BRCGS | Food Safety

ISSUE 8
FOOD SAFETY

Frequently Asked Questions

August 2020

FREQUENTLY ASKED QUESTIONS
FAQs

brcgs.com

Liability

BRCGS 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 for Food Safety 8: Frequently Asked Questions (FAQs) 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

For more information about BRCGS, contact:

BRCGS
Second Floor
7 Harp Lane
London EC3R 6DP

Tel: +44 (0) 20 890 5537
Email: enquiries@brcgs.com
Website: brcgs.com

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

Contents

Introduction

A new issue of the Global Standard for Food Safety (hereafter referred to as the Standard) often generates questions as sites, certification bodies and specifiers ensure that they understand the new requirements. The most frequently asked questions relating to Issue 8 of the Standard are detailed below.

BRCGS also operates an enquiry service. If you are unable to find an answer to your particular question, then please contact enquiries@brcgs.com.

General questions – background

Why did Issue 7 need changing?

Food safety does not stand still; new risks, legislation and practices to improve food safety are continually emerging so as a matter of principle the Standard needs to be periodically reviewed and updated. The most significant changes in Issue 8 concern:

- expansion of the requirements for environmental monitoring
- further development of the requirements relating to food defence/product security
- additional requirements to assist sites with the packing and labelling of products
- re-organisation of the requirements for high-risk, high-care and ambient high-care production risk zones
- additional requirements for traded products (in Issue 7, these formed a separate voluntary module).

Is a document highlighting the changes from Issue 7 to Issue 8 available?

The key changes from Issue 7 to Issue 8 are listed in the Global Standard for Food Safety Issue 8 Guide to Key Changes. It is available from the BRCGS bookshop (https://www.brcgsbookshop.com/bookshop/global-standard-for-food-safety-issue-8-guide-to-key-changes/c-24/p-454) and on the BRCGS Participate information management platform (www.brcgsparticipate.com). It highlights all of the changes that have been made to the requirements and provides explanations for the changes.

When did audits against the new issue of the Standard begin?

Audits to Issue 8 of the Standard commenced on 1 February 2019.

What has happened to the unannounced audit programme?

Previous versions of the Standard provided two options for unannounced audits:

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

The Option 2 split audit has consistently proven to be unpopular, with very few sites electing to be audited in this way. It has therefore been removed from the Standard. The unannounced audit programme remains voluntary and a site can choose whether its audit will be announced or unannounced.

How do I download a copy of the Standard?

The Standard is freely available to download from the BRCGS bookshop (www.brcgsbookshop.com).

Access to all the Standards and guidelines published by BRCGS are also available on the online platform, BRCGS Participate (www.brcgsparticipate.com).

What has happened to the BRCGS Global Markets Programme?

The BRCGS Global Markets programme has been completely reviewed and updated. The new product is called START! Copies are available from both BRCGS Participate (www.brcgsparticipate.com) and the BRCGS bookshop (www.brcgsbookshop.com).

Where do I find the different language versions of the Standards?

The different language versions can be found on the BRCGS Participate platform (www.brcgsparticipate.com) or are available from the BRCGS bookshop (www.brcgsbookshop.com). Simply click on the free download of the English Standard and then scroll down to find the alternative language versions.

Where can I download a copy of the self-assessment document for Issue 8 of the Standard?

This document is available from the BRCGS website at https://www.brcgs.com/brcgs/food-safety/help-and-guidance/ and from BRCGS Participate (www.brcgsparticipate.com).

What would you expect to see for a risk assessment, since the Standard bases many of its requirements on this?

We would expect to see documented evidence of the thought processes and conclusions made regarding the risks posed to products by the specific situation or hazard being considered.

The principles and objectives behind a risk assessment are to ensure that the company has considered the issues relevant to the requirements and introduced relevant controls (e.g. procedures, policies or actions) based on the assessment. The risk assessment and associated controls must be justifiable, and it is likely that the auditor will challenge them by asking the site to demonstrate the thoroughness of the assessment and/or the justification of the conclusions. In some instances, it would be appropriate to have a detailed document (along the principles of a HACCP plan) showing those considerations; examples of this could be the risk rating for suppliers and the subsequent approval process, or an inclusion in the HACCP plan of the risks to products from physical contamination. However, other requirements (such as the policy concerning where beard snoods must be worn) could be evidenced in other ways – these could range from a documented policy and the reasoning behind it, to the understanding by staff of the need for its implementation. This policy would include considerations of best practice within the industry and be open to challenge by an auditor. The need for a documented risk assessment would be particularly pertinent where you have decided not to adopt procedures for a particular requirement (such as not wearing beard snoods in a particular area).

Has the expectation of the word 'documented' changed as it was removed from various sections/ clauses within Issue 8?

The Standard requires policies, procedures, records, risk assessments etc. to be documented in sufficient detail to ensure consistent application throughout the site. They must be demonstrable and made available to the auditor as evidence that activities have been completed. These documents can either be in hard copy (i.e. paper-based) or electronic form.

This is explained further in the document, Key Changes Issue 7 to Issue 8, which is available from the BRCGS bookshop (https://www.brcgsbookshop.com) and on BRCGS Participate (www.brcgsparticipate.com).

Questions relating to the audit protocol

1 Audit duration

Will the audit duration change for Issue 8 audits?

Initial Issue 8 audits were completed using the same audit duration as for Issue 7. However, experience indicates that Issue 8 audits actually take slightly longer to complete. BRCGS has therefore published an updated audit duration calculator which is applicable for audits from 1 April 2020 onwards. The typical total audit time will still be between 2 and 3 days).

Additional time will also be required for any voluntary additional modules that are added to the audit.

A typical audit day is 8 hours (not including lunch breaks) and should not exceed 10 hours, except where there are exceptional circumstances.

Do sites that previously achieved a high grade undergo a shorter audit at their next audit (for Issue 8)?

No, the audit duration is not automatically reduced based on a previous audit grade.

However, section 2.3 of the audit protocol highlights that any non-conformities from the previous audit shall also be checked during the next audit to verify their effective close-out. In addition, clause 1.1.12 of the requirements section states that the site's senior management shall ensure that the root causes of any non-conformities raised against the Standard at the previous audit have been effectively identified and addressed to prevent recurrence. Therefore, a site with a large number of non-conformities at the previous audit will undoubtedly require a longer audit, as the auditor will need additional time to confirm that:

- non-conformities have been closed-out
- root cause analysis has been completed
- preventive actions have been effectively managed.

Where can I find the position statements for Issue 8?

Several position statements have been published for Issue 8 of the Standard. These are all collated into a single document entitled F837– Position Statements for Food Safety Issue 8. The document can be downloaded from the BRCGS website (www.brcgs.com/brcgs/food-safety/help-and-guidance) and is also available on BRCGS Participate (www.brcgsparticipate.com).

2 Additional modules

What are additional modules?

The Standard has been designed to enable additional modules to be included in the scope of the audit. The aim of these additional modules is to enable sites to demonstrate compliance with specific sets of requirements in order to meet specific market or customer requirements without the need for a separate audit, thus reducing the number of audits at the site.

It is expected that new modules will continue to be developed and become available for use throughout the life of Issue 8. A list of available modules will be kept on the BRCGS website (www.brcgs.com) and the applicable requirements and any specific protocols will be available to download from the BRCGS bookshop (www.brcgsbookshop.com) and from BRCGS Participate (www.brcgsparticipate.com).

If a site wishes to include an additional module (or modules) within the scope of its audit, then it must notify the certification body in advance of the audit.

Can traded (factored) products be included in the scope of the audit?

Traded products are those products which are purchased and sold or distributed by a site, but which do not undergo any process at the audited factory. Traded products are often bought in by a company to complement the range of products manufactured at the site, to provide a more comprehensive product range.

Packing or re-packing operations are classified as a process and would not be considered as traded products.

For Issue 7, BRCGS developed and published a Traded Goods Additional Module. For Issue 8, the requirements for traded products have been incorporated into the Standard (section 9). This section of the Standard remains voluntary, but where a site opts to be audited for traded products, any non-conformities will be included in the assessment of the site's grade.

If a site wishes to include traded products within the scope of its audit, then it must notify the certification body in advance of the audit. Where a site has traded products on site but elects to omit them from the audit, this will be recorded on the audit report.

Are the additional module numbers the same (from Issue 7 to Issue 8)?

Numerical order for most of the additional modules remains the same; however, some numbers have changed slightly:

- Additional module 10: GLOBALG.A.P. chain of custody
- Additional module 11: Meat supply chain assurance
- Additional module 12: Association of European coeliac societies (AOECS)
- Additional module 13: Food Safety Modernization Act (FSMA)

3 Exclusions from scope

Have the rules for exclusion from scope changed?

We have deliberately maintained the rules on exclusions from scope. There are a number of reasons for this, including:

- to minimise the potential for a product or activity that is outside the scope to have an adverse effect on products or processes that are in scope
- to ensure that no stakeholder using the report or certificate can misunderstand the scope of the audit
- to protect the reputation of the audit, BRCGS and the certification body in the event of an out-of-scope product or activity causing a problem at a site.

The Standard states that products can only be excluded if:

- the excluded product(s) can be clearly differentiated from products within scope (i.e. they have a different physical appearance or packaging) and
- the product(s) are produced in a physically segregated area of the factory (i.e. they are produced in a physically separate area and not in the same room).

The BRCGS logo may only be used by sites where there are no exclusions from scope or the only exclusion is a traded product.

4 New factories

When can we book an audit for our newly built factory?

Manufacturing units that are newly built or 'commissioned' must ensure that their systems and procedures are compliant before the initial BRCGS audit is undertaken. Whilst it is at the discretion of the company when to invite a certification body to carry out an audit, it must be able to demonstrate that its systems and processes are

well established, compliant and monitored. It is therefore unlikely that full compliance could be satisfactorily demonstrated within the first 3 months of operation. A company may wish to consider a pre-assessment towards the end of this 3-month period.

5 Non-conformities

Our site has had an audit and we are not happy with the non-conformities identified or the grade awarded – what can we do?

The company has the right to appeal against the certification decision made by the certification body. This must be made in writing to the certification body within 7 days of the decision. The certification body shall give a full written response within 30 days following a full and thorough investigation.

If a site appeals against a non-conformity within the 28 days following an audit, then it should be noted that the site is still expected to progress corrective action and submission of the evidence for this to the certification body.

If resolution cannot be obtained by the two parties, then the company has the option to contact the BRCGS. (Note that BRCGS will only be involved in appeals after completion of the certification body's review and response).

What happens if the site cannot complete corrective action within 28 days?

According to section 2.3.2 of the audit protocol in the Standard, 'No certificate shall be issued until all the major and minor non-conformities have been demonstrated as having been corrected, either permanently or via a temporary solution that is acceptable to the certification body.' Therefore, if a site fails to provide sufficient evidence of correction of the non-conformities within 28 days, then it cannot be certificated and will be required to complete another full audit before certification can be considered.

Where a non-conformity requires a prolonged action which cannot be completely scheduled within 28 days (e.g. where significant building works are required), it is acceptable for the site to introduce a temporary solution within the 28 days and provide evidence of this temporary solution, along with evidence that a permanent solution is scheduled. In this situation, the certification body will confirm that the temporary solution effectively manages the identified non-conformity.

In accordance with clause 1.1.12 in the requirements section, all non-conformities will be assessed at the next audit to ensure that effective action was put in place to prevent recurrence.

It should be noted that sites with critical non-conformities cannot be certificated until another full audit is completed.

Is the requirement to close non-conformities for the additional modules within the 28 days detailed in the Standard?

The management of non-conformities is explained in the protocol sections for the individual modules.

Is there a requirement for a site to include a root cause analysis when closing out non-conformities from an audit?

This requirement hasn't changed from Issue 7 to 8. The site will need to identify the root cause so that it can develop a proposed preventive action plan. A summary of the root cause analysis and proposed preventive action will be recorded on the audit report. The effectiveness of these measures will be looked at during the next audit (clause 1.1.12).

6 Audit Scope

Why is pet food added to the Standard?

Pet food has always formed part of the permitted scope of the Standard. This is because the manufacture of pet food often follows similar production processes and is subject to similar legislation. However, Issue 8 contains three new requirements which are only relevant to pet food manufacturers.

It should be noted that animal feed (e.g. for livestock, wild animals or wild animals kept in captivity) is not permitted in the scope as the product composition and required legislation are considerably different.

Can a certificated food manufacturing site produce pet food, and is this permitted within the scope of the Standard?

The Standard does allow pet food to be included within the scope of certification. Before starting, however, the site needs to ensure that it understands any relevant legislation regarding the production of pet and human food in the same facility. This legislation varies in different countries (e.g. in countries across the EU) with some having considerable restrictions.

What information must be included in the product safety rationale?

The aim of the product safety rationale in the audit report is to act as an aide memoire of the most vital features that make the product safe to consume. The relevant information will be dependent on the product type and product safety controls used to produce the product. It may therefore contain a range of different parameters such as cooking time/temperature, water activity (aw), pH, storage conditions etc. The site must understand the key product safety controls for its products and be able to articulate them to the auditor.

For the Issue 8 audit, what information should be included in the boxes labelled 'certificate issue date' and 'certificate expiry date' (section 2 of the audit report)?

The 'certificate issue date' and 'certificate expiry date' are for the current audit being completed (i.e. they are future dates usually added to the report at the point of certificate issue).

Will the auditor view product changeover and line start-up activities during the audit?

A key element of the audit is clause 6.2.2, which requires sites to manage product changeovers to ensure that they are completed to an appropriate level of quality and control. 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. Examples include:

- 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.

Therefore, the audit shall include at least one product changeover. (In exceptional circumstances, such as where sites have very long production runs, there may be 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 the inclusion of a product changeover is not possible; however, this must be considered exceptional and any exceptions or omissions must be fully explained in the audit report.)

It is good practice to discuss product changeovers during the opening meeting to establish when they will take place to ensure that the auditor is available at the relevant times.

As with product changeover, the audit shall, wherever possible, include an assessment of at least one line start-up. (In exceptional circumstances, such as when no line start-up is scheduled to take place during the audit, this may not be possible, and any exceptions or omissions must be explained in the audit report.)

Full details on the composition of a BRCGS audit are provided in the Auditing Techniques Guideline (F812) and within the auditor training courses.

Questions relating to specific requirements of the Standard

1 Senior management commitment

Clause 1.1.2: When will the food safety culture requirements be audited?

This new clause requires the site to introduce and implement a plan for the development and continuing improvement of a food safety and quality culture. In the first year of Issue 8, sites are expected to have devised a plan of action to improve this culture and to be able to demonstrate that the planned actions have commenced (i.e. at their first audit against Issue 8). However, as the third bullet point is asking for evidence of a review of the effectiveness of the completed actions, this item will not be audited until Year 2.

It must be emphasised here that auditors are not expected to audit the actual food safety and quality culture of the site (which is, to a large extent, subjective), but the evidence of compliance to the requirements of the clause, as explained above.

Please note that BRCGS has published a position statement on this clause which can be downloaded from its website (www.brcgs.com/brcgs/food-safety/help-and-guidance/).

Clause 1.1.6 (staff reporting/whistle blowing): What are the minimum requirements for a confidential reporting system?

The company must have a system that allows individuals to report hazards or infractions anonymously and confidentially.

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). This is to protect the employee. For example, an email or a telephone call to an on-site manager is unlikely to be anonymous or confidential as the manager is likely to know the employee's email address or recognise their voice, and therefore this would not be considered a confidential system that protects the employee's anonymity.

The site must also be aware of any local legal requirements that prohibit certain activities around confidentiality or such reports and ensure that the system employed meets these legal requirements. This will be acknowledged by the auditor and compliance with this clause noted within the context of the legal framework.

Clause 1.1.6: Can the TellBRCGS system be used as evidence of compliance with clause 1.1.6?

The TellBRCGS enquiry system 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 investigate 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 the whistleblowing clause (clause 1.1.6) 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 by BRCGS or a customer.

Therefore, a site using the TellBRCGS system without its own confidential reporting system is not going to achieve the intended aim of clause 1.1.6, 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.

Clause 1.1.7: Where can I find a list of the position statements?

Position statements can be found on the BRCGS website (www.brcgs.com/brcgs/food-safety/help-and-guidance/)

and on the online subscription service, BRCGS Participate (www.brcgsparticipate.com).

At the time of publication of this document, there were four position statements relating to Issue 8:
- clause 1.1.2 on compliance and non-conformities relating to the food safety culture plan
- changing the certification body to obtain an earlier-than-scheduled re-audit
- production risk zones (i.e. the use of high-risk and high-care areas) for cooked crustacea
- risk assessments for environmental monitoring.

However, sites are advised to check the details on the website as new position statements may have been published in the intervening period.

Clause 1.1.13: Has the BRCGS logo changed?

In April 2019 BRCGS started a process of re-branding, highlighting that 'BRC' now stands for 'brand reputation through compliance' and that BRCGS is the appropriate term to use when referring to the Standards and certification. As part of this process, BRCGS has developed a new set of logos which eligible, certificated sites can use to advertise their achievement in gaining certification (although it is recognised that transition to the new logo needs time to be phased in).

Unfortunately, there have been some misinformed comments online suggesting that auditors may raise non-conformities where sites are using the old logo. This is, of course, not the case, and BRCGS has re-emphasised this to its certification body partners and their auditors. However, we do want all sites to use the correct BRCGS logo from August 2020.

2 The Food Safety Plan - HACCP

Will a site receive non-conformities for using different terminology instead of the Codex terms in its food safety plans?

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

Clause 2.7.1: Are irradiated ingredients the intent behind the addition of radiological contaminants to this clause?

Based on feedback from various working groups, it was decided to include radiological contamination as a separate hazard (it was previously included within chemical hazards) to aid clarity to the requirement, especially as radiological hazards are listed separately in some countries' legislation.

The aim of this clause is to identify the relevant hazards and therefore it is important to consider potential contamination by radioactive isotopes which may be present in water or soil (either from a naturally occurring source or resulting from a disaster caused by humans).

If the site needs to prevent the use of irradiated material or the contamination of products with irradiated materials (such as when irradiated material is not permitted in the intended country of sale), then this should also be considered as a hazard in the context of this clause.

Clause 2.7.1: Why do we include food fraud and malicious contamination in the HACCP section when different sections of the Standard are used to cover these risks?

An effective HACCP plan must ensure that:
- all the potential hazards have been considered by the HACCP team
- all relevant hazards are controlled, and that these controls are adequately implemented and monitored
- there is an appropriate process for reviewing and updating.

Therefore, the Standard has referenced food fraud and malicious contamination in the list of hazards in clause 2.7.1 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.

It is not necessary for the site to repeat these activities (as part of the HACCP plan, and then in compliance with sections 4.2 and 5.4); the site can simply reference the additional assessments within the HACCP plan.

Clause 2.8.1: Are preventive controls (as defined in FSMA legislation) to be considered as critical control points (CCPs)? Or just those that are not considered to be prerequisite preventive controls?

CCPs are process preventive controls (PPCs) in an FSMA-compliant food safety plan, but it doesn't matter which way you reference them as their management would be the same.

Other preventive controls were formerly described as PRPs (prerequisite programmes) in food safety plans, and in some cases portions of them were elevated to preventive controls for areas such as food allergens, sanitation and the supply chain, based on known or reasonably foreseeable risks of serious adverse health consequences or death to humans or animals. The management components of these controls will not contain all the same elements as CCPs/PPCs as some don't apply; however, the site would be expected to combine the most stringent requirements of FSMA legislation and the Standard. For example, a sanitation preventive control doesn't require validation for allergen cleaning under FSMA legislation, but it is required in the Standard.

Clause 2.9.2: What constitutes a CCP validation? CCPs require both verification and validation; what is the difference?

Validation is defined as obtaining objective evidence that a control or measure, if properly implemented, will deliver the desired outcome. Validation is therefore used during product and process design (or before changes are made to products or processes) to ensure that food safety hazards will be consistently and satisfactorily managed. In simple terms, validation aims to answer the question 'Will it work?' For example, if a site's hazard analysis identified a pathogen hazard such as Salmonella, the control might be to complete a full cook, equivalent to a kill step for Salmonella, on all implicated products. The site would need to identify suitable times and temperatures for the proposed cooking and conduct a validation study to confirm that the proposed process had worked (i.e. product is fully cooked). The result must be consistently produced to guarantee a safe product.

Verification is defined as the use of tests or evaluations (in addition to monitoring) to determine whether the control or measure that is being used has been operating correctly. Verification is therefore used as a review tool to ensure that the operating conditions have been consistently maintained. Verification is used on CCPs to ensure that ongoing processing work is satisfactory. In simple terms, verification seeks to answer the questions 'Did it work?', 'Is it being done correctly?' and 'Is it still working effectively?'

It should be noted that whilst often viewed as similar, routine monitoring is not the same as verification. Monitoring is limited to taking a measurement and comparing it to a predefined limit, and seeks to answer the question 'What is happening right now to this product or process?'

There are many verification techniques and the most appropriate will depend on the product or process being verified. For example, internal audits can be used to watch processes in practice; data trending can examine and confirm the acceptability of data and highlight any trends towards unacceptable levels; product testing can be used to confirm outcomes; and calibration can confirm whether equipment such as ovens or temperature probes is operating correctly etc.

3 Food safety and quality management system

Clause 3.4.1: Does the standard require 4 separate internal audits at sites producing seasonal products where the site is only open for part of the year?

For seasonal production, particularly when the season is very short (e.g. 4 weeks or less), the site must have in place a system for the management of start-up processes. The site is not expected to complete a series of internal audits when the site is not operating; however, internal audits are expected to start before the season commences to ensure that 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. Evidence of this 'pre-start internal auditing' must be demonstrable (i.e. it should be documented and available during the audit).

Further information is available in the BRCGS Fresh Produce Guideline available from the BRCGS bookshop (www.brcgsbookshop.com/) and BRCGS Participate (www.brcgsparticipate.com).

Clause 3.4.1: Can the risk assessment required by this clause be used to reduce the number of internal audits per year?

No, as discussed above, all sites, with the exception of seasonal operations, are expected to conduct a minimum of four internal audits per year.

The aim of the risk assessment in this clause is to:

- identify the frequency with which each part of the product safety and quality management system needs to be audited. For example, internal audits of CCPs are likely to be more frequent than internal audits of raw material specifications due to the greater implications of a concern or error
- identify the most relevant dates for each internal audit.

Clause 3.4.1: Are all internal audits required to be done prior to the initial certification or is it just a schedule for the coming year that is needed?

It is not a requirement for all the internal audits to be completed prior to the initial audit at the site. The Standard requires the site to have a planned schedule or programme of internal audits spread throughout the year, and to complete the individual audits according to this plan.

As the internal audit dates must be spread throughout the year, it is likely that at any stage some audits will have been completed, whilst others will be scheduled for later in the year.

Clause 3.4.2: What training do internal auditors have to complete and what does 'independent' mean?

Internal auditors should be able to show (via training records) that they have received formal training either by attendance on an external course or training within the company. Training should cover the planning and scheduling of internal audits, preparing reports, the correct use of audit techniques (e.g. process auditing, audit trails and interviewing), and the following up of audit findings.

The objective behind the requirement for auditors to be independent (i.e. not to audit their own work) is to ensure that the auditor is rigorous and thorough, and not influenced by the work which may be needed to make corrections and improvements.

The use of an external consultant is acceptable, provided that the internal audit programme is scheduled throughout the year and not in a single block of activity.

Clause 3.4.3: If corrective actions identified during internal audits are not completed before the BRCGS audit, will the auditor issue a non-conformity? For example, if a correction has not been made, the issue will still exist and no mitigation will have occurred.

If during an audit, the auditor identifies a non-conformity against a clause of the Standard, then this will be raised as a non-conformity, regardless of whether the site has identified the same non-conformity within their internal audit programme.

A non-conformity will only be raised against clause 3.4.3 if there is a non-conformity in the operation of the internal audit programme itself. For example, if the audit schedule is not properly implemented or if corrective and preventive actions are not completed within the agreed timescales.

Clause 3.5.1.2: Does the *START!* programme fulfil the requirements of clause 3.5.1.2?

The *START!* programme does fulfil the requirements of clause 3.5.1.2. Even though it is not a GFSI-benchmarked standard, clause 3.5.1.2 also permits the use of other third-party audits providing the following criteria are complied with:

- demonstrable competency of the auditor; audits to the *START!* programme can only be completed by trained and approved auditors
- the scope includes product safety, traceability, HACCP and good manufacturing practices (all of these are included in the *START!* programme)
- a copy of the full audit report is made available; sites audited in the *START!* programme can provide their customers with a copy of the audit report via the BRCGS Directory.

Note that it is a requirement of clause 3.5.1.2 that a company using suppliers in the *START!* programme must receive and review the full audit report. It is not sufficient to just receive a certificate.

Clause 3.5.1.5: If a site purchases raw materials from an agent who is certificated to a BRCGS Standard, does the site still have to obtain details of the last manufacturer or packer?

The aim of this clause is to aid supply chain transparency and ensure that timely action can be taken in the event of an incident or issue within the supply chain.

If the agent or broker is certificated to the BRCGS Standard for Agents and Brokers or an appropriate BRCGS Standard, then the site simply needs to know the identity of the manufacturer, packer or place of consolidation of the material (i.e. the location where the material underwent a process other than storage or distribution).

If the agent or broker is not certificated to a BRCGS Standard, then the site will need to know the identity of the manufacturer, packer or place of consolidation of the material and receive sufficient information to complete a supplier approval procedure in accordance with clause 3.5.1.2.

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 co-operative 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 the 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.

When this requirement was first introduced in 2015, sites were provided with a transition period during which they could communicate with the agents and brokers within their supply chains to obtain the required information. This transition period has now passed, and sites are expected to be fully compliant with the requirement.

Clause 3.5.1.6: How do we ensure that our raw material suppliers have effective traceability systems?

Sites must ensure that their raw material suppliers have suitable traceability systems in operation. This assurance can be obtained from certification, auditing or by directly testing traceability. Examples include:

- Where the raw material supplier is certificated to a GFSI-benchmarked standard, assessment of traceability systems will form 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 to ensure that, if the raw

material supplier were to lose its certification, the site would be made aware of this change.
- If the raw material supplier has been audited by the site and the audit included an assessment of the traceability systems, this would comply with the requirement of clause 3.5.1.6 as traceability would have been assessed.
- If supplier approval is based solely on a questionnaire with no additional testing of the traceability system, traceability verification will be required unless the raw material is a primary agricultural product purchased directly from a farm or fishery (where additional testing of the traceability system is not mandatory). This verification could include, for example:
  - a test of the raw material supplier's traceability system. 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 material and return the relevant records to the site
  - a worked example from the raw material supplier, which clearly shows how the traceability works
  - a detailed description of the traceability system provided by the raw material supplier.

Clause 3.5.1.6: How soon must verification of our raw material supplier's traceability systems be completed?

The Standard expects verification of a raw material supplier's traceability systems to occur over a 3-year period, in line with the minimum 3-year re-issue of supplier approval questionnaires. It therefore follows that all supplier traceability systems must be completed within a 3-year cycle. Consequently, as a guide, you should be able to demonstrate verification of the traceability systems for at least a third of the suppliers in Year 1, two-thirds by Year 2, and all suppliers by Year 3.

Clause 3.5.4: If part-processing of a product is completed at another site and the processed product doesn't return to the certificated site, is this considered outsourced processing or contract processing (e.g. high-pressure processing or a process/contract blending operation into a fully enclosed package)?

Packing of products by third parties (e.g. contract packing) has been removed from this section as this should not form part of the scope of the audit (the packing site can have its own site certification).

Outsourced processes occur when a partially processed product is sent to another site for one or more process steps before being returned to the site for completion of the production/packing operation. If the site being certificated sends sealed packs to another site, and these are shipped back to the original site for further processing or further actions, then it is considered to be outsourced processing. If the product doesn't return to site, then it falls outside the definition of an outsourced process and is categorised as a subcontracted service.

An outsourced product that returns to the site for further processing would normally be permitted to appear in the scope.

Figure 1 A simple manufacturing process

For example, consider a simple manufacturing process, as shown in Figure 1. A number of different production models exist for the product, as shown in Figure 2, and these affect the scope and applicability of the Standard.

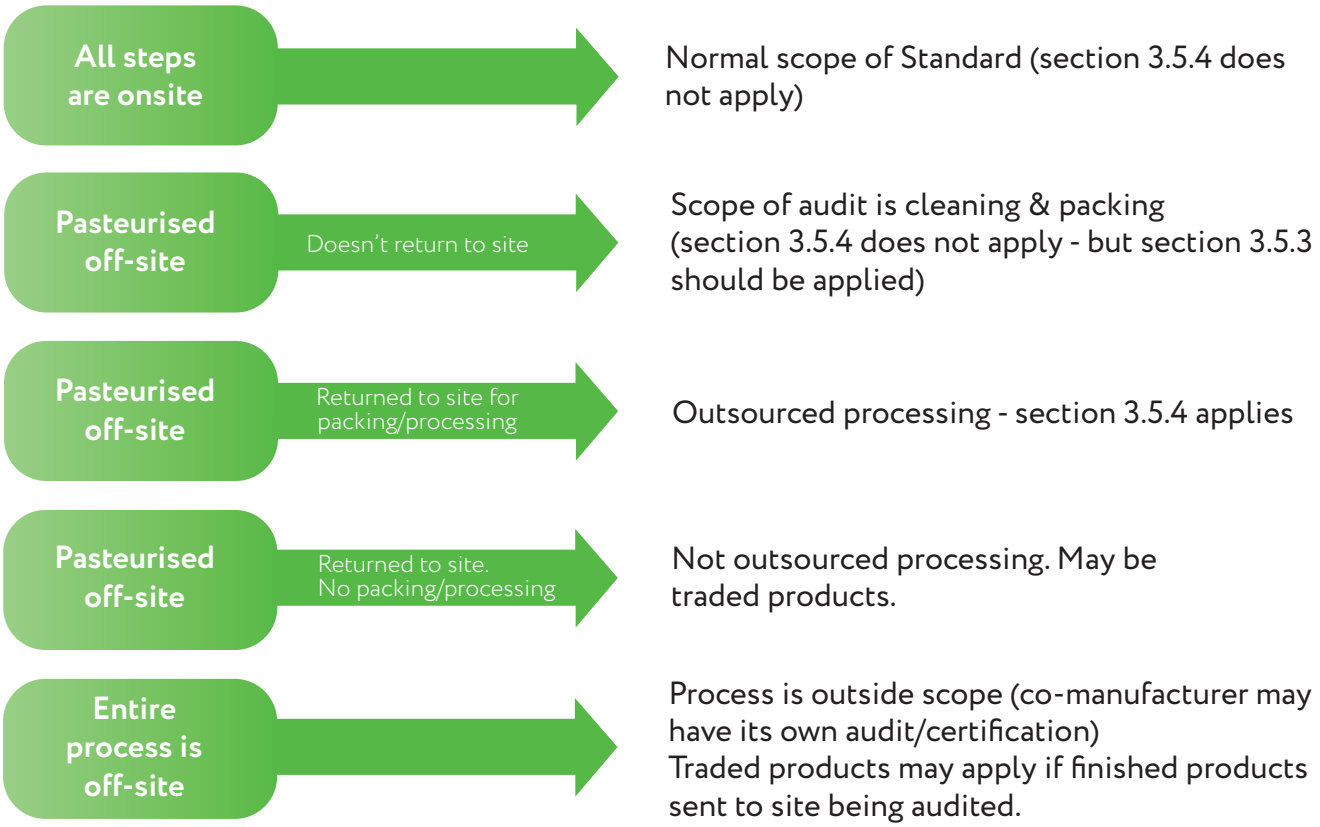

Figure 2 Possible production models for products processed on and off site

Clause 3.5.4.1: Why doesn't the statement of intent for section 3.5.4 refer to contract packing when clause 3.5.4.1 does?

Clause 3.5.4.1 is primarily focused on communication with brand owners, and both the outsourcing of production and the use of an external packing company are of relevance to them, whereas the rest of the requirements in section 3.5.4 specifically refer to outsourced processes.

Section 3.9: What is the definition of primary packaging? For example, would shrink wrap and pallet slips be classed as primary packaging?

Primary packaging is defined as the packaging that constitutes the unit of sale to the consumer or customer (e.g. the bottle, lid and label that forms the retail pack sold to a consumer, or a raw material bulk container). Shrink wrap or pallet slip sheets are not items that a consumer would see; therefore, these items are not primary packaging.

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 stuck onto the surface of a permeable food contact material (e.g. migration of inks 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 classed as primary packaging (e.g. pallets, pallet wrap, any label on the outside of the pallet wrap, recyclable travel containers etc.).

Clause 3.9.2 – Is the interpretation guideline for this clause correct?

Unfortunately, there is an error in the interpretation for this clause and the reference to food contact should be removed. The correct text would therefore read:
The traceability system needs to include primary packaging.

Sites should refer to the glossary in the Standard for the definition of primary packaging.

Clause 3.9.3: Is 100% traceability recovery no longer required (the word 'full' was removed from the clause)?

The word 'full' was removed from this clause as it was a common cause of confusion during Issue 7. However, the meaning and intent remains unchanged from Issue 7 to Issue 8.

It is unlikely that the mass balance check will be able to account for all materials to an accuracy of 100%; however, the company needs to be able to justify any discrepancies and demonstrate that it understands the nature of the variance (e.g. through processing factors such as dehydration of fresh ingredients, typical wastage on equipment, or portion variances).

The Standard requires the site to test traceability 'across the range of product groups' each year. Where the 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 a group of products, this may necessitate additional tests related to that product or group of products.

In addition, where the site makes a product claim, the requirements of clause 5.4.4 apply (i.e. traceability tests should occur at a frequency to meet any particular scheme requirements or at least every 6 months in the absence of a scheme-specific requirement).

Clause 3.11.2: What evidence is acceptable to show compliance for key timings for a mock recall?

The Standard requires an actual record of the times at which key activities took place (e.g. the time the mock activity started, the time the traceability exercise completed etc.).

Clause 3.11.3: What are the key timings that need to be recorded in a mock recall?

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 during a mock recall is to ensure that timely action can be taken in a real incident. There are various times that should be recorded, including when:

- the mock incident started
- internal communications and key decisions were made
- traceability and mass balance exercises were carried out
- communication to customers/regulatory authorities would occur.

Clause 3.11.4: What is classified as a 'significant food safety incident'?

When a significant food safety incident occurs, the site manufacturing or processing the implicated product is required to notify its certification body of the situation. This is to ensure that the integrity of the certificate can be maintained by allowing the certification body to assess whether the incident affects the certification. Situations that should be notified to the certification body 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.

It should be noted that only the site where an incident occurs is required to notify its certification body.

4 Site standards

Section 4.3: Do sites manufacturing products in a low-risk area need a site map or is this only required for high-risk and high-care (clause 8.1.1)?

Section 4.3 of Issue 7 of the Standard contained several clauses relating to site maps that have now moved to section 8.1.

Clause 4.3.1 (Issue 8) still requires sites manufacturing products in low-risk areas to have a site map, but additional information is required in clause 8.1.1 for sites producing products in high-risk and/or high-care areas.

Clause 4.9.5.1: Are wooden pallets permitted in open product areas?

The use of wood is not permitted in open product areas except where it is an essential requirement of the process (e.g. wooden casks for some alcoholic beverages, or wooden crates used for incoming raw materials in fresh-produce packhouses where the use of plastic has been shown to increase the risk of cross-contamination with pesticide residues). Therefore, items such as wooden pallets will not be present in open product areas unless there is an essential and justifiable need. This avoids the potential hazards of wooden splinters and microbial contamination.

'Combos' or plastic-lined cardboard boxes on pallets (typically single boxes measuring 3 ft×3 ft×3 ft (1 m3) on a pallet) are permitted where the pallets are single-use wood, and only located in a specific location at the end of a packing line. Other uses, such as the storage of open products or work in progress, are not acceptable.

Where wood cannot be avoided, the condition of the wood shall be continually monitored to ensure that it is in good condition and free from damage or splinters.

Clause 4.5.3 Does each individual air filter need to be located near the food product or could a filter be located near the central compressor?

The objective of the filter is to prevent dust particles and lubricating oil from the compression system contaminating the products. A single central filter is unlikely to provide sufficient product protection. Therefore, the best position and size of the filter will depend on the position of the compressor, the layout of the compressed air system, and the source of the air used. The site must be able to justify the effectiveness of the filtration system employed.

Clause 4.9.6.2: If a factory has pens with small detachable parts, should they be replaced with a new design that has no small parts to ensure compliance with the new clause?

There have been a number of organisations communicating information relating to the suitable design of factory pens, not all of which has been helpful or an accurate interpretation of the requirements of the Standard. Sites are recommended to consider the requirements of this clause and the interpretation provided in the BRCGS Food Safety Issue 8 Interpretation Guideline.

The Standard does not require pens to be of a specific design, nor does it state (or imply) that most pens available on the market are not compliant, nor that the site must test every batch of pens through its metal detector. It does, however, require sites to consider the design of pens being used, to ensure that potential food safety hazards have been considered and are managed appropriately.

The Standard does not prescribe what the suitable or necessary controls should be. For example, if a pen has small, easily detachable external parts, then these could represent a potential hazard and the site would need to consider this and manage the risk accordingly (for example, by choosing a design with less easily detachable pieces or opting for a metal-detectable design). Note that the Standard does not state that all pens must be metal-detectable but suggests this feature as a control example; other controls may be more suitable in certain circumstances (for example, there would be minimal value in the use of metal-detectable pens if the site doesn't use a metal detector). The aim of the clause is to minimise or prevent product contamination; good practice usually involves not using pens with small, easily detachable external parts in open product areas. The internal parts of pens may not be relevant unless they can 'fall out' or become detached.

The clause applies only to open product areas.

Clause 4.10.3.4: Why does the clause not require X-ray detectors to meet the requirements?

X-ray detectors generally require slightly different test procedures and the working group felt that including both metal and X-ray detectors in the same clause would confuse rather than improve operation.

Note that clause 4.10.3.3 requires sites to have a defined procedure for setting up and testing the X-ray equipment, and therefore auditors would still expect sites to have properly documented operating systems in place.

Clause 4.10.3.4: What is meant by 'checks of failsafe systems'?

Many modern metal detector designs (and other foreign-body detection systems such as X-rays) have failsafe systems. These are systems that monitor their own functions and raise an alarm (usually audible) if something stops working. For example, if the product rejection system is powered by compressed air and the air supply fails, this will sound the alarm immediately, prompting staff to investigate the fault, rather than waiting until the next metal detector check to find a problem. Where these systems exist, it is important to run occasional checks to make sure 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..

Clause 4.10.6.1: What is the definition of rigid containers? For example, are plastic bottles considered rigid containers?

Section 4.10.6 applies to products packed in glass, jars, cans and other rigid containers.

In this context, 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 aim of section 4.10.6 is to remove any foreign bodies prior to use of the container.

Section 4.11.8: Do all sites need an environmental monitoring programme or can risk assessment demonstrate that it is not required?

The aim of the environmental monitoring programme is to identify and monitor any potential risks in open product areas and those areas handling ready-to-eat products. The majority of sites will therefore require an environmental monitoring programme.

BRCGS has published a position statement which details the evidence a site will need to provide to the auditor if it believes that there are no relevant pathogen and/or spoilage organisms, and hence that an environmental monitoring programme is not necessary. This position statement can be found on the BRCGS website (www.brcgs.com) and on BRCGS Participate (www.brcgsparticipate.com).

Section 4.11.8: Can BRCGS provide some examples of target organisms that would be acceptable in open product areas where the product is not high care or high risk?

It is difficult to provide a definitive list for relevant target organisms for all product categories as these will vary according to the product and processing.

The section of the Standard relating to environmental monitoring highlights that the programme should be risk-based, so the food safety or HACCP plan should indicate those risks that may need to 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 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.

BRCGS will publish additional guidance on environmental monitoring which will be available on BRCGS Participate (www.brcgsparticipate.com).

Clause 4.14.6: How frequently do bulbs in insect-killing devices need to be changed?
There is no minimum frequency for changing bulbs as this will depend on a number of factors, including the brand of bulb used. However, all equipment must be maintained in a fully operational state. Therefore, bulbs on insect-killing devices must be changed at regular intervals (in accordance with the manufacturer's instructions) to maintain optimal luminosity, and pheromone traps must be replenished quarterly (or in accordance with the manufacturer's instructions). Documentation must provide evidence of this maintenance.

5 Product control

Clause 5.2.5: How can cooking instructions that use a microwave be validated, given that microwaves vary in power and efficiency?
Microwaves certainly provide some additional challenges for the validation of cooking instructions.

The key aim of the requirement is to ensure that the target product is sufficiently heated to destroy any heat-resistant pathogenic bacteria and remove any appreciable risk of food poisoning which may be present in the food. The risk is especially high from those bacteria that are able to grow at chilled storage temperatures. Campden BRI (a food research association based in the UK) has produced a short technical document which covers many of the challenges associated with the validation of cooking instructions. It is available on the BRCGS Participate platform (www.brcgsparticipate.com).

Section 5.3: Should allergens be considered and controlled at pet food manufacturing sites?
The site is 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, this section of the Standard may be considered as 'not applicable' for pet food destined for those countries.

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

Please note that this reflects an update on the requirements for Issues 6 and 7, which required pet food manufacturers to meet the allergen requirements of this section regardless of whether a claim was being made.

Clause 5.3.6: What is meant by an allergen warning? Is this the 'may contain' statement or the listing of an allergen in the ingredients?
Clause 5.3.6 refers to production processes where the risk of cross-contamination from an allergen cannot be prevented. It therefore relates to allergy warnings such as 'may contain' rather than to the deliberate inclusion of ingredients in the product, which are referred to elsewhere in the Standard (e.g. clause 5.2.1).

Clause 5.4: Do we need to consider packaging in food fraud risk assessments?
Section 5.4 applies to food raw materials and ingredients, and therefore packaging does not need to be considered under this section.

Clause 5.4.4: If a site makes multiple claims (e.g. provenance and GMO-free claims), does it need to conduct a mass balance test every 6 months for each claim or a single mass balance test every 6 months?
Where a site makes a product claim, the Standard requires traceability and mass balance tests to be conducted at the frequency specified by the scheme to which the claim is certificated, or at least 1 test every 6 months in the absence of a scheme-specific requirement. This means that in the absence of scheme-specific requirements, the site will be expected to complete at least 2 traceability and mass balance tests per year, not 2 tests for every claim per year.

6 Process control

Clause 6.1.5: Are the examples given in this clause a prescriptive list?
Clause 6.1.5 includes a list of the most common situations where variations within the equipment may potentially lead to unsafe products if the equipment and process are not validated and periodically verified. This list is not prescriptive, 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, pH distribution in a mixing vessel may need to consider the thoroughness of the mixing process to achieve the desired pH throughout the batch and/or the quantities of acidifying material added.

Clause 6.2.4: Does the Standard require sites to test online vision equipment using test packs?
Where a site uses online verification equipment to check product labels and printing, it is vital that the equipment is set up and checked to ensure that it is operating correctly. The site must be confident that the system will reject any non-conforming packaging.

Clause 6.2.4 requires sites using this type of equipment to have processes to check and confirm its correct operation. This includes the requirement to 'implement procedures for the operation and testing of the equipment' at a defined frequency (based on risk). However, the Standard does not prescribe how this testing is to be completed.

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), then good practice is to test the system using incorrect packs to ensure that the equipment identifies and rejects those packs. Many metal detectors are also tested in this way, and the method can be used to check each function of the equipment (e.g. detection system, reject 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 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, alternative testing solutions may be devised by the site. For example, prior to the commencement of the packing run, a test programme could check each function of the verification equipment by causing the instrument to reject the existing/correct packaging.

7 Personnel

Clause 7.2.1: Can items such as a 'Fitbit' and 'Apple' watches be considered under acceptable personal items for a medical alert?
The key aim of this clause is to enable the site to eliminate potential sources of contamination, including those from jewellery. It is therefore good practice to minimise the number and types of items that are permitted within production areas. Exceptions are made for simple wedding bands, other religious items that would be inappropriate

to ask staff to remove, and medical items.

Medical alert items are those which ensure that vital information is made available in an emergency (e.g. individuals with severe allergy) and where the absence of such information could delay emergency treatment. Generally, Fitbit-style products do not contain emergency information and are not linked with ongoing medical treatment, but exceptions may apply. In any situation where an item needs to be permitted, the site should complete a risk assessment and put in place suitable controls to prevent product contamination.

Clause 7.4.3: Can protective clothing be home-laundered?

The expectation of the Standard is for protective clothing to be effectively cleaned (laundered). For a majority of sites, the requirement states that this must be completed by an approved contracted or in-house laundry.
The Standard does allow home laundering of protective clothing by employees, but only in exceptional circumstances, where the clothing is worn primarily to protect the worker from the product, and the clothing is worn either in:

- enclosed product areas **or**
- low-risk areas.

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 for bakeries because although the protective clothing is being used in a low-risk area, it is an open product area where the clothing is clearly designed to protect the product not the employee.

Situations where the clothing is specifically intended to protect the worker from the product are those where there is minimum risk of product contamination, but workers need clothing to protect themselves. For example, there are situations where workers need protection from dirt or waste generated by a process, such as the handling root vegetables direct from the field; here the clothing is predominantly designed to protect the individual from the soil adhering to the vegetables.

Enclosed product areas and low-risk areas are both defined in Appendix 2 of the Standard.

8 High-risk, high-care and ambient high-care production risk zones

If a site packs product prepared or manufactured at other sites, does it need to follow the high-risk or high-care requirements in the Standard?

The 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 product requires high-risk or high-care production zones during its manufacture and initial packing (see Appendix 2 of the Standard for details of these products), 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).

Does the manufacture of ice cream require high-care or low-risk production zones?

There have been a number of product recalls associated with ice cream contaminated with pathogens such as Listeria spp. It is therefore vital that sites manufacturing ice cream products operate suitable controls to prevent adverse microbiological contamination, which is often achieved using high-care production risk zones (see Appendix 2 of the Standard and the BRCGS guideline on understanding high risk, high care and ambient high care for full definitions of the production risk zones and the products which need to be produced in them). A large proportion of the ice cream manufacturing process is completed in enclosed product areas (e.g. in pipework) and high-care facilities are not required for these areas.

Where the product is open (i.e. exposed to the factory environment), the site must operate suitable processes to prevent product contamination. Many sites have therefore concluded that high-care facilities are appropriate for their product range. However, if a site concludes that high-care production zones are not necessary and a low-risk zone can be used, then this must be supported by justifiable evidence. In this situation, the chosen risk zone must be supported by a risk assessment in the HACCP plan (i.e. the HACCP plan must include a thorough risk assessment which considers the potential pathogen contamination risks and a demonstration of how these will be mitigated). It should be noted that simply stating that a product is frozen is not considered a thorough risk assessment. Pathogen test results (product and/or environmental monitoring) can be useful to demonstrate that the controls are working effectively, but they are not considered an alternative to a thorough risk assessment, as they demonstrate the absence of pathogens rather than identifying the correct controls. In the absence of this risk assessment, the expectation is that a high-care zone will be operating.

Regardless of the production zone, sites are also expected to meet any specific legislation in the countries where the product is intended to be sold.

Clause 8.4.1: Do high-risk and high-care clothing need to be separated, if both are used in the same site?

The expectations for compliance to this clause hasn't changed from Issue 7 to 8. Where a site has a high-risk and/or high-care area it must be separate from any lower-risk area; therefore by definition a high-risk area would need to be separate from a high-care area. The same principle applies to protective clothing, equipment, changing areas etc.

Further explanation can be found in the interpretation guideline for Issue 8 of the Standard and in the guideline on understanding high risk, high care and ambient high care. Both of these guidance documents are available on the BRCGS Participate platform (www.brcgsparticipate.com).

Clause 8.4.1: Are boot-wash facilities acceptable at the entrance to high-risk areas?

The site needs a system to control footwear effectively. This may include:

- the use of clean footwear to be worn only in the high-risk area and the provision of effective measures for changing into such footwear
- by exception, the use of boot-wash facilities at the entrance to the high-risk area. This will be acceptable where such facilities demonstrably provide an effective control. The site must have undertaken a risk assessment to identify the suitability of the boot-wash facilities and the controls to manage the effective sanitation of footwear.

For such controls to be effective, they would be expected to include:

- consideration of the potential for cross-contamination of boots prior to boot-washing. Permitted areas where footwear can be worn prior to entry to a high-risk area must be clearly defined (e.g. the same footwear must not be worn outside the facility or in low-risk processing areas)
- boot-wash equipment that is suitably designed, well-maintained and demonstrably effective in cleaning and sanitising the footwear
- minimum cleaning times and concentrations of detergent and sanitiser to be used. These must be determined, monitored and controlled to ensure the effective cleaning of footwear
- a cleaning schedule (i.e. a schedule for the cleaning of the boot-wash facility and equipment) to ensure that the boot wash does not become a source or vector of microbiological contamination
- records of detergent/sanitiser checks and of the effectiveness of the boot-wash facilities.

Regardless of the method of footwear control, the site must ensure that:

- the footwear controls are validated by microbiological monitoring of the factory environment (e.g. the footwear, floors and drains in the high-risk area) to demonstrate the absence of pathogens such as *Listeria* spp
- the footwear is company-issued and of a design that is easily cleaned (i.e. smooth upper surfaces and cleats on soles that are sufficiently spaced so as not to trap dirt which may not be easily removed by boot-wash equipment).

Clause 8.5.2: 8.4.1: Do bullet points 3 and 4 refer to one action or two separate actions (i.e. is the operative required to wash their hands after they put their hair net and boots on, and then again before they go into production, or would it be acceptable to wash their hands only once after they have put their hair net and boots on)?

For high-risk areas the intention is that both of these actions are completed: during the changing, and before entry to the area. This is to minimise the risk of contamination of hands during the changing operation, particularly when handling the hair and footwear.

Clause 8.5.2: Is visual inspection still a method of determining the acceptability of cleaning, since the clause requires microbial limits?

The Standard provides some flexibility in what systems are used and when to adhere to above clause. However, visual cleanliness will be less relevant in high-risk and high-care areas than in other parts of the site. It is expected that sites will have different systems for validating and verifying the cleaning procedure, compared with ongoing routine monitoring. It is ultimately the responsibility of the site to develop appropriate controls and then to be able to justify them to the auditor.

9 Requirements for traded products

What are traded products?

The Standard defines traded products (sometimes referred to as traded goods) as those products that could be incorporated within the scope of the audit if they were manufactured at the site, but are not actually manufactured, processed or packed at the site; instead they are purchased from an outside supplier and stored at the site before being sold on.

Where products are not purchased or sold, they are not considered to be traded products (e.g. products stored by a multi-site company at a site which is not the manufacturer, processor or packer of those products). In these situations, the certification body will record the information in the company profile section on the audit report, but it will not form part of the scope of the audit.

Where products are returned to the site for further processing or packing, then the requirements for outsourced processing (section 3.5.4) must be considered.

Is section 9 of Issue 8 of the Standard still a voluntary additional module, and is it the site's choice whether to include it in the scope of the audit?

It is still a voluntary additional module and a site may choose to include it in the audit scope. However, it is worth noting that where a site handles traded products but elects to omit this activity from the scope of the audit, this will be recorded as an exclusion from scope on the audit report and certificate.

If a sealed product is purchased and then added to a box that includes items manufactured at the site, would this be a traded product or part of the main scope?

The section on traded products relates only to those situations where a site purchases, stores and sells the material, but does not complete any processing or packing activity. The process described in the question would be part of the production process for the final product, and therefore the process would have to meet the requirements of sections 1–8 of the Standard rather than section 9. The wording of the scope (on the certificate and audit report) would make it clear that the purchased item was not manufactured on site.

If a site sends a raw material to another company and finished goods return to the site, can the site treat this contracted manufactured product as a traded product? Would this change if the product was labelled on return?

If the product comes on to the site and is simply stored and dispatched, the traded products section of the Standard may apply. However, if any further activity is undertaken (e.g. the product is relabelled after it returns to the site), then the activity that was completed off site should be considered an outsourced process.

The activities that occur at the contracted site are not included in the scope of the audit as the certificate is site-specific; however, the audited site will need to demonstrate how it manages the contracted services.

A certificated site intends to provide cold storage and dispatch services for a new product that it doesn't buy or sell (it is packed at a different site). Which Standard is applicable for this service?

The key principle here is that the traded products section of the Food Standard can only apply to products that are purchased by the site and stored at the site prior to sale to the customer. Therefore:

- if the site purchases the products, the Food Standard would apply (possibly with an extension to scope visit if the process is different)
- if the product is not purchased but is stored on site, then the Storage and Distribution Standard would apply
- if the product is not stored on site, then the Agents and Brokers Standard would apply.

If a site chooses to include traded products, is the audit duration increased?

In Issue 7 of the Standard, this module added approximately 1 hour to the audit duration, depending on the complexity of the operation. It is therefore likely to increase the length of the audit duration slightly.

Auditors have the flexibility to increase/decrease audit duration by 30%, so if the duration is slightly longer, this can be accommodated in the audit.

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 **brcgsbookshop.com**

9 781784 903671