.1.1	The company shall either: • have a HACCP or food safety plan specifically for the traded products handled on site, or • incorporate the traded products into its existing HACCP or food safety plans (see section 2). The scope of traded products HACCP or food safety plan shall include the products and the processes for which the site is responsible. At a minimum, this shall include goods receipt, storage and dispatch.
Interpretation	The purpose of this requirement is to create a food safety plan to mitigate any food safety hazards associated with the traded products. The site may either: • complete a separate HACCP or food safety plan solely relating to the traded products. A separate plan is most useful in situations where the traded products are considerably different from the products manufactured, processed or packed on site, or have considerably different hazards associated with them; or • include the traded products within the existing HACCP or food safety plan completed in accordance with section 2 of the Standard. A combined food safety plan may be useful where the traded products are similar to those manufactured, processed or packed on site, and therefore have similar hazards. The scope must include all the products and processes for which the site is responsible. As a minimum, this will include: • receipt of goods • storage • dispatch.

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

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

Interpretation

All traded food products brought onto the site must be sourced from approved suppliers who are regularly monitored for their performance. The risk assessment process should focus more on those products and suppliers that present a greater risk (in terms of safety, authenticity, legality and quality).

Clause	Requirements
9.2.1	The company shall have a documented supplier approval procedure which identifies the process for initial and ongoing approval of suppliers and the manufacturer/processor of each product traded. The requirements shall be based on the results of a risk assessment which shall include consideration of: • the nature of the product and associated risks • customer-specific requirements • legislative requirements in the country of sale or importation of the product • source or country of origin • potential for adulteration or fraud • potential risks in the supply chain to the point of receipt of the goods by the company • the brand identity of products (i.e. customer own-brand or branded product).
Interpretation	**Supplier approval and monitoring system: risk assessment** For easier management, sites could choose to integrate the approval process for their traded products suppliers with that for their raw materials suppliers, or organise the traded products suppliers as a separate work stream. All suppliers of traded products must be evaluated on the basis of a documented risk assessment for their ability to meet the specifications of the products they are supplying to the certificated site; in particular the requirements for safety, quality and legality. For example, the assessment should consider: • known hazards associated with the product provided (e.g. microbiological, chemical or foreign-body risks). Access to reference information and an awareness of emerging food issues are essential to ensure all known risks are assessed (see clause 1.1.8) • customer or legislative requirements (e.g. suppliers may be specified by customers, but this does not negate the need for risk assessment). Legislation in the country of expected sale should be considered • geographic origins (products from particular countries may carry a greater risk because of environmental conditions, more relaxed local legal requirements or a less developed food safety culture) • the potential for fraudulent activity or food defence issues in the supply chain (e.g. undeclared additions, dilution or substitution of the raw material or a component of it). Additional focus must be placed on products where claims are being made (e.g. organic, or suitable for individuals with food allergies). Suppliers and their control systems must be assessed robustly to ensure compliance with the requirements. The outcome of this activity must also be considered when assessing the requirements for supplier approval and monitoring procedures (clauses 9.2.2 and 9.2.4).

Clause	Requirements

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

Interpretation

Supplier approval and monitoring system: approval procedure

The company must document its procedure for supplier approval and monitoring. This needs to include the methods of approval, frequency of monitoring, staff responsibilities and how the process will be managed.

Approval will be dependent on the product and the risks associated with it (the output of clauses 9.2.1 and 9.1.1) and will include one or more of the following activities:

- certification to the relevant BRCGS Standard (such as food safety, packaging, storage and distribution, or agents and brokers) or a GFSI-benchmarked scheme. The site must confirm the validity of the certification. This will include:
  - confirmation of the certification status (this could be confirmed on an independent database; for BRCGS Standards, it can be confirmed in the BRCGS Directory). Photocopies of certificates are not recommended and on their own are not considered suitable validation of certification status. During the BRCGS audit, the site may be asked to demonstrate its validation process
  - confirmation that the certification remains up to date (e.g. by receiving confirmation of successful completion of the recertification process or by recording certificate expiry dates and completing checks for ongoing certification)
  - confirmation that the products are within the scope of the certification.

Clause	Requirements
Interpretation *continued*	• a successful site audit which at a minimum covers product safety, traceability, HACCP and good manufacturing processes. This audit must be completed by an appropriately experienced and competent auditor (i.e. someone who has completed training in auditing techniques, has experience of auditing, and has knowledge of the product, ingredient or processes being audited). Non-conformities should be addressed (e.g. in an agreed action with timescales) unless they are critical to product safety or legality, in which case supply should not be permitted until non-conformities have been satisfactorily addressed. If the supplier is audited to a standard that is not GFSI-benchmarked, this may be acceptable providing that: • the scope of the audit meets the requirements of the Standard • the site has a copy of the full audit report (not just a certificate) • the site can demonstrate the competence of the auditor. Where the risk assessment (completed as part of this clause) indicates that a supplier is low risk (because of the history of trading with the site, the nature of the products traded etc.), the completion of a supplier questionnaire with a focus on food safety and quality may be sufficient. If a supplier questionnaire is the only mechanism used to assess a supplier (i.e. there are no additional activities such as supplier audits), then it is important that the questionnaire (and the replies from the supplier) contains all the relevant information to allow the site to confidently decide on approval. The auditor will expect to see, and will challenge, any risk assessments that determine that suppliers have been deemed to be low risk.
9.2.3	Records shall be maintained of the manufacturer's/packer's approval process, including audit reports or verified certificates confirming the product safety status of the manufacturing/packing sites supplying the products traded. There shall be a process of review and records of follow-up of any issues identified at the manufacturing/packing sites with the potential to affect food products traded by the company.
Interpretation	**Records of approval** The site is required to maintain records of the approval methods along with the evidence used to approve that supplier. Approval and associated risk assessments must be up to date and the site should therefore review the supplier assessment whenever there is an issue at the site manufacturing the traded food product.
9.2.4	There shall be a process for the ongoing review of manufacturers/packers, based on risk and using defined performance criteria, which may include complaints, results of any product tests, regulatory warnings/alerts, customer rejections or feedback. The process shall be fully implemented. Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status. Records of the review shall be kept.

Clause	Requirements
Interpretation	**Ongoing monitoring** As much as it is important to know how and why suppliers are approved, it is also vital to ensure that ongoing approval is justified. The site is free to determine how it confers continuing approval on its suppliers, but it must ensure that the supplier's performance is matching its own food safety objectives. The defined performance criteria can be determined by the site. These may include: • punctuality of deliveries against planned delivery times • incidences of contamination • quality of material supplied. Frequency of ongoing approval is also left for the site to determine; however, it must reissue the questionnaires (where used) at least once every 3 years. The site should be able to demonstrate to the auditor that the monitoring it uses is appropriate, justified and risk-based. Examples of different types of monitoring will be required. All records of the review must be maintained.

9.3 Specifications

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

Interpretation

A finished product specification must exist for all traded food products to ensure that legislation requirements and customer expectations are met.

Consideration must be given to the legislative requirements in the country where the product will be sold or used.

Clause	Requirements
9.3.1	Specifications shall be available for all products. These shall either be in the agreed format as supplied by the customer or, where this is not specified, include key data to meet legal requirements and assist the customer in the safe usage of the product. Specifications may be in the form of a printed or electronic document, or part of an online specification system.
Interpretation	**Product specifications** Specifications for all products must be provided and adequately detailed. They must include the defined data for all parameters critical to the safety, legality and quality of the product. The specifications may be in the format provided by the supplier or in the company's own format, as long as the information controlling the product's safety, quality and legality are clearly defined.
9.3.2	The company shall seek formal agreement of the specifications with relevant parties. Where specifications are not formally agreed, the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place.

Clause	Requirements
Interpretation	**Formal agreement of specifications** The site must have a formal specification approval process for its customers and suppliers. For example, customer-branded finished product specifications must be formally agreed and, wherever possible, signed by both parties. However, where signature or approval is not formally available, proof that specifications have been issued (such as an email request for formal acknowledgement, or specifications uploaded onto a customer IT specification system) is required. In this situation the site must be able to demonstrate it is following a formal process agreed with its customer.
9.3.3	Companies shall operate demonstrable processes to ensure that any customer-specified requirements are met. This may be by inclusion of customer requirements within buying specifications, or by undertaking further work on the purchased product to meet the customer's specification (e.g. sorting or grading of product).
Interpretation	**Customer requirements** Many customers have specific requirements relating to product safety, authenticity, quality and legality and the site needs to ensure that it is aware of these requirements and understands them (e.g. by retaining copies of relevant customer's policy documents or service-level agreements). The site must also have a mechanism for ensuring these requirements are met. For example, by communicating with the relevant suppliers of products, by incorporating the information in specifications, or by recording minutes of review meetings in which the requirements are agreed with the supplier. Occasionally the site may arrange for additional work to be completed on the product before it is sent to the customer. Good practice is to ensure that any changes to the requirements are communicated and agreed in a timely manner.
9.3.4	Specification review shall be sufficiently frequent to ensure that data is current or at a minimum every 3 years, taking into account product changes, suppliers, regulations and other risks. Reviews and changes shall be documented.
Interpretation	**Review of specifications** Specifications must be reviewed whenever changes occur to the product, process or formulation. Where no known changes have occurred, the specifications should be reviewed at least every 3 years, or more frequently if required, to ensure they remain completely up to date and accurate. Evidence that a review has been completed needs to be available. This could, for example, be achieved by the addition of a signature and date to the specification, or by using a matrix showing specifications and the latest review date and reviewer. The control of the amendment and approval of specifications should be documented in a procedure. The procedure should also detail who can approve the amendments.

Clause	Requirements
Interpretation *continued*	Some sites, companies or customers use cloud-based services which are able to notify the user when there has been a change to the data. In this case the site should have a mechanism to review the specification/change to understand whether there is any impact on the product.

9.4 Product inspection and laboratory testing

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

Interpretation

The company needs to identify and schedule critical inspections and analyses for its traded food products. These may include:

- identification of known product safety risks associated with the product type
- assessment of legal requirements, particularly those associated with the country of intended sale (where known)
- assurance of product authenticity (e.g. where a genuine risk of adulteration, substitution or fraud has been identified during a vulnerability assessment; see clause 5.4.3)
- inspection of quality attributes (e.g. where these form part of a specification agreed with the customer).

The frequency and types of inspections and analyses are not prescribed by the Standard, but should be risk-based, specific to the type of products.

Clause	Requirements
9.4.1	The site shall have a product sampling or assurance programme to verify that the products are in accordance with buying specifications and meet legal and safety requirements. Where verification is based on sampling, the sample rate and assessment process shall be risk-based. Records of the results of assessments or analysis shall be maintained.
Interpretation	**Product test schedules** The company needs to have a documented schedule of product sampling or assurance tests which are carried out on the products. The objective of product tests is to ensure that products are manufactured to specification and in compliance with safety and legislative requirements. The frequency and type of product tests should be based on risk and on any particular customer requirements. They may, for example, include: • quality tests (e.g. appearance, colour or organoleptic qualities) • safety tests (e.g. chemical or microbiological) or tests to confirm legality (e.g. country of origin or species) • customer-specific requirements based on the specification or the customer's contract with the company.

Clause	Requirements
Interpretation *continued*	The site should be able to explain and justify the basis for the frequency of tests with reference to historical or scientific information as appropriate. Good practice is for the test method and specifications to be documented. Where the results of a test are not quantitative, colour standards or reference samples must be used to provide a reference point for the test results (i.e. to define pass/fail criteria). Where tests are completed on site, the location of the testing should be considered. For example, laboratory facilities will need appropriate siting and controls, and organoleptic tests should be completed in a designated area rather than on the production line (see clause 5.6.5).
9.4.2	Where verification of conformity is provided by the supplier (e.g. certificates of conformity or analysis), the level of confidence in the information provided shall be supported by commissioning periodic independent product analysis.
Interpretation	**Verification of conformity** The company must be able to demonstrate that each product meets legal requirements for its use. Products are often traded with supporting evidence provided by the supplier (e.g. in the form of a certificate of analysis or certificate of conformity relating to the specific batch or lot of product supplied). Where these are used, they must be supported by procedures to substantiate the reliability of the information using independent product analysis. The frequency of this periodic assessment should be based on risk assessment that considers the likelihood of an error occurring and the potential consequences if an error occurred.
9.4.3	Where claims are made about the products being handled, including the provenance, chain of custody and assured or 'identity preserved' status of a product or raw materials used, supporting information shall be available from the supplier or independently to verify the claim.
Interpretation	**Status verification of products** The types of claim covered by this clause relate to the provenance of products that differentiates it from the norm. Such a claim may be made either on the product label for the consumer or in business-to-business communication. The types of claim include: • varietal claims (e.g. basmati rice, Aberdeen Angus beef, Bramley apples and cod fish cakes) • origin claims (e.g. Madagascan vanilla and Florida grapefruit) • assurance claims (e.g. GLOBALG.A.P., Red Tractor, Marine Stewardship, dolphin-friendly tuna and sustainable palm oil) • identity-preserved claims (e.g. GMO (genetically modified organism) free). It is the responsibility of the site to obtain sufficient supporting information to ensure that the product claims are genuine and proven.

Clause	Requirements
Interpretation *continued*	For many assurance schemes, such as GLOBALG.A.P., it is possible to check the assurance status and the scope of products of the supplier on a database. Reliance solely on a declaration from a supplier will not be sufficient. Where claims relate to variety or species (e.g. varieties of fruit), examination of visual characteristics may suffice. However, for claims where visual analysis is not possible (e.g. block frozen fish), certificates of analysis and periodic sample analysis will be required.
9.4.4	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025. Documented justification shall be available where non-accredited test methods are used.
Interpretation	**Analyses critical to safety and legality** This clause applies to tests which are critical to product safety or legality. Results from such tests must be credible and may be called upon in a court of law. The company needs to identify which tests are critical to product safety or legality, such as compliance with label claims/declarations (e.g. nutritional claims, alcohol content) and tests for contamination (e.g. by pesticides, aflatoxins). Note that while the laboratory itself may have accreditation, the actual test methods must also be accredited. Any method of analysis that is not accredited needs justification as to why it was used (e.g. it may be a method for which no accreditation is yet available). Where critical tests are carried out by non-accredited laboratories (either contracted or on-site laboratories), there must be suitable documentary assurances that the laboratory is working to the requirements and principles of ISO/IEC 17025. This must include confirmation of the laboratory's procedures to meet the following general principles: • staff competency and documented training • documented test methodology based on accepted standards • equipment that is fit for purpose and appropriately calibrated • a documented quality assurance programme, including paired testing, ring testing etc. • completion of internal audits of the laboratory's operation.
9.4.5	Test and inspection results shall be retained and reviewed to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.
Interpretation	**Reviewing test results** Systems of recording and review must be formalised and must include evidence of actions taken on identified trends, or where unsatisfactory results have been recorded. The use of graphs or charts of test results provides a good method of identifying trends and anomalous results. It is important that the employees completing the review understand the results and their significance such that appropriate actions can be taken; for example, if a result is outside specification, or exceeds a legal or safety limit.

9.5 Product legality

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

Interpretation

The company needs to maintain awareness of, and ensure compliance with, relevant legal requirements for its products in the countries where the products are sold. These may be associated with composition, labelling or how the products are sold.

Clause	Requirements
9.5.1	The company shall have documented processes to verify the legality of products which are traded. These processes shall include as appropriate: • labelling information • compliance with relevant legal compositional requirements • compliance with quantity or volume requirements. Where such responsibilities are undertaken by the customer, this shall be clearly stated in contracts.
Interpretation	**Legal compliance** Products traded must meet all the legal requirements for the intended country of use. The site must therefore have processes to ensure it remains up to date with requirements such as labelling in that country and that these requirements are met and fulfilled. At a minimum the Standard requires labelling, composition, and quantity or volume requirements as applicable, depending on the product to be considered. Where labelling is not controlled by the company but is the responsibility of the customer, this shall be clearly stated in contracts. Good practice is to ensure that all the relevant information is transferred to the customer and that any changes are communicated in a timely manner.

9.6 Traceability

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

Interpretation

In keeping with the traceability requirements for manufactured and processed products, sites that trade food products are required to maintain traceability, allowing food businesses and authorities to withdraw or recall products that have been identified as unsafe. The system must ensure that products supplied to customers are adequately labelled or identified to facilitate traceability. Traceability details need to be retained in a format that allows access in a timely manner.

Clause	Requirements
9.6.1	The site's traceability procedure (see clause 3.9.1) shall include details of the system used for the traceability of traded products. The traceability system shall ensure that, for all batches of product, the site can identify the last manufacturer or, in the case of primary agricultural products, the packer or place of last significant change to the product. Records shall also be maintained to identify the recipient of each batch of product from the company.
Interpretation	**Identification of product** The site's traceability procedure must include details of the system used for the traceability of traded products, to ensure legal requirements are maintained and that the site can identify implicated batches of traded product in the event of a product recall or withdrawal. Products may be identified by physical labelling or through the use of computerised bar-coding systems. The level of traceability must be able to identify the supplier of the product and to whom it is supplied (i.e. one step forwards and one step back). This will enable the product to be identified if a particular batch needs to be recalled. Consider how the traceability system operates in practice (with the effective physical identification of products). For example, if batches or lots of product are broken down into smaller consignments for individual customers, is all of the necessary information available to the customer (i.e. was there any additional information on the original outer packaging that the customer would need to ensure traceability?), and can the site confidently identify all of these individual customers? Strict controls on identification, traceability and segregation are also required to preserve the integrity of any claims made, such as organic status. Where logos are used that make specific claims about production systems (e.g. farm assurance), full traceability and validations must be demonstrated (see also section 5.4).
9.6.2	The company shall test the traceability system at least annually to ensure that traceability can be determined back to the last manufacturer and forward to the recipient of the product from the company. This shall include identification of the movement of the product through the chain from the manufacturer to receipt by the company (e.g. each movement and intermediate place of storage).
Interpretation	**Tests of the traceability system** The site's traceability system for traded products must be tested at least annually. Traceability testing may be completed as part of a real product recall or withdrawal scenario if one has occurred, since the objective is to test the system and identify areas for improvement, rather than supply records of a 'test' for its own sake. The system must provide traceability 'forwards' and 'backwards'; therefore it should be tested in both directions. For example, a product could be selected and traced forwards to show to whom it was dispatched. Further information on the content of the BRCGS audit, including the vertical audit, can be obtained in the BRCGS guide to auditing techniques, available from BRCGS Participate.

Clause	Requirements
9.6.3	The traceability test shall include the reconciliation of quantities of product received by the company for the chosen batch or product lot. Traceability should be achievable within 4 hours (1 day when information is required from external parties).
Interpretation	**Traceability results** The test of traceability should be timed, and full traceability would be expected to be achieved within 4 hours, unless information is required from external parties, such as suppliers. This is to reflect the need for rapid traceability in the event of a recall. Where traceability takes longer than 4 hours, the site should review the areas where the retrieval of information is slow, in order to identify improvements. The tests must also include a reconciliation of quantities (sometimes referred to as a quantity check or mass balance exercise). The objective is to be able to account for the usage of a full batch of product. This helps to ensure that the traceability systems are capable of operating effectively should a product recall be required. The reconciliation exercise is usually undertaken as follows: • Select a batch code of a particular specific product. • Identify the quantity of product received under that batch code. • Identify the customers purchasing that product and the amounts each received of the specific batch. • Calculate the quantity of any unused part of the batch in the warehouse. • Reconcile the quantity received against the amounts sold plus any residual unused stock.

Appendices

Appendix 1
Glossary

Accreditation	The procedure by which an authoritative body gives formal recognition of the competence of a certification body to provide certification services against a specified standard.
Adulterant	An undeclared material added into a food item or raw material for economic gain.
Adulteration	The addition of an undeclared material into a food item or raw material for economic gain.
Agent	A company that facilitates trade between a site or company and their raw material or packaging suppliers or their customers through the provision of services, but does not at any point own or take title to the goods.
Allergen	A known component of food which causes physiological reactions due to an immunological response (e.g. nuts and others identified in legislation relevant to the country of production or sale).
Allergen cross-contact	Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic substance.
Ambient high care	An ambient area designed to a high standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to minimise potential product contamination by pathogenic micro-organisms.
Animal primary conversion	Sites that complete the slaughter and/or evisceration of animals (including red meat, poultry and game) or the slaughter and/or gutting of fish. (Applicable sites will therefore fall within BRCGS product categories 1, 2 and 4.)
Announced audit	An audit where the company agrees the scheduled audit day in advance with the certification body.
Annual/annually	Within 12 months since the action was last conducted.
Assured status	Products produced in accordance with a recognised product certification scheme, the status of which needs to be preserved through the certified production facility (e.g. GLOBALG.A.P.).
ATP bioluminescence techniques	A rapid test for cleanliness of surfaces based on ATP (adenosine triphosphate) – a substance used in energy transfer in cells and therefore present in biological material.
Audit	A systematic examination to measure compliance of practices with a predetermined system, and whether the system is implemented effectively and is suitable to achieve objectives, carried out by certified bodies.
Auditor	A person possessing the appropriate competence and skills to carry out an audit.
Authenticity/authentic product	Food authenticity is ensuring that food or raw materials purchased and offered for sale, are of the nature, substance and quality expected.
Batch	The quantity of material prepared or required for one production operation.

Blended audit	An audit that is completed in two parts: • a remote audit of documents and records using ICT • an on-site audit concentrating on production, storage, good manufacturing practices and other on-site activities.
Brand owner	The owner of a brand logo or name who places the said logo or name onto retail products.
Branded product	Products bearing the logo, copyright or address of a company that is not a retailer.
Broker	A company which purchases or 'takes title to' products for resale to businesses (e.g. manufacturers, retailers or food service companies) but not to the ultimate consumer.
Business continuity	A framework that enables an organisation to plan and respond to incidents of business interruption in order to continue business operations at an acceptable predetermined level.
Calendar days	Calendar days are consecutive days, inclusive of Saturdays and Sundays.
Calibration	A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or reference material, and the corresponding values realised by standards.
Certificate suspension	Revocation of certification for a given period, pending remedial action on the part of the company.
Certificate withdrawal	Where certification is revoked. Certification may only be regained following successful completion of the full audit process.
Certification	The procedure by which an accredited certification body, based on an audit and assessment of a company's competence, provides written assurance that a company conforms to a standard's requirements.
Certification body	Provider of certification services, accredited to do so by an authoritative body and registered with BRCGS.
Certification extension	Where a site is operational, but an on-site audit has been prevented by Covid-19 restrictions, a site may apply to its certification body for the validity of the current certificate to be extended by a maximum of 6 months. A certificate extension can only be granted due to Covid-19 restrictions. Full details can be found in BRCGS072, Certification Extension for Audits Impacted by Covid-19, available on the **BRCGS website**.
Checkweigher	A checkweigher is a piece of automated equipment for checking that the weight of products is correct and within the relevant limits (e.g. meets legislative and customer limits).
Clause	A specific requirement or statement of intent that a site must comply with in order to achieve certification.
Cleaning	Cleaning is the process of achieving and maintaining an area to a standard deemed visually free from debris that can include dirt, food, faeces, blood, saliva and other bodily secretions. In other words, it is the removal of soil, food residues, dirt, grease and other objectionable matter.

Cleaning in place (CIP)	The process of cleaning and sanitising food-processing equipment in its assembled position without the need for dismantling and cleaning the individual parts.
Codex Alimentarius Commission	A body responsible for establishing internationally recognised standards, codes of practice and guidelines, of which HACCP (hazard analysis and critical control points) is one standard.
Company	The entity with legal ownership of the site which is being audited against a Global Standard.
Competence	Demonstrable ability to apply skill, knowledge and understanding of a task or subject to achieve intended results.
Compliance	Meeting the regulatory or customer requirements concerning product safety, legality and quality.
Consultant	A company, organisation or individual that is subcontracted by the site to provide technical services relating to the product safety and quality management systems (for example, the development, implementation or maintenance of the product safety management system; the development or implementation of the HACCP plan; and the production of manuals or procedures).
Consumer	The end-user of the finished product, commodity or service.
Contamination	Introduction or occurrence of an unwanted organism, taint or substance to packaging, food, raw material or the food environment. Contamination includes physical, chemical, radiological, biological and allergen contamination.
Contract packer	A company that packages the final product into consumer packaging.
Contractor or supplier	A person or organisation providing services or materials.
Control	To manage the conditions of an operation to maintain compliance with established criteria, and/or the state wherein correct procedures are being followed and criteria are being met.
Control measure	Any action or activity that can be used to prevent or eliminate a product safety hazard or reduce it to an acceptable level.
Controlled document	A document which is identifiable and for which revisions and removal from use can be tracked. The document is issued to specified individuals and their receipt of the document is recorded.
Cook	'Cook' is a thermal process which is designed to achieve typically a 6 log reduction in *Listeria monocytogenes*, equivalent to 70°C for 2 minutes. Alternative cooking processes may be accepted or required where these meet recognised national guidelines and are validated by scientific data. Note that other processes achieving a 6 log reduction (e.g. irradiation, high-pressure processes) should be considered in the same way as conventional 'cook' processes when assessing product safety requirements.
Corrective action (correction)	Action to eliminate a detected non-conformity or non-conforming product.
Critical control point (CCP)	A step at which control can be applied and is essential to prevent or eliminate a food or product safety hazard or reduce it to an acceptable level.

Cross-contamination (cross-contact)	The transfer of any material from one surface or food to another. The terms 'cross-contact' and 'cross-contamination' are used interchangeably in guidance about allergen management. See allergen cross-contact.
Cross-docking	Material is unloaded at distribution premises, and handled, but not formally put away into storage. This may be a staging area where inbound materials are sorted, consolidated and temporarily stored until the outbound shipment is complete and ready to ship.
Customer	A business or person to whom a service or product has been provided, either as a finished product or as a component part of the finished product.
Customer focus	A structured approach to determining and addressing the needs of an organisation to which the company supplies products and which may be measured by the use of performance indicators.
Despatch/dispatch	The point at which the product leaves the factory site or is no longer the responsibility of the company.
Disinfection	Disinfection is the process or act of destroying pathogenic micro-organisms; it removes most organisms present on surfaces.
Distribution	The transportation of goods within any container (goods on the move) by road, rail, air or ship.
Enclosed product area	An area of the factory where all products are fully enclosed and therefore not vulnerable to environmental contamination.
End-consumer	The ultimate consumer of a foodstuff, who will not use the food as part of any food business operation or activity.
Flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.
Food defence	Procedures adopted to ensure the safety of raw materials and products from malicious contamination or theft.
Food fraud	Fraudulent and intentional substitution, dilution or addition to a product or raw material, or misrepresentation of the product or material, for the purpose of financial gain, by increasing the apparent value of the product or reducing the cost of its production.
Food handler	Anyone who handles or prepares food, whether open (unwrapped) or packaged.
Food integrity	Products that are of the nature, substance and quality expected (e.g. not substituted, diluted, adulterated or misrepresented).
Food raw materials	Food ingredients, additives and processing aids used in the manufacture of a product.
Food safety	Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
Food safety and quality culture	The attitudes, values and/or beliefs which are prevalent at the site, relating to the importance of product safety and the confidence in the product safety systems, processes and procedures used by the site.

Food safety plan	Often referred to as a HACCP plan. The food safety plan is a set of documents prepared in accordance with the Codex Alimentarius HACCP principles to ensure the control of food-borne hazards. The specific terminology used in the Standard, such as 'prerequisites' and 'critical control points' (CCPs), is intended to reflect the global terminology used to describe expectations. Sites are not required to use the specific terminology in the Standard; alternatives are acceptable providing it is evident that all the requirements have been fully met.
Food security	Procedures adopted to ensure the continued availability of raw materials and products.
Fundamental requirement	A requirement of the Standard that relates to a system which must be well established, continuously maintained and monitored by the company as absence or poor adherence to the system will have serious repercussions on the integrity or safety of the product supplied.
Genetically modified organism (GMO)	An organism whose genetic material has been altered by the techniques of genetic modification so that its DNA contains genes not normally found there.
Global Food Safety Initiative (GFSI)	Managed by the Consumer Goods Forum, a project to harmonise and benchmark international food safety standards (**www.mygfsi.com**).
Good hygiene practice	The combination of process, personnel and/or service control procedures intended to ensure that products and/or services consistently achieve appropriate levels of hygiene.
Good manufacturing practice (GMP)	Implemented procedures and practices undertaken using best-practice principles.
Hazard	An agent of any type with the potential to cause harm (usually biological, chemical, physical or radiological).
Hazard Analysis and Critical Control Point (HACCP)	A system that identifies, evaluates and controls hazards which are significant for food safety.
High-care area	A zone (or area) designed to a high standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to minimise product contamination by pathogenic micro-organisms.
High-care product	A product that requires chilling or freezing during storage, is vulnerable to the growth of pathogens, has received a process to reduce the microbiological contamination to safe levels (typically 1–2 log reduction) and is ready to eat or heat.
High-risk area	A physically segregated zone (or area), designed to a high standard of hygiene, where practices relating to personnel, ingredients, equipment, packaging and environment aim to prevent product contamination by pathogenic micro-organisms.
High-risk product	A chilled or frozen ready-to-eat/ready-to-heat product or food where there is a high risk of growth of pathogenic micro-organisms.
Identity preserved	A product which has a defined origin or purity characteristic which needs to be retained throughout the food chain (e.g. through traceability and protection from contamination).
Importer	A company facilitating the movement of products across an international border. Usually the first recipient of the products in that country.

Incident	An event that has occurred that may result in the production or supply of unsafe, fraudulent, illegal or non-conforming products.
Initial audit	The audit for certification to a BRCGS standard at a company or site that is not in possession of a valid certificate. This may be the first audit at a site or a subsequent audit of a site whose certification has lapsed.
Inspection	Targeted verification (often a visual check against a 'tick list' for fabrication, environment and equipment) to ensure operation to safe expected levels.
Integrity	See food integrity.
Internal audit	General process of audit, for all the activity of the company. Conducted by or on behalf of the company for internal purposes.
Job description	A list of the responsibilities for a given position at a company.
Key staff	Those staff whose activities affect the safety, legality, authenticity and quality of the finished product.
Label	Any tag, mark, picture or other descriptive matter, whether it is written, printed or otherwise marked, on or attached to the packaging of the product. Where a product is unlabelled, specifications or information to meet legal requirements and to assist customers in the safe usage of the product shall be maintained, and are included in the definition of a label.
Labelling	Any words, picture or symbol relating to the food and placed on any packaging or label accompanying the product.
Legality	In compliance with the law in the place of production and in the countries where the product(s) is/are intended to be sold.
Lot	See batch.
Low-risk area	An area where the processing or handling of foods presents minimum risk of product contamination or growth of micro-organisms, or where the subsequent processing or preparation of the product by the consumer will ensure product safety.
Malicious contamination	Deliberate contamination of a product or raw material with the intention to cause harm to the consumer or damage to the company or brand owner.
Manufacturer	A company that produces product from raw materials and/or components and packs the product or supplies product in bulk. A packer that packs product into retail units from bulk-supplied material can also be classed as a manufacturer.
May	Indicates a requirement or text which provides guidance but is not mandatory for compliance with the Standard.

Measurement uncertainty (sometimes referred to as uncertainty of measurement)	A parameter that is associated with the result of a quantitative measurement. It characterises the range of values that could reasonably be expected for the attribute being measured (e.g. the micro-organism, allergen or chemical). It is sometimes referred to as the margin of doubt for the result. Measurement uncertainty is important when making conformity decisions (i.e. assessing whether a test result is within legal, safe or acceptable limits) as the uncertainty or range of probable values may cross the limit. A full explanation of measurement uncertainty is given in the Global Standard Food Safety Interpretation Guideline for clause 5.6.2.
Mitigation strategies	Controls to remove, or reduce to an acceptable level, an identified risk, vulnerability or threat. It is often used in food defence where controls are needed to prevent potential threats from occurring.
Monitoring	A planned sequence of observations or measurements of defined control parameters to assess whether predefined limits are being met.
Non-conformity	The non-fulfilment of a specified product safety, legal or quality requirement or a specified system requirement.
Online verification equipment	Automated equipment (e.g. bar code scanners) that are used to check the accuracy or quality of product labels and printing.
Open product area	An area in which product is open to the environment (i.e. not fully enclosed in packaging or within equipment/pipes).
Outer packaging	Packaging which is visible when the product is released from the site. For example, a cardboard box could be considered outer packaging even if wrapped in clear film.
Outsourced processing (subcontracted processing)	Outsourced processing (also referred to as subcontracted processing) is when intermediate production, processing, storage or a step in the manufacture of a product is completed at another company or site. Outsourced processing is an intermediate step; therefore during outsourced processing, the product or partly processed product leaves the site being audited for the completion of the outsourced processing before returning to the site. The audited site may or may not complete the additional packing or processing steps of the product. Where raw materials receive additional storage or processing prior to their arrival on site, this is not considered to be outsourced processing, but should be managed by the site using supplier approval mechanisms, raw material risk assessments and raw material specifications. When a product leaves the site and does not return, this is not outsourced processing; the activities completed off site are outside the scope of the audit.
Ownership (change of company ownership)	A change of ownership occurs when the title is transferred from one individual or entity to another and results in a change of control of the organisation.
Performance indicators	Summaries of quantified data that provide information on the level of compliance against agreed targets (e.g. customer complaints, product incidents, laboratory data).
Plant-based product	A product that does not intentionally contain materials of animal origin, and has not intentionally used ingredients (including additives, carriers, flavourings and enzymes), processing aids or any other substances that are of animal origin, at any stage during production and processing.

Position statement	Where clarification of the interpretation of a requirement of a BRCGS Standard or its protocol is necessary, this will be published on the **BRCGS website** as a position statement. Such statements are binding on the way that the audit and certification process are carried out and are considered to be an extension of the Standard. They are applicable from the date specified for implementation (or the date of publication on the BRCGS website, where no date is specified).
Positive release	Ensuring a product or material is of an acceptable standard prior to release for use.
Potable water	Water that is safe to drink, free from pollutants and harmful organisms, and conforms to local legal requirements.
Premises	A physical building or place owned by the company and audited as part of a site.
Pre-packaged products	Products in their final packaging that is designed for sale to the consumer.
Prepared primary product	A food product which has undergone a washing, trimming, size-grading or quality-grading process and is pre-packed.
Prerequisite	The basic environmental and operational conditions in a food business that are necessary for the production of safe food. These control generic hazards covering good manufacturing and hygiene practices, and form a foundation for the food safety or HACCP plan. Prerequisites shall be considered as part of that plan.
Preventive action	Action to eliminate the fundamental underlying cause (root cause) of a detected non-conformity and prevent recurrence.
Primary packaging	The packaging that constitutes the unit of sale to the consumer or customer (e.g. bottle, closure, label and tamper-evident seal of a retail pack or a raw material bulk container). When identifying primary packaging, due consideration must be given to the processes that minimise or eliminate any risk which may result in contamination of a food product; for example: • using suitable food contact materials • consideration of anything that is applied onto the surface of a permeable food contact material (e.g. potential for migration of ink components through cardboard is a well-documented risk that has affected a range of packaging). As a general rule, the Standard would not expect transit materials to be classified as primary packaging (e.g. pallets, pallet wrap, shrink wrap, pallet sheets, labels or cable ties applied on the outside of the pallet wrap, recyclable and re-usable travel containers, and plastic crates used to hold glass bottles).
Procedure	Agreed method of carrying out an activity or process which is implemented and documented in the form of detailed instructions or process description (e.g. a flowchart).
Processed food	A food product which has undergone any of the following processes: aseptic filling, baking, battering, blending, bottling, breading, brewing, canning, coating, cooking, curing, cutting, dicing, distillation, drying, extrusion, fermentation, freeze drying, freezing, frying, hot filling, irradiation, microfiltration, microwaving, milling, mixing, being packed in modified atmosphere, being packed in vacuum packing, packing, pasteurisation, pickling, roasting, slicing, smoking, steaming or sterilisation.

Processing aid	Any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of the residues of the substance or its derivatives in the final product – provided that these residues do not present any health risk and do not have any technological effect on the finished product.
Product recall	Any measures aimed at achieving the removal of an unfit (e.g. unsafe) product from customers and final consumers.
Product security	For the purposes of the Global Standard Food Safety, product security refers to measures to prevent theft or malicious damage to products.
Product withdrawal	Any measures aimed at achieving the removal of out-of-specification or unfit (e.g. unsafe) products from customers, but not from final consumers. A withdrawal is normally used to remove product where there is no risk to consumers; for example, where the product has not reached the point of sale to consumers.
Production risk zones	Zones or areas within the processing and storage facilities that require specified levels of hygiene and segregation to reduce the potential for product contamination with pathogenic micro-organisms. The Standard recognises five production risk zones: • high risk • high care • ambient high care • low risk • enclosed product areas. Sites will also have a range of non-product areas which are separate from the processing and storage areas. Full details of the risk zones appropriate to the Standard are located in Appendix 2 of the Standard.
Protective clothing	Clothing and protective equipment (for example, overalls, hairnets, hats and beard snoods) designed to protect the product from potential contamination by the wearer.
Provenance	The origin or the source of food or raw materials.
Quality	Meeting the customer's specification and expectation.
Quantity check/mass balance	A reconciliation of the amount of incoming raw material against the amount used in the resulting finished products, which also takes into account process waste and rework.
Quantity control	A check on the amount of product in the pack. May be related to weight, volume, number of pieces, size etc.
Quarantine	The status given to any material or product set aside while awaiting confirmation of its suitability for its intended use or sale.
Raw material	Any base material or semi-finished material used by the organisation for the manufacture of a product. Raw materials include food ingredients, packaging materials, additives, processing aids etc.
Ready-to-cook food	Food designed by the manufacturer to require cooking or other processing to effectively eliminate, or reduce to an acceptable level, micro-organisms of concern.
Ready-to-eat food	Food intended by the manufacturer for direct human consumption without the need for a full cook.

Ready-to-heat food	Food designed by the manufacturer to be suitable for direct human consumption without the need for cooking. The heating of the product is intended to make the product more palatable.
Recognised laboratory accreditation	Laboratory accreditation schemes that have gained national and international acceptance, have been awarded by a competent body, and are recognised by government bodies or users of the Standard (e.g. ISO/IEC 17025 or equivalents).
Reference sample	Agreed product or components for referral by the manufacturer for production.
Requirement	Those statements comprising a clause with which compliance will allow sites to be certificated.
Retail brand	A trademark, logo, copyright or address of a retailer.
Retailer	A business selling products to the public by retail.
Retailer-branded products	Products bearing a retailer's logo, copyright, address or ingredients used to manufacture within a retailer's premises. These are products that are legally regarded as the responsibility of the retailer.
Retained production sample	Representative product or components taken from a production run and securely held for future reference.
Risk	The likelihood of occurrence of harm from a hazard.
Risk analysis	A process consisting of three components: risk assessment, risk management and risk communication.
Risk assessment	The identification, evaluation and estimation of the levels of risk involved in a process to determine an appropriate control process.
Root cause(s)	The underlying cause(s) of a problem, which, if adequately addressed, will prevent a recurrence of that problem.
Sampling plan	A documented plan defining the number of samples to be selected, the acceptance or rejection criteria and the statistical confidence of the result.
Sanitisation	Sanitisation means to adequately treat cleaned surfaces by a process that is effective in destroying the vegetative cells of pathogens, and in substantially reducing the numbers of other undesirable micro-organisms, but without adversely affecting the product or its safety for the consumer.
Satellite depot	A warehouse/distribution site receiving products only from another site within the same company.
Schedule	A tabulated statement giving details of actions and/or timings.
Seasonal production site	A site that is opened for a short duration (typically 12 weeks or less) during a 12-month cycle; for example, to specifically harvest and process a product. Details of the additional considerations for the management of the audit and certification process for seasonal production sites are given in Part III, section 2.7.8.
Secondary packaging	Packaging that is used to collate and transport sales units to the retail environment or customer (e.g. corrugated case).

Senior management	Person or group of people who direct and control an organisation at the highest level. Note that top (senior) management has the power to delegate authority and provide resources within the organisation.
Shall	Signifies a requirement to comply with the contents of the clause.
Should	Signifies that compliance with the contents of the clause or requirement is expected or desired.
Site	A unit of a company; the entity which is audited and which is the subject of the audit report and certificate.
Specification	An explicit or detailed description of a material, product or service.
Specifier	A company or person requesting the product or service.
Standard, the	The Global Standard Food Safety (Issue 9).
Supplier	The person, firm, company or other entity to which a site's purchase order to supply is addressed.
Suspension	Where certification is revoked for a given period, pending remedial action on the part of the company.
Threat assessment	A risk assessment designed to examine site processes for potential product security and food defence issues.
Traceability	Ability to trace and follow raw materials, components and products, through all stages of receipt, production, processing and distribution both forwards and backwards.
Traded goods/products	Traded products are defined as food products that would normally fall within the scope of the Standard and are stored at the site's facilities, but are not manufactured, processed, reworked, packed or labelled at the site being audited.
Trend	An identified pattern of results.
Unannounced audit	An audit undertaken on a date unknown to the company in advance.
Uncertainty	See measurement uncertainty.
User	The person or organisation who requests information from the company regarding certification.
Utilities	Commodities or services, such as electricity or water, that are provided by a public body.
Validation	Obtaining evidence through the provision of objective evidence that a control or measure, if properly implemented, is capable of delivering the specified outcome.
Vehicle	Any device used for the conveyance of product that is capable of being moved upon highways, waterways or airways. Vehicles can be motorised (e.g. a lorry) or non-motorised (e.g. container or rail truck).
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control or measure is or has been operating as intended.
Vulnerability assessment	A risk assessment designed to examine processes and supply chains for potential food fraud.

Where appropriate	In relation to a requirement of the Standard, the company will assess the need for the requirement and, where applicable, put in place systems, processes, procedures or equipment to meet the requirement. The company shall be mindful of legal requirements, best-practice standards, good manufacturing practice and industry guidance, and any other information relating to the manufacture of safe and legal product.
Work in progress/work in process	Partially manufactured products, intermediates or materials waiting for completion of the manufacturing process.
Working day	A day on which work is usually or routinely done at the site.
Workwear	See protective clothing.

Appendix 2
Sources of further information

BRCGS Standards
A series of globally recognised certification standards for manufacturers, storage and distribution, agents and brokers, and retail companies. Available from the **BRCGS website**.

BRCGS guidelines
BRCGS publishes a series of best-practice guidelines on topics including complaint-handling, pest control, internal auditing, product recall, traceability and foreign-body detection. These may be purchased from the **BRCGS Store** or viewed online at **BRCGS Participate**.

BRCGS Performance Enhancement
BRCGS Performance Enhancement provides businesses and individuals with BRCGS training and personal development programmes.

Codex Alimentarius
The Codex Alimentarius Commission was created in 1963 by the FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme.

The downloadable materials include:

- General Principles of Food Hygiene (CXC 1-1969 as revised), which contains detailed information on HACCP steps and principles
- Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008).

Codex standards, guidelines and codes of practice can be downloaded from the **'Codex Texts'** page on the FAO website.

Food and Drug Administration (FDA)
The **Bad Bug Book** provides examples of microbiological sources.

RASFF
The **Rapid Alert System for Food and Feed** (RASFF), established in 1979, enables the rapid exchange of information whenever a risk to food or feed safety is identified. Members comprise 27 member states, the European Commission, the European Food Safety Authority, Iceland, Liechtenstein, Norway and Switzerland. The **2020 Annual Report** is available for download from the Europa website.

Note: Links and references are made to websites which are intended to help the user with further information. BRCGS cannot, however, be responsible for the content or continued existence of any external website. Also note that legislation and standards change frequently, and a user should confirm for themselves that any references are current and still applicable.

BRCGS Food Safety

BRCGS
Floor 2
7 Harp Lane
London EC3R 6DP

T: +44 (0)20 3931 8150
E: enquiries@brcgs.com

To learn more about the BRCGS certification programme please visit **brcgs.com**

To learn more about the BRCGS online publication service for certificated sites, please visit **brcgsparticipate.com**

To purchase printed copies or PDFs from the full range of BRCGS publications please visit **brcgs.com/store**

Part of LGC ASSURE