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Part 1. Introduction and Guidance Protocols

1.1 Introduction

The use of this guidance is to assist in meeting those requirements for manufacturing of Dietary Supplements or to provide additional clarification to requirements of the SQF Food Safety Code for Manufacturing. The guidance and requirement clarification was created by comparing the SQF Food Safety Code for Manufacturing against the FDA's CFR 111 for Dietary Supplements. The guidance can be referenced for any SQF certification audit to assist in meeting specific regulatory or customer/supply chain requirements.

1.2 Scope and application

The guidance can be applied to any site seeking certification or re-certification to the SQF Food Safety Code for Manufacturing and Food Sector Category 31. It must be used in conjunction with the SQF Code and the *SQF Dietary Supplement Checklist*. All requirements within the specific SQF Code element must be met in addition to those identified and **bolded** within this guidance and in the checklist.

1.3 Dietary Supplement additional audit duration

The certification body, using the audit duration guide in the SQF Code to assist it, will determine if any additional time is required to complete assessment of the additional guidance. A reference to the application of the guidance shall be included in any contractual documents the certification body has with the site. The time allotment may or may not be completed in conjunction with the audit as determined by the certification body's ISO 17065 requirements but shall be clearly indicated in the audit agenda provided by the certification body.

The allotted time shall allow auditors to spend additional time observing the process, interviewing employees and completing audit trails to determine root causes to any non-conformities found. While these are auditing skills and tools normally applied to an SQF certification audit, they shall be used specifically to assess conformance to the additional information in this guidance.

1.4 Addendum report and non-conformances

Non-conformities identified during the audit against the additional information in this guidance shall be graded in a similar fashion to that described within the SQF Code, namely critical, major and minor. Any critical non-conformance shall be appropriately applied to its associated SQF Code element and included and handled in the certification report, along with a failure rating and/or SQF certification withdrawal. Non-conformities shall require corrective actions by the site within SQF Code required timelines and be closed and approved by the certification body prior to SQF certification or re-certification. Where SQF certification is not achieved, the addendum shall be considered as not being successfully completed and must be included in any subsequent certification audits.

An additional report or the *SQF Dietary Supplement Compliance Checklist*, that aligns with the guidance can be issued at the discretion of the certification body or as requested by the site. The report or checklist shall be written with the same detail expectations as used in the certification audit report and can include observations and best practice descriptions where asked for within the requirements. The report is not graded or scored but minimally requires observations and/or non-conformances to be included in the certification audit report rated accordingly.

1.5 Requirements format

The following section explains the elements and/or sub-elements of the *SQF Dietary Supplement Manufacturing Guidance*. It also provides guidance on what a site needs to do to develop, document and implement within an SQF system, and provides information on what evidence the auditor may be looking to show compliance. Additions or changes to current code and guidance documents are **bolded** for clear identification.

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The following format is used throughout:

Element Number and Name

Sub-element Number and Name. Mandatory elements will be indicated by: "(Mandatory)".

This section will describe what the SQF Code, edition 8.1 requires. This is the text from the SQF Code and is the auditable standard. Where there is disagreement between the text of the SQF Code and the guidance, the SQF Code in English prevails.

Implementation Guidance
<p>What does it mean?</p> <p>This will include the interpretative comments of what the sub-element requires or definitions of the terms used.</p>
<p>What do I have to do?</p> <p>This will include suggestions of what is required to be done by the site to document and implement this sub-element. The information provided is not considered exhaustive and may not apply in every situation. It is meant to provide guidance and interpretation.</p>
Auditing Guidance
<p>This will include suggestions of what the auditor may seek as evidence of compliance for this sub-element. The information provided is not exhaustive and may not apply in every situation.</p>

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Part II - Guidance

2.1 Management Commitment

The level of commitment, support, and leadership demonstrated by senior company and site management is fundamental to the effective implementation of an SQF food safety management system. Senior management must create the environment within the site that encourages a pro-active attitude amongst staff towards food safety.

The requirements detailed in 2.1 provide an important measure of the level of leadership within the site.

2.1.1 Food Safety Policy (Mandatory)

What the SQF Code says

2.1.1.1 Senior management shall prepare and implement a policy statement that outlines as a minimum the: Senior site management shall prepare and implement a policy statement that outlines as a minimum the:

- i. The site's commitment to supply safe food;
- ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and
- iii. The site's commitment to establish and review food safety objectives.

2.1.1.2 The policy statement shall be:

- i. Signed by senior site management;
- ii. Made available in language understood by all staff; and
- iii. Displayed in a prominent position and effectively communicated to all staff.

2.1.1 Implementation Guidance

What does it mean?

Commitment to a policy by senior management is a visible sign of leadership – the creation of a “culture of food safety” within the site. The policy statement provides a focus on what the site aspires to and is working to achieve in terms of food safety.

“Senior” means the person who has operational control within the supplier’s site. It is considered to be the senior person on site. Some larger sites may be influenced by a Board of Directors or senior management team based at Head Office. However as considered in the SQF Code, it is the site senior management that is referred to, and the person who must sign the policy.

Senior management must sign the document as an indication of their commitment to implement it. The policy statement sets out the objectives of the site’s SQF System, and provides the framework for achieving objectives at an operational level. Objectives must be written in a way that every employee at the site can contribute toward achieving them.

Commitment to regulatory and customer requirements underpins the site’s SQF System and must be included in the policy statement.

What do I have to do?

This element is mandatory. The policy statement is generally the first part of the supplier’s food safety manual (refer to 2.1.3). The owner or most senior responsible person within the supplier site is required to:

- document and sign a policy statement that clearly demonstrates their understanding of their food safety responsibility under the SQF System;
- outlines how the supplier will achieve and maintain food safety;
- includes a stated commitment to comply with regulatory and customer requirements; and
- includes a stated commitment to continually improve the SQF System.

The policy statement must be reviewed at least annually by senior management. This review is normally done when the review of the SQF System is undertaken.

The policy statement must be available to all staff in a form and language that is understood by all staff.

2.1.1 Auditing Guidance

The content of the policy statement will be reviewed by the auditor initially at the desk audit. However

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during the first and subsequent site audits, the auditor will check to confirm that the contents of the policy statement are applied in practice on a daily basis.

The auditor will seek evidence of compliance to management commitment and thereby a “culture of food safety” through observation and interview. Evidence may include:

- A documented policy statement, signed by the senior site manager, that commits to meeting regulatory and customer requirements and indicates how those requirements shall be met; setting and achieving food safety objectives; reviewing food safety objectives on a regular (at least annual) basis; and continually improving their SQF food safety management System.
- The currency of the policy statement.
- The availability of the policy statement to all staff within the site. This includes confirming employee understanding of the policy statement.
- Food safety objectives are established and realistic.
- Activities within the site meet regulatory and customer expectations.
- Activities within the site reflect established food safety objectives. The auditor may seek company food safety meeting minutes and check if management participated in these meetings.
- The policy statement, including food safety objectives, is reviewed at least annually.

The policy statement need not only be posted, however the actions for management commitment must be implemented.

There are also situations that may either singly or in combination indicate poor management commitment such as:

- A plant environment in which employees and management are not engaged or have no awareness of food safety objectives;
- Staffing positions that are recently created (indicating they were created simply to meet the element of the Code and not proactively to address food safety objectives), outdated or have been vacant for an extended period of time;
- Recent recalls or ongoing audit pressure;
- Plant is for sale or a public announcement has been made that the plant or division will be sold;
- The use of a large, temporary labor pool.

2.1.2 Management Responsibility (Mandatory)

What the SQF Code says

2.1.2.1 The reporting structure describing those who have responsibility for food safety shall be identified and communicated within the site. **It shall clear indicate the designated quality control person or other resource responsible for regulations.**

2.1.2.3 The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System. **Resource allocation and responsibility shall ensure regulation and any associated licensing is maintained and aligned with the SQF system.**

2.1.2.4 The owner/senior site manager shall designate an SQF practitioner for each site with responsibility and authority to:

- Oversee the development, implementation, review and maintenance of the SQF System, include Good Agricultural Practices outline in 2.4.2 and the food safety plan outlined in 2.4.3;
- Oversee and ensure all regulatory requirements are being met;**
- Take appropriate action to ensure the integrity of the SQF System; and
- Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

2.1.2.5 The SQF practitioner shall:

- Be employed by the site as a company employee on a full-time basis;

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ii. Demonstrate awareness of the regulatory requirements for the designated food safety person (e.g. Quality Control Person, PCQI)

- iii. Have completed a HACCP-based training course;
- iv. Be competent to implement and maintain Good Agricultural Practices; and
- v. Have an understanding of the SQF Code and the requirements to implement and maintain SQF System relevant to the site's scope of certification.

2.1.2.6 Senior site management shall ensure the training needs of the site are resourced, implemented and meet the requirements outlined in system elements, 2.9, and that site personnel have met the required competencies to carry out those functions affecting the legality and safety of food products.

2.1.2.7 Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF food safety Code, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action.

2.1.2 Implementation Guidance

What does it mean?

Tangible actions must follow commitment. Management must ensure that the resources required to implement the policy, food safety objectives and **regulations** are available. Resources are often scarce in many organizations. Regardless, management must demonstrate that employees understand their responsibility for food safety and be allowed the time, tools and authority to carry out these responsibilities.

By providing and communicating an organizational chart and position descriptions that demonstrate the interrelationships and responsibilities within the site, each employee will know his/her role in assuring food safety and continuous improvement. This must be understood by all employees and staff members of the site. Management must clearly identify and provide the resources to achieve food safety objectives and **regulation**.

This element also includes the requirements for, and responsibilities of, the SQF practitioner. This is a key role within the supplier's site, being the person designated by senior management to manage the development, implementation, daily operation, validation and verification of the SQF System. **They may also be the designated person as described by any licensing requirements in regulations or are aware of the impact of regulatory oversight on the SQF program.**

What do I have to do?

This element is mandatory. The senior responsible person is required to document the organizational reporting structure that describes each position that has responsibility for food safety **and regulations**. The organisational structure provides a snapshot of how these positions interact and share that responsibility. **The food safety and regulatory management functions may be the same person or separate.**

Senior management must convey **food safety and regulation responsibilities** to every employee. This will be written into job descriptions for all roles within the site that impact food safety **and regulation**. Job descriptions for key personnel must include a provision for coverage on all shifts and replacement during absence. There must be documented instructions and training for all staff to report food safety problems to personnel with the authority to initiate actions.

Senior management must also document how they will provide resources to achieve food safety objectives **including regulation**. They must demonstrate their support of the development, implementation and maintenance and ongoing improvement of the SQF System.

The SQF practitioner is the individual designated by senior management to develop, validate, verify and maintain the company's Food Safety Plans, and assume control of the daily operation of the SQF System. The SQF practitioner may engage the services of an SQF consultant to assist with the development of the SQF System, or support its validation and verification, but overall responsibility remains with the supplier through the SQF practitioner. **The SQF practitioner may also be the designated person responsible for regulatory compliance such as the Quality Control or PCQI. If they are not the same person then they will need to be aware of the impact regulatory oversight has on the SQF program.**

The requirements of the SQF practitioner are clearly outlined in 2.1.2.5, and are further described in the SQFI guideline on SQF practitioners. Note that SQF practitioners are not required to complete an Implementing SQF Systems training course or Implementing SQF Systems examination, it is not compulsory although either or both is recommended. However the practitioner is required to understand and demonstrate knowledge of the SQF Code and its application within the site. **They must also be able to demonstrate competency in understanding and implementing regulations that apply. This may require specific training as per the regulations.**

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The commitment of management to ensuring that employees are trained and assessed as competent to carry out job functions pertaining to food safety must be documented. The job descriptions must reflect the competencies required of each employee to carry out their food safety responsibilities and the training that is necessary to assure those competencies (refer to 2.9). The person(s) **responsible for your quality control operations must be identified. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations. Each supervisor must be qualified by education, training, or experience to supervise.**

2.1.2 Auditing Guidance

The auditor must avoid making a quick decision on *2.1.2 Management Responsibility*. Although this element is at the beginning of the Code, the auditor is unlikely to make a full judgment on compliance with this element until the end of the audit.

The documented organizational structure and job descriptions shall be audited as part of the initial desk audit. However during the first and subsequent site audits, the auditor will check to confirm that the contents of the organizational structure and job descriptions are applied in practice on a daily basis – that a “culture of food safety” has been created.

The credentials of the SQF practitioner shall also be checked at the initial desk audit. However the competence of the practitioner and his/her ability to effectively manage the SQF System **and applicable regulations** shall be confirmed at each site audit.

The auditor will seek evidence of compliance to this requirement by observation and interview. Evidence may include:

- There is a current, documented organizational structure in place that identifies those responsible for food safety, and their interrelationship, and is agreed by senior management. **It clearly outlines the Quality Control person responsible for regulatory compliance.**
- Job descriptions are in place for positions that have responsibility for food safety. The auditor may question why positions have been vacant for a long period of time or the site chooses to use a large, temporary labor pool.
- Adequate resources are in place to meet food safety objectives and the requirements of the SQF System. This includes coverage for all operational shifts and absences.
- Employees within the site with responsibility for food safety **and regulation** are clearly identified, are aware of their responsibilities and are trained and competent to carry out these responsibilities.
- Senior management ensures that all designated food safety **and regulatory** practices and activities are correctly documented, meet the requirements of the SQF Code and are correctly and fully implemented on all shifts. This would include a review as to the timeliness of implementation of corrective actions, action on complaints, and addressing identified gaps in the site’s programs.
- There is a designated SQF practitioner who manages the implementation and maintenance of the SQF System **and applicable regulations** on a daily basis.
- The designated practitioner has the qualifications necessary to be an SQF practitioner (identified in 2.1.2.4 and 2.1.2.5) and is capable and competent to carry out this function.
- The designated practitioner has the support of senior management and has the time and availability to monitor the effectiveness of the SQF System; is competent and has the authority to take appropriate corrective actions when necessary; and communicates to relevant employees any information necessary to maintain or improve the System and **meet regulations.**

2.1.3 Management Review (Mandatory)

What the SQF Code says

2.1.3.1 The senior site management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include:

- i. The policy manual;
- ii. Internal and external audit findings;
- iii. Corrective actions and their investigations and resolution;
- iv. Customer complaints and their resolution and investigation;

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- v. Hazard and risk management system; and
- vi. Follow-up action items from previous management review.

2.1.3.2 The SQF practitioner (s) shall update senior site management on a (minimum) monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented. The SQF System in its entirety shall be reviewed at least annually.

2.1.3.3 Food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be reviewed and updated as needed when any potential changes implemented have an impact on the site's ability to deliver safe food.

2.1.3.4 Records of all management reviews and updates shall be maintained.

2.1.3 Implementation Guidance

What does it mean?

This element is closely linked to 2.1.2 and is one of the tangible actions which demonstrate management commitment and involvement.

The supplier must review their SQF System when any changes occur that impact food safety. This may include changes to product formulations, raw or packaging materials, processing or packaging equipment or changes to personnel. The SQF practitioner is responsible for managing such changes, but senior management is responsible for authorizing and approving these changes.

The SQF System shall be reviewed and update changes communicated (at a minimum) monthly to senior site management as part of the review of all operational activities. Additionally, a full review of the SQF System must be completed annually by senior management.

What do I have to do?

This element is mandatory. This (at a minimum) annual review, including monthly updates for site management, shall include the policies outlined in company's policy statement, findings from the regularly scheduled internal and external audits, customer complaints, test records, deviation reports and outcomes of corrective actions.

A procedure documenting how the review of SQF System is conducted shall be included in the food safety manual. The review must be conducted by senior management with the objective of ensuring the continued integrity of the food safety management system.

The review shall measure the effectiveness of the SQF System against the food safety objectives established by senior management and the effectiveness of corrective actions taken in response to deficiencies in the System. The focus shall also be on the effectiveness of pre-requisite programs and the ongoing accuracy and validation of the Food Safety Plan (s).

All reviews and major changes to the SQF System shall be recorded by the SQF practitioner, including the reasons for any changes and the actions taken as a result of changes or reviews.

Major changes to a process, a process control or any changes that could impact on the ability of the System to deliver a safe food shall trigger a review of the Food Safety Plan in addition to the annual review. Any major changes to Food Safety Plans shall be validated and verified before implementation.

2.1.3 Auditing Guidance

The auditor will seek evidence of the existence of a management review procedure at the desk audit and compliance to this requirement through a review of records and interviews with senior management and the SQF practitioner. Evidence may include:

- Review of the management review procedure.
- Records of SQF System reviews by senior management and the depth of coverage of the review meetings (e.g., food safety objectives, food safety measures, customer complaints, test records, product and process changes, etc.).
- Identified actions from review meetings, and follow up on progress and outcomes of corrective actions.
- Changes to the products and/or operational processes since the last audit, and the extent to which these changes are reflected in the food safety manual.
- The extent to which changes in materials, process or products have been validated.
- Records of product and process changes and their validation.

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2.1.4 Complaint Management (Mandatory)

What the SQF Code says

2.1.4.1 The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products manufactured or handled on site, shall be documented and implemented. **It shall minimally include:**

- i. The qualified person responsible for reviews, approvals and follow-up activities**
- ii. Specific actions when complaints determine that products are possibly not meeting finished product specifications.**

2.1.4.2 Trends of customer complaint data shall be investigated and analyzed by **qualified** personnel knowledgeable about the incidents.

2.1.4.3 Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3.

2.1.4.4 Records of customer complaints and their investigations shall be maintained.

2.1.4 Implementation Guidance

What does it mean?

Customer complaints provide an important measure of how well the SQF System is performing. By accurately recording customer complaint types, a site can objectively measure changes in their management system and show improvements in a process. Customer complaints may also show trends that have not been identified during processing and normal process control checks. The SQF Code, requires the site to implement a procedure for resolving customer complaints. The procedure shall outline the methods used and identify responsibilities for ensuring complaints are investigated and appropriate action is taken.

What do I have to do?

Although this is not a mandatory element, it is extremely unusual for site's NOT to have any customer complaints.

The site shall develop a procedure showing how customer complaints are received, investigated and responded to and the methods used to investigate complaint trends.

The procedure must detail the responsibility for investigating customer complaints, initiating follow up actions and communicating back to the customer how the complaint has been resolved. The procedure should include criteria for the determination of the validity of complaints **as well as describing how a qualified person must:**

- **Review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of CFR 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury;**
- **Investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements CFR 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury;**
- **Review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow up action of any investigation performed; and**
- **Apply all investigations to all relevant batches, lots and records.**

Any trending or data management of complaints need to be included in the procedure. The procedure can include criteria when trends show issues that require corrective action plan development and/or process adjustment. Complaints may be locally received or received from a central site, call center, or corporate entity and shall include complaints from customers, consumers and/or regulatory authorities. All should be available for use in the complaint procedure.

In the case of when the site's corporate entity is responsible for creating and executing the complaint management program, the procedure must describe how the site is made aware of the program, how it is communicated to the site, how the site has implemented the program, and how the site verifies that the program is being followed. The site will need to verify how it is using the information that is provided by corporate to develop corrective action plans.

Records of complaints must be retained and include corrective actions taken by the supplier.

2.1.4 Auditing Guidance

Customer complaints may be the first record that an auditor asks to review when beginning the site audit.

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Customer complaints can provide an auditor insight into the performance of the supplier's SQF System and any trend areas that may require greater focus. The customer complaint procedure shall be reviewed during the desk audit and the implementation of the procedure (including follow-up and corrective actions) checked as part of the site audit by interview, observation and review of records. Evidence may include:

- Review of customer complaint records (i.e., complaints from customers, consumers and/or regulatory authorities);
- Review of the customer complaint procedure including the responsibility for collecting customer complaint data, investigating complaints and managing corrective action (refer to 2.5.5);
- Investigation of the interface between a corporate reporting function and site knowledge and investigation of customer complaints (where applicable);
- Investigation of outcomes of corrective actions taken as a result of customer complaint investigations (refer to 2.5.5).

2.1.5 Crisis Management Planning

What the SQF Code says

2.1.5.1 A crisis management plan that is based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis.

2.1.5.2 The crisis management plan shall include as a minimum:

- i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident;
- ii. The nomination and training of a crisis management team;
- iii. The controls implemented to ensure a response does not compromise product safety;
- iv. The measures to isolate and identify product affected by a response to a crisis;
- v. The measures taken to verify the acceptability of food prior to release;
- vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers;
- vii. Sources of legal and expert advice; and
- viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

2.1.5.3 The crisis management plan shall be reviewed, tested and verified at least annually.

2.1.5.4 Records of reviews of the crisis management plan shall be maintained.

2.1.5 Implementation Guidance

What does it mean?

A "crisis management plan" is often confused with a "product withdrawal and recall plan" (2.6.3). They are two separate functions and programs. A crisis management plan prescribes actions that will be taken as a result of external, environmental, climatic, equipment failure or other potential business threats that will impact the ability of the supplier to provide their customers with safe products. These threats, depending upon the supplier's product, location and other factors may include fire, flood, power failure, storm damage, acts of terrorism, etc.

A recall plan however prescribes actions to be taken when sub-standard product, i.e., product that deviates from established safety limits, is distributed and has to be recovered from the market (refer to 2.6.3).

For some smaller suppliers, the crisis management team and recall team may be one and the same. For larger suppliers, they may differ.

It is expected that all SQF suppliers have considered the potential threats to their business and the controls necessary to ensure continuous, safe food supply.

What do I have to do?

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The supplier is required to identify a crisis management team including a senior decision maker and ensure the team is trained in crisis management procedures. The team shall identify known threats to the business which could disrupt or impact its ability to produce and provide safe food and prepare a plan describing the methods and controls the supplier will implement to address these threats if they were to occur and how to maintain continuity of product supply during the crisis.

The plan must document in detail the controls the supplier will implement to assure that food safety are not compromised and that if the integrity of any product is compromised, how the product will be isolated and controlled. The plan should ensure that everyone on the crisis management team is familiar with the withdrawal and recall procedures the supplier has documented under 2.6.3.

The plan needs to include criteria for when controls will be implemented (e.g., numbers of hours with no power, rise in product temperature prior to moving to alternative storage locations, etc.) and how criteria will be monitored during the business threat condition. Criteria are to be product specific, as appropriate. Also included are product review and disposition criteria to determine what product is recoverable, what is salvageable and what is to be destroyed. Methods for recovery, salvage, and destruction shall be described within plan.

Communication during a crisis is important. Methods for communication with customers, stakeholders and news media must be described and the individual (s) who is/are responsible for communication (s) must be identified.

The crisis management plan shall include a crisis alert contact list, sources of legal and practitioner assistance which may counsel senior management in a crisis situation and designation of responsibilities for internal and external communication during a crisis.

The crisis management plan shall be reviewed at least annually. All elements of the plan need to be tested. This could include a mock press release, mock incident, requirement to contact external storage locations, etc. The key provision is to have a mock crisis identified, product identified, criteria for monitoring of affected product, actions that would be taken based on results from monitoring, and final disposition of identified product. If a mock communication is created, it is not recommended to contact customers for fear of confusion.

Records of this review are required.

2.1.5 Auditing Guidance

The crisis management plan shall be reviewed during the desk audit and the implementation of the plan, and its annual review (including follow-up and corrective actions) checked as part of the site audit by interview, observation and review of records. Evidence may include:

- A crisis management team has been established, trained and includes a senior decision maker;
- A crisis management plan is in place and has been tested at least annually;
- The crisis management plan includes known business threats, controls that need to be implemented, measures to isolate affected product and a contact list of relevant authorities, legal advice and other key stakeholders;
- The crisis management plan includes identification of the individual (s) responsible for communication, including communication within the site;
- Where the annual review of the crisis management plan has identified non-compliances or areas requiring improvements, corrective actions (refer to 2.5.5) have been identified and implemented;
- Records of business continuity plan reviews and their corrective actions are available.

2.2 Document Control and Records

2.2.1 Food Safety Management System (Mandatory)

What the SQF Code says

2.2.1.1 A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site will use to meet the requirements of the SQF Food Safety Code for Manufacturing, be made available to relevant staff and include:

- i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard;
- ii. The food safety policy statement and organization chart;
- iii. The scope of certification;
- iv. A list of the products covered under the scope of certification;
- v. Food safety procedures, pre-requisite programs, food safety plans;

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- vi. **Production and Process Control procedures and specifications supporting regulatory limits/claims; and**
- vii. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

2.2.1.2 All changes made to food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be validated or justified.

2.2.1 Implementation Guidance

What does it mean?

In general, food safety management systems involve “saying what you do,” e.g., documenting policies, specifications, procedures, HACCP plans and work instructions that agree with the standard (in this case, the SQF Code), and “doing what you say,” e.g., operating based on those documented policies and procedures. This is reflected throughout the SQF Code in the use of the terms “documented and implemented.”

In the SQF Code the food safety manual is the documented system (“saying what you do”) that must be implemented (“doing what you say”).

The food safety manual must be practical, usable, and available to all employees with a responsibility for food safety. It can be stored electronically or in hard copy, and the currency and security of the manual must be controlled (refer to 2.2.1). The form and structure of the manual is determined entirely by the site. It must be in a language and a form that is understood by all relevant employees.

What do I have to do?

This element is mandatory. The site must prepare a food safety manual that documents the policies, procedures, pre-requisite programs, Food Safety Plan(s), specifications and work instructions necessary to support the development, implementation, maintenance and control of the SQF System **and compliance to regulations.**

The manual will include the company policy statement and an organizational chart. It will include the HACCP Food Safety Plan(s) (refer to 2.4.3) for all products included in the site’s scope of certification.

There is no prescribed format for how the manual (s) is/are to be constructed. Format is determined by the site. It can be divided into a policy manual, food safety manual, or combined into one manual. It can be integrated with other operational procedures, or housed in a separate SQF manual - the choice depends on what best suits the site’s business.

The main criteria are to ensure that the manual conforms to the requirements of the SQF Code that are relevant for that industry sector and site, and that it is readily useable by the staff located at the site. It therefore is to be brief and concise and be available in a form and language that meets the access needs, language and literacy levels of the operating staff.

2.2.1 Auditing Guidance

The food safety manual shall be thoroughly audited as part of the initial desk audit. Any non-conformances raised at the desk audit must be corrected before proceeding with the initial site audit. The content of the manual shall be reviewed and verified, but not the format.

Thereafter at subsequent recertification audits, the desk audit is blended with the site audit. The auditor shall review changes and conduct checks of the documentation, including specifications or procedures that may impact on food safety. The content of Food Safety Plans shall be reviewed at every audit.

The auditor will seek evidence of compliance to this requirement by reviewing documentation. Evidence may include:

- The manual includes the company policy statement (refer to 2.1.1) and organizational structure and job descriptions (refer to 2.1.2)
- The manual includes a summary of the site’s food safety policies, and covers all relevant elements of the SQF Code.
- The manual includes procedures and/or work instructions for all pre-requisite programs included within the site’s scope of certification.
- The manual includes specifications for all products included within the site’s scope of certification.

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- The manual includes the HACCP Food Safety Plan(s) for all products included in the site's scope of certification.
- **The manual includes production and process control procedures that relate to regulatory/label claims.**
- The manual is current, concise, available, and usable by employees within the site's site.

2.2.2 Document Control (Mandatory)

What the SQF Code says

2.2.2.1 The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented.

2.2.2.2 A register of current SQF System documents and amendments to documents shall be maintained.

2.2.2.3 Documents shall be safely stored and readily accessible.

2.2.2 Implementation Guidance

What does it mean?

This element relates back to *2.1.3 Food Safety Management System*. All management system documents (e.g., policies, procedures, specifications, food safety plans plans, work instructions), plus any other operational reference documents (e.g., external codes, regulations, customer requirements, equipment instructions, etc.), must be controlled to ensure their currency and relevance. This includes forms which are the templates for records that are used to report test, inspection and audit results.

Documents can be stored electronically or be paper-based, or a blend of both. However the current copy of the relevant documents must be available to staff and employees that need to use them. A list of documents and amendments to documents must be maintained to identify the current documents in use.

What do I have to do?

This element is mandatory. To comply with this requirement, the supplier must designate a staff member who is responsible for document storage and security and how documents are controlled; distributing current versions to relevant employees; and ensuring that documents are up-to-date. Worn, illegible or out-of-date documents must be replaced. A written procedure describing how documents will be maintained, updated and replaced must be developed and in place.

A register of all documents must be maintained including when they were issued, updated and who has a copy of each document. Documents referred to include, for example, pre-requisite programs, food safety plans, SSOPs, SOPs, other work instructions and raw material and finished product specifications, etc.

Any requirements for corrections or maintenance of records must be recorded in document control procedures, including the appropriate methods for addressing corrections.

2.2.2 Auditing Guidance

The auditor needs to seek evidence of the existence of a document control procedure at the desk audit and compliance to this requirement by observation, interview with the responsible person and interviews with staff to ensure they have current documents available. Evidence may include:

- Review of the document control procedure;
- Review of the document register and list of amendments, and their accuracy;
- Availability and currency of documents in use;
- Security and storage of documents;
- All personnel who need access to specific documents such as food safety plans, procedures, customer specifications and applicable food regulations have such access.

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2.2.3 Records (Mandatory)

What the SQF Code says

2.2.3.1 The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented.

2.2.3.2 All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.

2.2.3.3 Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations. **Software programs and electronic data and records shall be backed-up on hard drives or cloud remote from the site's system.**

2.2.3 Implementation Guidance

What does it mean?

Records are the information about processing operations recorded on forms, which must be clear, concise, legible and accurate. Records must be stored to avoid being damaged so they can be retrieved for investigation purposes. Storage can be electronic or paper-based. The SQF Code states that records must be suitably authorized and must be stored as required by the corporation, customer or legislation.

Regulation requires software and electronic data to be backed up remotely.

Various roles within the business may be responsible for completing records, including those who are responsible for monitoring, testing, and/or auditing. Other staff members (including the SQF practitioner) may be responsible for verifying the accuracy of records (refer to 2.5.4), and one or more may be responsible for retrieving and storing records. All such individuals must be identified and made aware of their responsibilities.

What do I have to do?

This element is mandatory. The site must develop a written procedure documenting responsibilities for completing records (e.g., monitoring records, inspection and test records, etc.) and identifying those responsible for verifying the records.

Records must be retained under secure conditions as required by customer specifications and legislation.

Employees who are responsible for monitoring and recording activities must be made aware of the importance of maintaining all records in a clear and legible manner and the importance of recording the information at the time the activity is performed.

The employees responsible for monitoring critical food safety points (CCPs, CQPs) in the process are required to sign the record indicating the entry and the date it was made (or electronically authorize the entry). In addition, the supplier is required to ensure that staff responsible for verifying food safety records sign and date each record they review as part of their verification activities (refer to 2.5.4). These responsibilities and actions must be documented in the procedure.

Electronic records are acceptable. The site must have the means to manage electronic security of records, electronic signatures of monitors and reviewers and the means for electronic review. **This includes having the software, both current and past versions, as well as any process and food safety data backed up remotely or in a cloud based system.**

On paper-based records, the use of correction fluid to address corrections is not recommended. A line through the inaccurate recording, with accurate recording and initials of the monitor is recommended.

There is no prescribed duration for retention of records. For some suppliers it may be prescribed by legislation, customer requirements or insurance coverage. Apart from those requirements, the general rule is to retain records for the commercial shelf-life of the product (i.e., the maximum time before consumption). However, for short shelf-life products, sites must retain records beyond the next recertification audit, as a minimum.

2.2.3 Auditing Guidance

At the desk audit, the auditor will seek evidence of the existence of procedures or work instructions for monitoring activities, verification activities, and record storage. At the site audit, the auditor will review a sample of records selected by the auditor and may interview employees who complete the records. Evidence may include:

- Documented procedures defining the methods and responsibilities for undertaking activities to

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monitor critical control points and other activities necessary to maintain food safety, and accurately and legibly recording results;

- Documented procedures defining the methods and responsibilities for verifying monitoring activities and accurately and legibly recording results;
- Documented procedures defining the methods and responsibilities for undertaking testing and/or auditing activities and accurately and legibly recording results;
- Accurate and legible records for all required activities;
- Understanding of actions required when recorded results show deviations from required values (e.g., outside critical limits);
- Records are securely stored and accessible, **including remote backup of software and electronic data related to process controls and food safety.**

It must also be mentioned that intentional, systemic falsification of records can result in a critical non-conformity and an immediate failure of an SQF certification or recertification audit and a potential withdrawal of the SQF certificate.

2.3 Specification and Product Development

2.3.1 Product Development and Realization

What the SQF Code says

2.3.1.1 The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.

2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing.

2.3.1.3 Shelf life trials where necessary shall be conducted to establish and validate a product's:

- i. Handling, storage requirements including the establishment of "use by" or "best before dates";
- ii. Microbiological criteria; and
- iii. Consumer preparation, storage and handling requirements.

2.3.1.4 A food safety plan shall be validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety.

2.3.1.5 Records of all product design, process development, shelf life trials and approvals shall be maintained.

2.3.1 Implementation Guidance

What does it mean?

New products and revisions to existing products are generally developed in the food research laboratory or at best, in pilot scale. However, commercially produced products are likely to have more process variability than bench or pilot products. The supplier must have a procedure in place to ensure the safety of products escalated from bench/pilot scale production to full commercial production. This will include a food safety plan for new or revised products, shelf-life trials and validation, label declarations, allergen cross-contact trials, raw material, ingredient and packaging trials.

This applies to new products, changes to existing products and introduction of new materials or pack sizes.

This is not a mandatory element as not all facilities are involved in product changes or new product introductions. However any SQF certified site that does introduce new products, packages or product revisions must have a documented procedure in place and implemented.

What do I have to do?

The supplier must describe the methods and people responsible for the process by which new products are converted into commercial applications. Methods should include specific procedures required for transition from pilot plants and test kitchens to full-scale in-plant production.

Even if the supplier's corporate function is responsible for creating the product development program, that program is the responsibility of the supplier once it reaches commercial development and products are being produced, sold and distributed into the market.

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Any product claims must be substantiated by means of product research and/or testing, and shelf-life testing will be carried out as required. Any testing that is required may be focused on product performance, customer handling or new packaging conditions. If the supplier determines that shelf-life testing is not required, the supplier must document the reason for this decision and any supporting evidence.

As the product is being prepared for transition from pilot or test phase to commercial production, any new processes, equipment, additional handling, new packaging or storage conditions must be reviewed with identification of any possible food safety risks associated with new conditions. These risks must be assessed, and adjustments made to food safety plans prior to implementation.

Any adjustments to food safety must be validated and verified by the SQF practitioner prior to commercial production of the subject product.

Safe handling information must be included on all packaging, as required by legislation (regulation) and/or customer use.

2.3.1 Auditing Guidance

The auditor will seek evidence of the existence of a product realization procedure at the desk audit and compliance to this requirement by observation, interview and review of amendments and records at the site audit. Evidence may include:

- Review of the product realization procedure;
- Review of product, process, material and/or equipment changes or introductions;
- Amendments to food safety plans, procedures or specifications as a result of product changes or introductions;
- Verification of changes to documentation;
- Communication of changes to relevant staff.

2.3.2 Raw and Packaging Materials

What the SQF Code says

2.3.2.1 Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety shall be documented and kept current.

2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known. **The specifications, where applicable, shall ensure that when raw materials are used according to formulation or recipe that the purity, strength and composition of the finished product meets label declarations and regulatory requirements**

2.3.2.3 The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented.

2.3.2.4 Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, or certificate of analysis, or sampling and testing.

2.3.2.5 Verification of packaging materials shall include:

- i. Certification that all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency.
- ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

2.3.2.6 Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.

2.3.2.7 A register of raw and packaging material specifications and labels shall be maintained and kept current.

2.3.2 Implementation Guidance

What does it mean?

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This element links with 2.4.4 *Approved Supplier Program* & 2.5.4 *Product Sampling, Inspection and Analysis*. Before an approved supplier program can be implemented, specifications must be in place for all materials that could impact product safety. This relates to raw materials, ingredients, packaging materials, processing aids, additives and chemicals used within their site including cleaning compounds. The site is required to keep Material Safety Data Sheets (MSDS) and labels for all chemicals that are in use on-site.

What do I have to do?

Specifications must fully describe the materials provided. Safety-related information in raw material and ingredient specifications may include threshold levels for microbiological pathogens, factors affecting microbiological growth such as pH and water activity, threshold levels for potential chemical or physical contaminants, **levels of purity, strength and composition** and the presence or absence of known allergens. The extent to which these factors need to be included in the specifications will depend on the use of the material, **formulation/recipe** and the food safety **and regulatory** risk to the finished product.

A register of all raw material and packaging specifications (including finished product labels) must be kept, including a version number and date so that there is proof that specifications are updated as needed. The supplier must ensure that all relevant departments and employees have the most current information.

All raw and packaging materials must be validated to ensure hazards and risks to finished product safety are identified and controlled. Raw and packaging materials should be included in the HACCP Food Safety Plan (refer to 2.4.3) to ensure that controls are in place to eliminate hazards or reduce them to an acceptable level.

Validation is testing over and above daily monitoring to ensure that established food safety limits are effective, i.e., they achieve the desired results, so that the supplier can have confidence that the product and process are safe. Validation methods will vary depending on the risk to finished product safety. Validation for low risk materials may include certificates of analysis or certificates of conformance, provided by a trusted vendor. For high risk materials, testing and analysis is required for validation, and must be carried out annually (refer to 2.5.2). For food-contact packaging material, this may include testing or assurances for potential chemical migration to the food product.

Specifications must also meet the standards set by regulation in the country of origin and the country (ies) of intended destination. This includes maximum residue levels, **purity, strength, composition**, allergen declarations, and in particular, in-country labelling requirements (refer to 2.4.1).

All current specifications for materials that could impact food safety must be included on a register (list).

2.3.2 Auditing Guidance

The auditor will seek evidence of the existence and currency of material specifications and a procedure for developing and approving specifications at the desk audit. During the first and subsequent site audits, the auditor will confirm compliance to this procedure; the material specification register and the process for checking compliance to specifications, validating specifications and ensuring relevant employees have access to current copies of specifications (refer to 2.2.1). Evidence will be sought by interview, review of specifications and record review, and may include:

- Review of the procedure for developing and approving specifications;
- Confirmation that the register of raw and packaging material specifications includes all on-site materials;
- Review of a selected sample of material specifications to confirm agreement with relevant legislation;
- Review of a selected sample of material specifications, in particular for high risk materials, to ensure potential factors impacting on product safety **and regulatory compliance** are included;
- Availability of current copies of specifications to relevant staff;
- Interview of staff conducting validation activities;
- Review of records of validation checks.

2.3.3 Contract Service Providers

What the SQF Code says

2.3.3.1 Specifications for contract services that have an impact on product safety shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of all contract personnel.

2.3.3.2 A register of all contract service specifications shall be maintained.

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2.3.3 Implementation Guidance

What does it mean?

Many duties within the food production or processing site may be conducted by individuals or organizations that are not employed by the business, but are contracted to provide specialist services. These may include companies involved in transport, construction, contract labor hire, engineering, pest control, sanitation, chemical management, trash collection, refrigerated storage or uniform cleaning.

The contract service does not need to directly involve product safety, but could still indirectly affect the product or site. For example, construction engineers may not have direct contact with food manufacturing, but their work and presence in a food handling site can indirectly impact food safety.

This element of the Code addresses how the services from these outside organizations are controlled monitored and verified to ensure that food safety is maintained and customer specifications are achieved.

What do I have to do?

Just as with raw and packaging materials, specifications must also be in place for all providers of contract services. The specification may be included in the contract, and will describe fully the services provided, and how the safety of product are protected from the actions and presence of contract personnel. This will include, as necessary, the qualifications of contract personnel and the equipment, tools, and chemicals permitted on site (e.g., a “no glass” policy).

Contractors working within the site will be subject to the same personal hygiene and welfare conditions as employees. These conditions shall be included in the contract specification.

The specification must include the training required by contract service providers. Training examples could be training done by service providers, training completed by supplier or certification as demonstration of training.

All current specifications for contract service providers must be included on a register (list).

2.3.3 Auditing Guidance

The auditor will seek evidence of the existence of a register of contract service specifications and will review a sample of specifications to ensure compliance with the requirements of the Code. Evidence will be sought by interview, review of specifications, and observation, and may include:

- Review of selected sample of contract service specifications to confirm compliance with the SQF Code requirements, including personnel hygiene and welfare;
- Qualifications and credentials of contract staff;
- Knowledge of contract service and Code requirements by contract personnel.

2.3.4 Contract Manufacturers

What the SQF Code says

2.3.4.1 The methods and responsibility for ensuring all agreements relating to food safety and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.

2.3.4.2 The site shall:

- Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and
- Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.

2.3.4 Implementation Guidance

What does it mean?

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Contract manufacturers are facilities that are contracted by the SQF certified supplier to produce, process, pack, and/or store part of all of one or more products included in the supplier's product scope. In some cases, a product may be manufactured interchangeably at the supplier's site and at a contracted site. In other cases, a contract manufacturer may only be used intermittently to fulfill or supplement the supplier's production.

Whatever the situation, any contract site used to manufacture, in part or in whole, an SQF certified product MUST fulfill the same requirements as the SQF certified supplier. The responsibility for ensuring that these conditions are met is part of the primary supplier's SQF System.

What do I have to do?

The supplier must have a documented procedure detailing how they will ensure that product in the care of the contract manufacturer meets their customer specifications and the requirements of the SQF Code. Control of the food safety management system in an external site that is under different management is not an easy task. However the supplier must ensure that facilities selected to contract manufacturer are committed to meeting SQF System requirements. This includes management commitment, pre-requisite programs, document control and records, adhering to specifications, food safety plans, and all other food safety controls.

The supplier may simply require the contract manufacturer themselves to be independently SQF certified, or may choose to control the conditions in the contract site via sampling, testing, inspections and internal auditing. In the latter case, a verification schedule, including a sampling plan and internal audit procedure must be included.

If the contract manufacturer is processing or packing high risk product on behalf of the supplier, then the contract manufacturer must undergo an audit to the requirements of the SQF Code for the particular food sector category. The audit may be conducted by the supplier, or by an independent third party agency, and must be conducted at least annually. The audit does not necessarily require certification but must confirm compliance to the requirements of the SQF Code.

An annual SQF audit of the contract manufacturer does not replace the need for other regular checks and inspections at regular intervals.

Any changes to customer specifications must be fully documented. Procedures must include a communication plan to contract manufacturer(s) with changes to specification identified. The supplier's procedure must include verification that the contract manufacturer is aware of the changes to specification and that product produced after the change has been implemented reflects those required changes.

2.3.4 Auditing Guidance

The auditor will seek evidence of the existence of a documented arrangement binding the contract manufacturer to the SQF Code and detailing the methods by which the supplier confirms those arrangements. Evidence will be sought by interview, observation and review of records. Evidence may include:

- Review of the contract agreement and procedure for monitoring and verification of contracted product;
- Records of certification, internal audits, product sampling and testing from contracted facilities.
- Records of SQF audits of facilities contracted to manufacture high risk food.

Note: in situations where the auditor feels that there is product risk from the contracted site, the auditor may require a visit to that site to confirm compliance to the Code and the agreed arrangements.

2.3.5 Finished Product Specifications

What the SQF Code says

2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include:

- i. Microbiological and chemical limits;
- ii. **Purity, strength and composition supporting label claims;**
- iii. **Limits or levels of possible adulterants; and**
- iv. Labeling and packaging requirements.

2.3.5.2 A register of finished product specifications shall be maintained.

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2.3.5 Implementation Guidance

What does it mean?

A written finished product specification must be provided for all products covered under the site's SQF Certification. In some cases, industry sector specifications may apply for example for bulk consignments exported to world commodity markets. In other cases, the specification may be provided by the customer. It is important that the site does not undertake to supply goods where the specification is not consistently achievable under all processing and raw material supply conditions.

What do I have to do?

The site must develop a written finished product specification for each product (or group of similar products) covered under the scope of certification. The specification must, as a minimum, comply with the appropriate food safety legislation (including labeling requirements **and claims**) and must be updated as required. The site must keep a copy of all finished product specifications and a register of all versions of these documents.

A finished product specification can include physical (e.g., size/grade, color, net weight, etc.), microbiological (e.g., aerobic plate count, yeast and mold, lactic, coliforms), chemical (e.g., salt, moisture, titratable acidity, pH, fat content, brix, viscosity, etc.), **purity, strength, composition** and the packaging specifications for the product.

The site needs to ensure that the annual review of the SQF System (refer to 2.1.4.2) includes a review of the finished product specifications and that the list of specifications is maintained and kept current in a register (list).

Customers **and/or brand owners** will normally provide finished product specifications and if this is the case, it is advisable that both the site and their customers agree the specification is achievable and agree on the safety attributes of the product to be supplied. For stock items that are not customer specific, the site is expected to develop finished product specifications for those items.

The specification must be made available to relevant processing staff in production, process control and QA personnel.

2.3.5 Auditing Guidance

Finished product specifications will be included in the food safety manual and will initially be reviewed at the desk audit. At each site audit, the auditor will ensure that all specifications exist for all products included in the scope of certification and that the site is capable of and ensures compliance with the specifications.

Evidence may include:

- Every product covered by the scope of certification is covered by a specification;
- Specifications are current and agreed with customers;
- Specifications include all significant parameters required to ensure the safety of the product;
- Current versions of specifications are available to all relevant staff;
- The site has methods and criteria for sampling and testing finished product (refer to 2.5.6) to ensure compliance with finished product specifications;
- The site has processes in place to ensure that product released (refer to 2.4.8) meets specifications;
- Specifications are reviewed as part of the management review process (refer to 2.1.4.2).

2.4 Food Safety System

2.4.1 Food Legislation (Mandatory)

What the SQF Code says

2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen and additive labeling, labeling of identify preserved foods, **purity, strength and composition claims**, any other criteria listed under food legislation, and to relevant established industry codes of practice.

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2.4.1.2 The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented.

2.4.1.3 SQFI and the certification body shall be notified in writing within twenty-four (24) hours in the event of a regulatory warning. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

2.4.1 Implementation Guidance

What does it mean?

Food legislation (regulations) always applies and underpins the SQF Code. Sites MUST meet all applicable food regulations in the country, state, or region that the product is processed (i.e., where the site is located) and the country in which the product will be sold, if it is known. In some cases, export destinations may not be known. However, if a product is intended for, labeled for, or known to be distributed to another legal jurisdiction, then the destination legislation must be known and applied.

If there is disagreement between food legislation and the SQF Code, the food legislation always takes precedent. This may include (but is not limited to) applicable maximum residue limits, **purity, strength, composition**, trade weights and measures, permitted pathogen levels, product description, country-of-origin, nutritional and allergen labeling, etc.

What do I have to do?

This element is mandatory. The site is required to know and keep up-to-date with all applicable legislation. A larger site may employ a regulatory affairs person with that responsibility. For a smaller site, this may be achieved through web updates or communications from trade organizations, consultants or retail customers. A procedure must be developed to demonstrate how the site is informed of applicable legislation and changes to legislation. The procedure must include information about scientific or technical developments within the specific industry sector and applicable industry codes of practice.

The site is required to demonstrate knowledge of and compliance to all applicable legislation for all products included within their scope of certification. Legislative requirements must be included in finished product specifications (refer to 2.3.5) and be tested for (refer to 2.5.6).

Specifications for raw materials, ingredients, packaging materials and in-plant packaging materials must also meet the standards set by regulation in the country of origin and the country (ies) of intended destination. This includes maximum residue levels, purity, strength, composition, allergen declarations and in particular, in-country labeling requirements (refer to 2.3.2).

In many jurisdictions, site operations must be approved by a relevant national or local authority (see module 11, 11.1.2, and other pre-requisite program modules 3-15), and sites must be registered, if applicable. The site must ensure compliance and be able to cite registration/approval documentation.

It is important to note here that where a site has been served with a regulatory infringement, or causes a food safety incident that requires public notification, the certification body and SQFI MUST be contacted within 24 hours of the event (refer Part A, 5.3 of the SQF Code, edition 7). Failure to notify the certification body and SQFI of the existence of a regulatory infringement of a public nature may result in suspension or withdrawal of the SQF certificate. The SQFI contact for food safety events is foodsafetycrisis@sqfi.com.

2.4.1 Auditing Guidance

Applicable legislation may be included in the food safety manual or stored separately. The auditor will seek evidence of the existence of information on applicable legislation and of a procedure for maintaining currency of food regulations. Compliance will be checked at the desk audit and by observation and interview during the site audit. Evidence may include:

- Review of the procedure to maintain and update legislative requirements;
- Applicable legislative requirements have been incorporated into specifications (refer to 2.3.2, 2.3.5);
- Applicable legislative requirements are being applied and being inspected and/or tested (refer to 2.5.6);
- Compliance with legislation is checked as part of internal audits (refer to 2.5.7) and the management review (refer to 2.1.4.2).
- Confirmation that SQFI and the Certification Body have been notified in writing in the event of a

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food safety incident requiring public notification.

2.4.2 Good Manufacturing Practices (Mandatory)

What the SQF Code says

2.4.2.1 The site shall ensure the Good Manufacturing Practices described in modules 3, 4, 9, 10 or 11 (as applicable) of this Food Safety Code are applied, or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

2.4.2.2 Those Good Manufacturing Practices applicable to the scope of certification that outline how food safety is controlled and assured shall be documented and implemented.

2.4.2 Implementation Guidance

What does it mean?

This series of elements point to the industry sector pre-requisite program (PRP) module (s) (i.e., modules 3 through 15) relevant to the supplier's scope of certification. The supplier must implement module 2 AND the PRP module that applies to the industry sector relevant to their certified product. Suppliers that are vertically integrated businesses may need to apply more than one PRP module. This is explained further in Part A, 1.2 of the SQF Code, edition 7.

SQFI recognizes that not all food businesses are the same, even though the PRP modules are sector-specific. For example, a confectionery business (food sector category 17, module 11) may or may not include cold storage, depending on the type of confectionery product. Thus some elements from the PRP modules may be excluded from audits by explaining via risk assessment documented in the food safety manual the reason why they are to be excluded.

In the same way, some businesses may implement an alternative method of control to replace one or some of the elements in a PRP module. Where this applies, it must be justified via risk assessment to demonstrate that control is still in place. The supplier's procedures must reflect the alternative control method.

What do I have to do?

This element is mandatory. The supplier must ensure all relevant pre-requisite programs (PRPs) applicable to their industry sector, site and product (s) are documented and effectively implemented. The PRPs for each industry sector can be found in modules 3 through 15. One or more PRP modules may need to be applied.

A site plan showing the location of the premises and the surrounding land use, and evidence from the local authority indicating that the premise is approved for the purpose.

The premises, buildings and equipment must be located, constructed and designed to facilitate proper processing, handling, storage and delivery of safe food. The premises are to be maintained structurally sound and in a sanitary manner.

Pre-requisite programs shall be documented and implemented as applicable to the scope of certification. Each applied pre-requisite program must be verified by the SQF practitioner to ensure that it is achieving its intended purpose. The SQF practitioner is required to sign off on each pre-requisite program indicating that the verification has been completed.

2.4.2 Auditing Guidance

Documentation for the pre-requisite programs (PRPs) will be checked at the desk audit. This includes procedures and work instructions applicable to the relevant PRP module(s), or alternative methods of control. The auditor will confirm compliance to this element at the site audit by interview, observation and sampling and checking records. Evidence may include:

- The supplier has documented and implemented the correct PRP module(s);
- Procedures and or work instructions are in place to cover all applicable PRPs in the relevant PRP module(s);
- Applicable PRPs are effectively implemented;
- Exempted PRPs are documented;

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- The effectiveness of PRPs, including alternative controls where applicable, have been verified to ensure that they achieve the desired result
- Records of PRP validations are available;
- The property, buildings and equipment meet the PRP requirements, and are clean and achieve hygienic production;
- Personnel practices and processing techniques meet the PRP requirements and the documented procedures.

2.4.3 Food Safety Plan (Mandatory)

What the SQF Code says

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. Feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

2.4.3.2 The food safety plan shall be effectively implemented and maintained and outline the means by which the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

2.4.3.3 The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant products and associated processes. Where the relevant expertise is not available on site, advice may be obtained from other sources to assist the food safety team.

2.4.3.4 The scope of each food safety plan shall be developed and documented including the start and end-point of the processes under consideration and all relevant inputs and outputs.

2.4.3.5 Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.5.1) plus any additional information relevant to product safety, such as pH, water activity, and/or composition.

2.4.3.6 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative use of the product.

2.4.3.7 The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, and service inputs (e.g., water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation.

2.4.3.8 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

2.4.3.9 The food safety team shall conduct a hazard analysis for every identified hazard, to identify which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

2.4.3.10 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

2.4.3.11 Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

2.4.3.12 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

2.4.3.13 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

2.4.3.14 The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.

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2.4.3.15 The documented and approved food safety plan (s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs or other changes affecting product safety occur.

2.4.3.16 Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5)

2.4.3.17 Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

2.4.3 Implementation Guidance

What does it mean?

The HACCP Food Safety Plan is the foundation of the site's SQF System. The Food Safety Plan must be prepared using the HACCP method, which means that all products and processes included in the SQF scope of certification must be addressed in one or more HACCP plans. The Codex HACCP model is to be used. All HACCP principles and implementation steps must be included in the HACCP Food Safety Plan. The HACCP Plan must be fully developed by the site, meaning the site may use the services of an SQF consultant, but takes full responsibility for the HACCP plan.

It is self-apparent but important to recognize that the HACCP plan cannot just be paper-based, but must be fully implemented. The HACCP system implemented by the site must be, in the words of the GFSI Requirements Document, seventh edition "systematic, comprehensive, and thorough."

What do I have to do?

This element is mandatory. The site must develop and fully implement a Food Safety Plan using the Codex HACCP method, that at a minimum follows the twelve HACCP implementation steps:

1. A multi-disciplinary HACCP team must be implemented which includes expertise on the process, product and food safety. A team leader must be appointed that is fully trained in the HACCP process. This team leader may be the SQF practitioner. Training must also be provided for all HACCP team members (refer to 2.9.4). The scope of the HACCP Food Safety Plan must also be determined, e.g., the products included in the plan and the start and end points of the process under consideration.
2. Product descriptions must be prepared for all products included in the HACCP Plan that includes all relevant product safety information. This may or may not already be included in the finished product specifications (refer to 2.3.5).
3. The intended use of each of the products included in the scope must be identified, e.g., is the product intended to be further processed, or cooked by the consumer prior to consumption, or is it ready-to-eat. Is the product intended for consumption by a vulnerable group, or by the general population (remembering that general population includes vulnerable consumers).
4. Construct a process flow diagram that covers the agreed scope (see step 1 above) of the process and includes all process inputs (e.g., raw materials, packing materials, processing aids), and outputs (including second grade product, product for rework). Every step in the process must be identified.
5. The HACCP team must walk the process and confirm the flow diagram, including any variations on back shifts or overtime shifts. The HACCP team leader must sign off on the flow diagram.
6. Steps 1 through 5 allow the HACCP team to gather all the necessary information to complete step 6, which is also Principle 1 of HACCP. This step can be separated into three components:
 - a) For each step of the process identified in step 5, the HACCP team must identify all food safety hazards, including potential food safety hazards. Hazards will, at a minimum, be classified as microbiological, chemical and physical, but may also at the discretion of the site separate out allergens, microbial contamination, microbial growth, radiological hazards, metal, glass, etc.
 - b) For each identified hazard, conduct a hazard analysis to determine the potential likelihood of the hazard occurring and the severity if it did occur (collectively referred to as the significance). There is no specified methodology for conducting a hazard analysis, although there are many methodologies used within the food industry. SQFI expects that the method used is logical, evidence based, consistently applied across all identified hazards in the HACCP Plan, and documented.
 - c) Determine the control measures required for each identified hazard, and ensure procedures (SOPs) and/or work instructions are in place to apply this control.

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7. Critical Control Points (CCPs) are steps in the process where control is essential to eliminate an identified hazard or reduce it to an acceptable level, e.g., cooking, pasteurizing, retort sterilizing, etc. Metal detection maybe, but is not necessarily a CCP. Codex includes a decision tree for determining CCPs, which works well for microbiological hazards. Again the methodology chosen for determining CCPs must be applied consistently.

If a hazard has been identified and no control measure exists for that hazard, then the process must be changed to ensure control can be applied at some point in the process.

8. All subsequent steps in the HACCP Plan relate to CCPs. Critical limits are according to the Codex definition, "criteria that separate acceptability from unacceptability." They are values that are set and easily measured, that identify "safe" from "unsafe" product. Critical limits must be established for each CCP and must be scientifically validated (refer to 2.5.1), or justified by regulation, customer requirements or industry code of practice.

9. Monitoring is the regular testing, or measurement of critical limits to ensure the process remains "safe." The HACCP plan must identify, for each CCP, what is to be measured; who (i.e., which position) is responsible for testing/measuring; when testing is to be carried out (e.g., every hour, once per shift), and how the testing is to be carried out. Monitoring applies to each CCP and must be supported by test work instructions and training of operators designated to carry out monitoring.

10. For each CCP, corrective actions must be established to identify action that will be taken for every deviation from critical limits (refer to 2.5.3). HACCP is a proactive system – it pre-determines actions that will be taken before they occur. Therefore corrective actions detailed in the HACCP Plan must be clear, concise and unambiguous. They must include actions to address or dispose of affected product (i.e., back to the last "good" check), and actions necessary to correct the process and prevent recurrence. Responsibilities for corrective actions must be identified.

11. Verification applies to the application of testing, audits and other procedures, other than monitoring, to determine compliance with the HACCP Plan. Verification is covered in element 2.5.

12. The HACCP Food Safety Plan must be included in the food safety system (refer to 2.2.1) and controlled as per 2.2.2. Records of monitoring, corrective actions and verification activities must be secured and retained according to 2.2.3.

The HACCP Plan is not a static document. Critical limits must be re-validated at least annually (refer to 2.5.1.1 ii) by the SQF practitioner, and the entire implemented Food Safety Plan verified annually. When changes occur in the process, the HACCP Plan must be updated and re-validated to reflect the changes (refer to 2.1.3.3).

If the country of production and/or sale requires by regulation a food safety control methodology other than a Codex-based HACCP plan, the site must develop and implement a food safety plan that addresses either singularly or jointly both the required food safety plan and a Codex based HACCP system.

2.4.3 Auditing Guidance

The HACCP Food Safety Plan shall be reviewed by the auditor at the initial desk audit to ensure all products within the site's scope are covered, all potential hazards are identified and the HACCP implementation steps have been followed. The HACCP Food Safety Plan, plus changes to the HACCP plan, shall be reviewed in full at every subsequent site audit. Implementation of the HACCP plan will be checked by interview, observation and review of records. Evidence may include:

- The HACCP team is in place, includes expertise of the subject process, and members are trained in HACCP principles;
- The HACCP team has been fully involved in the development and review of the HACCP system;
- The product and process scope of the HACCP plan is defined;
- Product descriptions are available and include relevant safety information;
- The intended use of the product is clearly defined;
- A process flow diagram has been developed and includes all process steps, inputs and outputs. It has been confirmed by the HACCP team;
- Potential hazards have been identified for all process steps and a hazard analysis conducted using a consistent and valid method;
- Control measures are in place for all identified hazards and procedures/work instructions are effectively implemented;
- CCPs are correctly identified using a valid methodology;

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- Critical limits are in place for every CCP, and are validated to ensure consistent product safety;
- All critical limits are monitored and test procedures, responsibilities, and frequency fully documented and implemented;
- Corrective actions are documented, are clear and unambiguous, and determine the disposition of product and action required to prevent recurrence (refer to 2.5.3);
- The corrective action procedure has been followed when monitoring shows deviation from critical limits (refer to 2.5.3);
- Staff with responsibility for monitoring, validation, verification of critical limits, or any other food safety control measures are aware of their responsibility, trained, and are carrying out their functions correctly;
- The SQF practitioner ensures that the Food Safety Plan is effectively developed, implemented, maintained, and verified (refer to 2.1.2.4 i).

2.4.4 Approved Supplier Program (Mandatory)

What the SQF Code says

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier.

2.4.4.2 The receipt of raw materials, ingredients, and packaging materials received from non-approved suppliers shall be acceptable only in an emergency situation, and provided they are inspected or analyzed before use.

2.4.4.3 The responsibility and procedure for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.

2.4.4.4 The site's food defense plan (refer to 2.7.1.1) shall include measures to secure incoming materials and ingredients and protect them from deliberate act of sabotage or terrorist-like incidents.

2.4.4.5 The site's food fraud vulnerability assessment (refer to 2.7.2.1) shall include the site's susceptibility to raw material or ingredient substitution, mislabeling, dilution and counterfeiting which may adversely impact food safety.

2.4.4.6 The food fraud mitigation plan (refer to 2.7.2.2) shall include methods by which the identified food safety vulnerabilities from ingredients and materials shall be controlled.

2.4.4.7 Raw materials, ingredients, and packaging materials received from other sites under the same corporate ownership, shall be subject to the same specification requirements (refer to 2.3.2) and approved supplier requirements as all other material providers.

2.4.4.8 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum:

- i. Agreed specifications (refer to 2.3.2);
- ii. Reference to the rating of the level of risk applied to a raw material ingredients, packaging materials and services and the approved supplier;
- iii. A summary of the food safety controls implemented by the approved supplier;
- iv. Methods for granting approved supplier status;
- v. Methods and frequency of monitoring approved suppliers;
- vi. Details of the certificates of conformance if required; and
- vii. Methods and frequency of reviewing approved supplier performance and status.

2.4.4.9 Supplier audits shall be based on risk and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

2.4.4.10 A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.

2.4.4 Implementation Guidance

What does it mean?

The objective of this element is to ensure that all incoming materials and services meet specifications and are safe. This element links with 2.3.2, which defines specifications for raw and packaging materials and 2.3.3, which defines specifications for contract service providers.

An approved supplier program is a set of procedures implemented by the supplier to assure the safety of incoming goods and services. It may be based on the safety risk presented by the raw material, or based on historical performance or prior history of the supplier.

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What do I have to do?

The supplier must be able to provide documented evidence that incoming materials have either been inspected or that they come from an approved supplier. The methods for selecting, evaluating, approving and monitoring an approved supplier must be documented. This will be risk-based and may be as simple as a good supply history, sourcing from certified suppliers (e.g., SQF certified suppliers) or personally auditing/inspecting the material supplier's operations, depending on risk, supplier knowledge and past history. The same principles for approved suppliers extend to the sites internal or suppliers that are under the same corporate ownership, even if they are under the same food safety management system (i.e., egg producers that feed into an egg processing site or roasted nut operation feeding into a nut butter site).

The supplier must require their material suppliers to verify they are complying with specifications for the products supplied. The methods of analyses must conform to recognized industry standards (refer to 2.5.6). The job functions responsible within the supplier business for material inspections and supplier approval must be included in the job descriptions outlined in 2.1.3.2.

The approved supplier program must include providers of contract services such as transport, pest control, maintenance, labor hire, etc. The program will identify methods to ensure service providers and their staff adhere to the specifications outlined in 2.3.3.

The supplier must maintain a list of approved suppliers, including contract service providers. All providers of goods and services must be included on the register.

The approved supplier program shall be reviewed at least annually (refer to 2.1.3.3) or more frequently, based on supplier performance.

The receipt of raw materials from non-approved suppliers is acceptable, but only in an emergency situation, and provided the materials are inspected before use. Records of the use of non-approved suppliers and their inspections shall be maintained.

The site shall also include, as part of their food defence plan (refer to 2.7.1.1), a means to secure incoming materials to prevent intentional adulteration and contamination.

As part of the food fraud plan (refer to 2.7.2.1 and 2.7.2.2) the site shall include within the vulnerability assessment and mitigation plan the potential risks for economic adulteration that may impact food safety for all incoming materials. Vulnerabilities may include ingredient substitution, mislabelling, dilution or counterfeiting. It is important to include minor ingredients such as spices, additives, and processing aids. These materials are often overlooked but many have a high rate of fraud.

2.4.4 Auditing Guidance

During the desk audit, the auditor shall review the documented approved supplier program. However, compliance to this element will mainly be reviewed during the site audits. The approved supplier will be audited by interview, observation and review of records. Evidence may include:

- Review of the documented approved supplier program to ensure all materials and services that may impact on product safety are included;
- The risk rating applied to suppliers is identified and controls implemented;
- There is a register of approved suppliers;
- All materials or services in-use are included on the supplier register or listed as a non-approved supplier;
- Approval methods test for compliance with agreed specifications (refer to 2.3.2, 2.3.3);
- The program specifies actions to be taken when non-compliance is identified;
- Documented test/inspection methods and corrective actions have been followed;
- Relevant staff are aware of their responsibilities and duties with regard to inspection and receiving of incoming goods;
- The approved supplier program is modified based on supplier performance;
- Where non-approved suppliers have been used, goods have been inspected and a record kept;
- The approved supplier program is reviewed at least annually (refer to 2.1.4).

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2.4.5 Non-conforming Product or Equipment

What the SQF Code says

2.4.5.1 The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure:

- i. Non-conforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product;
- ii. **Non-conforming product is reviewed for the nature of non-compliance, tested for conformance to specifications and dispositioned accordingly by qualified personnel;**
- iii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and
- iv. All relevant staff are aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status.

2.4.5.2 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.

2.4.5 Implementation Guidance

What does it mean?

Non-conforming product is product at any stage in the process that does not meet agreed food safety criteria. This can apply to raw materials, ingredients, packaging materials, work-in-progress or finished product. It can also apply to any other material used in the site that can impact product safety, e.g. cleaning chemicals, processing aids.

This element also includes how the site deals with non-conforming equipment.

What do I have to do?

The site documents the procedure that outlines how to label and identify products that are rejected or quarantined as a result of inspection, audit or process deviation. The site must describe how non-conforming product is isolated in order to avoid its re-use or shipment.

In circumstances where product is adulterated or condemned, the site must detail how the condemned product is identified and disposed of.

When non-conforming product is placed on hold it must be reviewed for the nature of the non-conformance, tested to determine if specifications are being met or not and dispositioned accordingly. These activities must be performed by qualified and designated personnel such as quality assurance, PCQI and/or SQF Practitioner.

The site must also document a procedure for equipment that has been found to be non-conforming. This procedure may be combined with, or separate from, that for non-conforming product. The equipment must be identified and placed out of production until it is repaired or otherwise disposed of.

The means of identification of non-conforming product and equipment must be communicated to relevant staff. This can be a system of tags, signs, designated storage locations, system holds or other methods that meet the intent of this section.

The site is required to keep all records of the disposition of non-conforming product and equipment including product that is reworked, repackaged, condemned and/or disposed of.

2.4.5 Auditing Guidance

The auditor will review the non-conforming product/equipment procedure at the desk audit, and compliance to this requirement by observation, interview and review of records at each site audit. Evidence may include:

- Review of the procedure for non-conforming product/equipment;
- Identification of non-conforming product and/or equipment and the action taken;
- Records of product that has not met specification

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- Records of finished product testing that is out of specification and how it has been resolved
- Records of product disposition;
- **Records supporting qualifications of personnel performing review and dispositioning; and**
- Records of repair of non-conforming equipment.

2.4.6 Product Rework

What the SQF Code says

2.4.6.1 The responsibility and methods outlining how ingredients, packaging materials, or products are reworked shall be documented and implemented. The methods applied shall ensure:

- i. Reworking operations, **including inspection, analysis and approval for release** are supervised by qualified personnel;
- ii. Reworked product is clearly identified and traceable;
- iii. Each batch of reworked product, **including any returned product**, is inspected or analyzed as required before release;
- iv. Inspections and analyses shall conform to the requirements outlined in element 2.5.4.1; and
- v. Release of reworked product shall conform to element 2.4.7

2.4.6.2 Records of all reworking operations shall be maintained.

2.4.6 Implementation Guidance

What does it mean?

The objective of this element is to ensure the products which are reworked or are of the same standards as first run product. The same applies to finished products in a warehouse that are recouped (i.e., warehouse finished product that is repackaged into new secondary packaging for distribution) **and to any returned product**.

If the site's process allows product to be reworked or recouped, the process must be defined and documented to ensure consistent application. This process must ensure that reworked or recouped product (s) meet the same requirements as first run product (s).

What do I have to do?

The site must document that the product has been reworked or recouped under qualified supervision and under an approved procedure. **Inspection, testing, and approvals must be by qualified personnel.**

Traceability is to be retained and product is to be clearly identified. Evidence is to be provided that each lot is released only after inspection **and includes any in-process materials, recouped products from warehousing or storage and returned product from customers.**

An important element of the rework procedure is the criteria for determination when product is to be reworked, how much can be reworked, under what conditions it can be reworked, and how is it to be identified and traced. Product, after being reworked, must be reviewed per company-designated food safety checks to ensure that it meets all applicable specifications. Care must be taken to ensure that allergens are not accidentally introduced into the product through rework.

Reworking of perishable product must take into consideration the shelf-life of the product being reworked (i.e., the oldest product).

Recouping operations must ensure that recouped product is not dented or damaged outside company specifications.

Records of all reworking/recouping operations shall be maintained.

2.4.6 Auditing Guidance

Rework and/or recoup policy, procedures and work instructions shall be reviewed (if applicable) as part of the initial desk audit. The implementation of these instructions shall be reviewed as part of the site audit. Evidence may include:

- A policy statement on rework/recoup included in the food safety manual;

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- Where applicable, procedures and/or work instructions that detail reworking/recouping methods;
- Observation of reworking/recouping operations;
- Interview of operators, supervisors **and qualified personnel** involved with reworking/recouping operations;
- Confirmation of the safety and integrity of work in progress and finished product that includes rework;
- Confirmation that the shelf-life of work in progress and finished product containing rework reflects the shelf-life of the included rework;
- Sampling and analysis of reworked product is conducted;
- Recoup operations discard damaged product;
- Records of rework or recoup operations are maintained.

2.4.7 Product Release (Mandatory)

What the SQF Code says

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released:

- i. By authorized personnel; and
- ii. Once all inspections and analyses are successfully completed and documented to verify legislative, **process controls, formulation** and other established food safety controls have been met.

2.4.7.2 Records of all product release shall be maintained.

2.4.7 Implementation Guidance

What does it mean?

A product release program ensures that only compliant products are released to the market. The site must prepare a procedure outlining the responsibility and protocols for the release of products and effectively implement that procedure.

Product release also applies to the procedures for releasing quarantined or held product (refer to 2.4.6).

Refer also to 2.5.6 *Product sampling, inspection, and analysis*, 2.6.1 *Product identification* and 2.6.2 *Product trace*.

What do I have to do?

This element is mandatory.

A site may do this by outlining in-line process measures that demonstrate that products are compliant with any regulations **such as labelling, finished product specification and formulation**. In this procedure, the site will identify those personnel responsible for collecting samples and carrying out inspections, or ensuring that inspections are carried out, and the methods for doing so.

The product release procedure not only applies to positive release of compliant products, but also outlining the procedure for releasing products from quarantine or hold status.

In all cases, the site shall identify those staff positions with responsibility for releasing products and indicate the action they will take when results are outside specification, including reference to other procedures for holding, reworking or disposing of product.

The site must ensure that:

- All products are confirmed as compliant before release to the market;
- All staff are familiar with product release procedures and that personnel authorized to release product are aware of their responsibilities; and that
- All products under quarantine or hold status are released by authorized personnel only after the product has successfully passed inspection.

All products released for distribution must have records maintained. These records should record the product name and identification, **batch or in-process confirmation of product checks and formulation**, and the product disposition (e.g., release, quarantine, hold).

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Products released from hold must also be recorded. Records must include the amount of product that was held and the reason for the hold. Records should be reviewed routinely to ensure that holds are closed out. Any product that is still on-hold must be physically or visually verifiable.

2.4.7 Auditing Guidance

Procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview and review of records at each site audit. Evidence may include:

- Review of product release procedure;
- Review of product release records;
- Understanding of personnel responsible for release, quarantine and hold of product release procedures;
- Visual confirmation and follow-up on held or quarantined product.

2.4.8 Environmental Monitoring

What the SQF Code says

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes.

2.4.8.2 The responsibility and methods for the environmental monitoring program shall be documented and implemented.

2.4.8.3 An environmental sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.

2.4.8.4 Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.

2.4.8 Implementation Guidance

What does it mean?

An environmental monitoring program must be in place for food processes that are handled, exposed, stored, processed or packed. This program should be included for food processes of all risk levels. This element outlines the specific conditions required in areas where foods are processed or handled. Conditions like these may contain pathogenic microorganisms and will support the formation of toxins or growth of pathogenic microorganisms, and has a likelihood of growth causing illness or injury to a consumer if not properly produced, processed, distributed and/or prepared for consumption. It may also apply to a food that is deemed high risk by a customer, declared a risk by the relevant food regulation or has caused a major foodborne illness outbreak (refer SQF Code, Appendix 2: Glossary).

What do I have to do?

The process flow is particularly relevant for high risk processes where the product is subject to handling or exposure after a "kill-step." This includes (refer to 11.7.1) segregation of the post-process end from the raw material end of the process; controlling pedestrian walkways to avoid personnel contamination; dedicated tools and equipment post-process; dedicated staff servicing the post-process end; and dedicated uniforms for staff working post-process.

The reference to the environmental monitoring program is self-explanatory, but is worth repeating as it is considered mandatory for areas in which high risk food is processed, handled or exposed. Failure to have an effective environmental monitoring program will result in a major non-conformance.

An environmental monitoring program (EMP) is a program which includes pathogen swabbing to detect risk in the sanitary conditions of the processing environment and is a verification of the effectiveness of the pathogen controls that a management site has in place for high risk foods (refer Appendix 2: Glossary of Terms).

Swabbing must include not only the smooth, accessible parts of the process, but also the transfer points, bearings, etc., where product is likely to build up.

2.4.8 Auditing Guidance

Control procedures for environmental monitoring shall be reviewed as part of the initial desk audit. Subsequently, these processes will be audited as part of each site audit through observation, review of

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records and interviews with operating personnel. Evidence may include:

- There are control procedures in place for food processes;
- Control procedures are effectively implemented for food processes;
- High risk areas are adequately segregated from raw material handling areas;
- High risk areas are only serviced by staff dedicated to that function;
- Post-process areas are not at risk from pedestrian walkways;
- Protective clothing is provided in high risk areas;
- Dedicated tools and equipment are available in high risk areas;
- Product transfer between equipment and between high risk areas and other areas poses no risk to product;
- An effective environmental monitoring program (EMP) is in place;
- The EMP includes a sampling schedule and responsibility for sampling;
- Swabbing includes transfer points and joints in equipment;
- Swabbing records are maintained.

2.5 SQF System Verification

2.5.1 Validation & Effectiveness (Mandatory)

What the SQF Code says

2.5.1.1 The methods, responsibility and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that:

- i. Good Manufacturing Practices are confirmed to ensure they achieve the required result;
- ii. Critical food safety limits are validated, and re-validated annually;
- iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and
- iv. All applicable elements of the SQF Program are implemented and effective.

2.5.1.2 Records of all validation activities shall be maintained.

2.5.1 Implementation Guidance

What does it mean?

Confirmation of the effectiveness of pre-requisite programs and validation of critical food safety limits is vital to ensuring that the programs and limits achieve their intended purpose, resulting in the production of safe food.

Validation involves testing over and above daily monitoring to ensure that established food safety limits are effective, i.e., achieve the desired results, so that the supplier can have confidence that the product and process are safe. Validation methods will vary depending on the risk to finished product safety. For hazards assessed as high risk, the critical limits must be re-validated annually.

Critical food safety limits are said to be validated because they have been confirmed by scientific analysis. Pre-requisite programs and other food safety controls, however are confirmed by observation, inspection or audit to ensure that they are achieving the desired result.

What do I have to do?

This is a mandatory element.

The SQF practitioner is responsible for documenting and implementing the methods, responsibility and criteria for confirming the effectiveness of pre-requisite programs and validating critical food safety limits to ensure they achieve their intended purpose. The supplier must demonstrate how the validation methods ensure that the selected critical limits achieve the level of control required for the targeted food safety hazard. The supplier must also have documentation showing that the methods and control measures provide the level of control needed.

Some potential methods for confirming the effectiveness of specific pre-requisite programs are listed below. The implementation of these specific methods is not necessarily required, but confirmation of the effectiveness of the program is required. This is not an exhaustive list, but provides some examples:

- Personnel practices: Observe employees during the internal audit or daily operational inspection to ensure they are meeting the requirements of the supplier's program.
- Personnel processing practices: Observe employees during the internal audit or daily operational inspection to ensure they are meeting the requirements of the program.

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- Training of personnel: Interview employees to ensure that job training has been effective and that key points are understood.
- Calibration of equipment: Engage an outside contractor to confirm that equipment is properly calibrated.
- Management of pests and vermin: Trend pest activity information to determine that the program is effective.
- Premises and equipment maintenance: Trend equipment breakdowns for signs of repeat problems.
- Cleaning and inspection: Perform environmental testing to ensure that microbiological loads are acceptable.
- Water microbiology: Perform water testing to ensure that it meets potability standards.

Validation methods for CCP's or CQP's must demonstrate that the hazard is adequately controlled. Possible validation for intervention steps used in the processing of product such as a "kill" step, may be one of the following:

- Scientific literature;
- Peer-reviewed published research;
- In-house or laboratory challenge studies;
- Reference to legally defined CCP's, such as for the pasteurization of milk.

If technology is being used in a manner that is different from that described within literature or research then the supplier must demonstrate how the revised manner of use conforms to the original claim of intervention.

Validation is required for the critical limits identified for ALL CCPs and CQPs. Validation of a CQP must prove that the chosen intervention controls the identified threat to the product.

All validation activities must be recorded to confirm and demonstrate they have been completed.

2.5.1 Auditing Guidance

Validation procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview with the SQF practitioner, interviews with other relevant staff responsible for validation activities and review of records at each site audit. Evidence may include:

- Documentation of the methods and responsibility and criteria for ensuring the effectiveness of the pre-requisite programs;
- Implementation of the methods and responsibility and criteria for ensuring the effectiveness of the pre-requisite programs;
- Pre-requisite programs achieve their intended purpose;
- Critical food safety limits are validated annually or when changes to process occur;
- Methods used to validate critical limits ensure that the process step is safe if critical limits are met;
- Critical limits effectively provide the designated level of control;
- Personnel conducting validation activities understand their roles and responsibilities (refer to 2.5.1);
- Records of all verification activities are current and accurate.

2.5.2 Verification Activities (Mandatory)

What the SQF Code says

2.5.2.1 A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented.

2.5.2.2 The methods, responsibility and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, **process controls, formulations/recipes**, other food safety controls, and the legality of certified products, shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.

2.5.2.3 Records of the verification of monitoring activities shall be maintained.

2.5.2 Implementation Guidance

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What does it mean?

A verification schedule is simple enough to create, but sometimes difficult to implement. The SQF practitioner is responsible for all verification activities but is not necessarily the one to conduct those activities. The practitioner must set the schedule to ensure all required verification activities are conducted and the frequency of these activities. The practitioner must also ensure that resources are available and suitably competent to conduct these activities.

What do I have to do?

Elements 2.5.1 and 2.5.3 require the site to define their validation and verification activities. This element simply requires the site (i.e., the SQF practitioner) to further identify when those activities will occur and who is responsible.

The site must have a verification schedule that:

- describes SQF System verification activities;
- outlines the frequency of verification;
- designates the person responsible for each verification activity; and
- provides for a log of verification activity.

2.5.2 Auditing Guidance

The verification schedule shall be reviewed initially at the desk audit and compliance to the schedule by observation, interview with the SQF practitioner, interviews with other relevant staff responsible for validation and verification activities and review of records at each site audit. Evidence may include:

- Review of the verification schedule including identification of those responsible for verification activities;
- Interview with those designated as responsible for verification activities;
- Designated personnel are trained and competent to conduct verification activities;
- Verification activities conducted as per schedule.

2.5.3 Corrective and Preventative Action (Mandatory)

What the SQF Code says

2.5.3.1 The responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits, and deviations from food safety requirements, shall be documented and implemented.

2.5.3.2 Records of all investigation and resolution of non-conformities including their corrections and corrective action shall be maintained.

2.5.3 Implementation Guidance

What does it mean?

Corrective action is an important part of any management system. Corrective actions are proactive, rather than reactive responses to a deviation from regular operations. It requires the development a procedure that describes, before the event, who, what, when, where and how the supplier will address an identified problem or deviation. Identifying a means to address a problem prior to its occurrence requires the supplier to consider immediate action to resolve the problem and deal with any affected product, and preventative action to prevent a recurrence of the problem.

What do I have to do?

This element is mandatory.

When problems or issues that involve food safety arise, the supplier is required to take corrective and preventive action to deal with any affected product (s) and to fix the process (es). The supplier must document a procedure describing the responsibility for investigating and identifying the causes of problems, including a breakdown of critical limits relating to critical food safety. Further, the supplier must document how these problems are to be resolved if and when they occur, the methods used to correct and control the situation and what action is to be taken to prevent the recurrence of the problem.

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Corrections are considered a short term fix, i.e., a quick action taken to remediate a specific problem and make adjustments to regain immediate control. A corrective action is a long term fix designed to identify the root cause of the problem and to take actions that will prevent recurrence. This process is designed to minimize the risk that the situation will occur again.

When monitoring activities show that critical limits have been exceeded, the supplier's corrective actions must describe what happens to the affected product (s) (i.e., the product processed since the last good result), as well as the preventative action to correct the process. These corrective actions are proactive – they are described in the HACCP plan before the event.

Corrections should be made when there is any observation within a site that leads one to believe that product food safety is at risk. After the correction is made, the supplier must investigate to determine the root cause of the issue. When the root cause of the problem is identified, corrective actions can be taken.

Corrective actions associated with deviations from critical limits for CCPs and CQPs must be documented on the HACCP plans (FSP, FQP – refer to 2.4.3, and 2.4.4). This shall describe responsibilities and actions required to deal with or dispose of affected product (e.g., back to the last good check) and actions necessary to correct the process. However, the supplier must also prepare a corrective action procedure (and log) to ensure corrections and corrective actions are documented, assigned, followed up, and confirmed.

This type of preventive action helps to assure the continuous improvement of the System, resulting in fewer future problems since the root causes have been addressed. Corrective actions shall also be reviewed as part of the management review process (refer to 2.1.4.1 iii).

The supplier also required to maintain records of corrections and corrective action taken.

Essentially, the supplier is asked to outline and demonstrate how they will manage corrective action, identify who is responsible for managing it and describe what methods are used to resolve any safety issues.

2.5.3 Auditing Guidance

The HACCP plans (i.e., the FSP and FQP) and corrective action procedure shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview with the SQF practitioner, interviews with other relevant staff responsible for carrying out corrective actions and review of corrective action records at each site audit (refer to 2.5.1). Evidence may include:

- Responsibilities and methods outlining how corrections and corrective actions are investigated/resolved/managed/controlled are documented;
- Responsibilities and methods outlining how corrections and corrective actions are investigated/resolved/managed/controlled/implemented;
- Root cause analyses have been carried out for non-compliance to critical food safety limits;
- Corrective actions have correctly dealt with affected product;
- Corrective actions have achieved resolutions that will prevent recurrence of process issues;
- Personnel carrying out corrective actions understand their roles and responsibilities;
- Records of corrective actions are current and accurate (refer to 2.5.1).

2.5.4 Product Sampling, Inspection and Analysis

What the SQF Code says

2.5.4.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress shall be documented and implemented. The methods applied shall ensure:

- i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements;
- ii. Inspections and/or testing are conducted to ensure raw materials, **packaging, labels**, work in process and finished products comply with the relevant specifications, **formulation/recipes**, regulatory requirements and are true to label;
- iii. **Sampling and testing shall ensure it is statistically sound, representative of the process/batch and ensures production and process controls are maintained to meet specification and formulation/recipes;**

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- iv. **Retention samples, if required by customers or regulations, shall be stored and maintained for the stated shelf-life of the product; and**
- v. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.

2.5.4.2 On-site personnel that conduct environmental or product testing shall participate in an applicable proficiency testing program at least annually to ensure accuracy of results **and that they are following Good Laboratory Practices.**

2.5.4.3 Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard and shall be included on the site's contract service specifications register (refer to 2.3.3.1).

2.5.4.4 Records of all inspections and analyses shall be maintained.

2.5.4 Implementation Guidance

What does it mean?

During the normal course of food production and manufacturing, product must be sampled and analyzed either during or after production, to ensure that it meets specifications, **is true to formulation/recipes** and to verify food safety aspects.

The site must determine what raw materials, work-in-progress and finished product is to be analyzed (usually part of verification and detailed in the verification schedule). In determining the type of analysis, any external laboratory undertaking tests or analyses must be accredited to ISO 17025 or an equivalent national standard. The methods and tests applied must also be referenced and control/**retention** samples withheld to ensure follow up sampling if required. The procedure must include a plan and a schedule for sampling activities and designate individuals who will be responsible for them.

What do I have to do?

The site shall document a procedure outlining the methods established to test finished product, work-in-progress and/or raw materials to ensure they meet specification in relation to food safety. Inspections, test or analysis of finished product must be finalized before delivery to a customer. Finished product testing may be defined by the site or their customer.

The site must identify those with responsibility for sampling, inspecting and testing finished product, work-in-progress and/or raw materials and identify the methods used to collect samples and complete these tests, inspection and analyses. **The methodology and resulting records must support the production and process controls to ensure final product is as per formulation/recipe and that nutrition and label claims are accurate.**

The types of testing that are conducted on finished product should be determined by the finished product specification. Examples are varied and can include sensory analysis (e.g., taste, color, flavor, odor), physical (e.g., count, weight, size, texture), chemical (e.g., fat, salt, moisture, brix, pH), **purity, strength, composition** or microbiological (e.g., aerobic plate count, yeast and mold, coliforms, lactics). It should be noted that if pathogens (e.g., *Salmonella*, pathogenic *E. coli*, *Listeria*) are found on finished product, that product should not be released into the marketplace until test results are obtained and negative results are verified. If microbiological retesting is required, the sampling plan and retesting must be more robust than the original sampling plan to ensure the validity of results. It is not valid to simply retest a sample when results are obtained that are not desired by the site.

If external laboratory analysis is used, the site must demonstrate that such analysis is completed by a recognized laboratory that is accredited to ISO 17025 or an equivalent national standard, and one that uses recognized industry standard methods. These methods may be described in the specifications.

If an internal or company laboratory is used, test methods should be checked against an accredited external laboratory at least once per year **and Good Laboratory Practices are followed.**

The site will demonstrate that sampling of product for inspection or analysis is completed using recognized statistical sampling methods **to ensure it is representative of the process/batch. Retention samples must be kept for the duration of the shelf-life of the product at a minimum.**

The site must ensure that staff is qualified, trained and competent to complete sampling inspection and analyses.

Records must be maintained of all inspections, tests and analyses.

2.5.4 Auditing Guidance

Product sampling and testing procedures shall be reviewed initially at the desk audit and compliance to this

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requirement by observation, interview with the SQF practitioner and other relevant staff responsible for sampling and testing, and review of records at each site audit. Evidence may include:

- Methods for sampling, inspecting, and/or analyzing raw materials, finished product and work in progress are documented;
- Documented methods are approved methods and meet regulatory and customer requirements;
- Inspections are conducted as documented, and at intervals sufficient to maintain **production and process** control;
- Inspections confirm specifications, label requirements and trade weights and measures;
- Analyses are conducted by qualified individuals and to approved methods;
- Alternative methods used are validated as equivalent to the national approved standard methods;
- External laboratories are accredited to ISO 17025 or equivalent national standard;
- Sensory evaluations are completed to internal and customer specifications;
- Records of all inspections and analyses (including sensory analyses) are accurate and maintained.

2.5.5 Internal Audits and Inspections (Mandatory)

What the SQF Code says

2.5.5.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted at least annually. The methods applied shall ensure:

- i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool;
- ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken;
- iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions.

2.5.5.2 Staff conducting internal audits shall be trained and competent in internal audit procedures.

2.5.5.3 Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and building/equipment maintenance is compliant to the SQF Food Safety Code for Manufacturing. The site shall:

- i. Take corrections or corrective and preventative action; and
- ii. Maintain records of inspections and any corrective action taken.

2.5.5.4 Where practical staff conducting internal audits shall be independent of the function being audited.

2.5.5.5 Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained.

2.5.5 Implementation Guidance

What does it mean?

Internal audits are an in-house check to identify gaps or deficiencies in the SQF System and provide a sound basis for deciding on measures for improvement. Internal auditing is a verification method and when used properly, can reduce the uncertainty and risk of external audits.

This element requires the supplier to audit the activities in their System on a regular basis to ensure that everything is running smoothly. Internal audits help the supplier to identify faults in their System so that it can be improved.

What do I have to do?

This element is mandatory.

The supplier is required to prepare an internal audit procedure describing how internal audits of the entire SQF System are conducted and identify who is responsible for scheduling and conducting internal audits.

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The internal audits must cover the entire SQF System, including the application of pre-requisite programs and the HACCP Food Safety Plan and critical food safety controls that have been implemented. The supplier must also confirm that legislative requirements are met, that inspections and tests are being conducted as required and that the premises, its surrounds and equipment are being maintained sanitarily and in good condition.

The audit program must include:

- An audit schedule (i.e., when audits will be conducted);
- Audit criteria (i.e., the area and requirements assessed);
- Responsibility (i.e., who will conduct the audit);
- Corrections and corrective actions (i.e., the response to the audit);
- Also a review of the trace back system as outlined in 2.6.2.

There must be at least one complete SQF System internal audit per year. Preferably this is conducted throughout the year or the season, depending on the length of the season within the site. Major physical or program non-conformities shall require a more effective internal audit program.

For internal audits to be effective, staff conducting internal audits must be trained in internal auditing techniques, information gathering and objective observation. This training need not be "formal" training provided by an external source. Internal auditor training covers internal audit procedures, including the planning and scheduling of internal audits, preparing internal audit reports and initiating and following up on audit findings. Internal audits should combine several information gathering techniques, including interview of personnel, review of records and observation of current conditions.

To ensure the objectiveness of the internal audit the supplier are required where possible to use personnel who are separate from the area being audited to conduct internal audits. The inclusion of the words "where possible" illustrates that in the case of some very small suppliers this may not be possible. In such cases, the supplier is required to demonstrate that the alternative internal audit arrangement meets the objective of this requirement and is communicated to all affected parties.

Finally, the outcomes of all internal audits, including any corrective actions taken, must be recorded. Any audit tool that is developed by the supplier can be utilized to perform the internal audits provided it covers the required areas and programs.

2.5.5 Auditing Guidance

The internal audit procedure and schedule shall be reviewed initially at the desk audit and compliance to this requirement through observation and interviews with staff conducting internal audits and review of records at each site audit. The SQF auditor will verify that the audit schedule is adequate based on the observations from the assessment of the site. Evidence may include:

- There is an internal audit procedure and schedule that adequately covers all SQF System elements;
- Sufficient resources are allocated to conduct internal audits as per schedule;
- Staff conducting internal audits are adequately trained;
- Staff conducting internal audits are independent of the area being audited;
- Corrections and corrective actions of identified deficiencies are correctly allocated, followed up, and completed (refer to 2.5.5);
- Internal audit results are communicated to relevant management and staff;
- Internal audit reports and their follow-up are reviewed as part of the management review process (refer to 2.1.4.1);
- Records are kept of internal audits and the corresponding corrective actions.

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2.6 Product Identification, Trace, Withdrawal and Recall

2.6.1 Product Identification (Mandatory)

What the SQF Code says

2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure:

- i. Raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are clearly identified during all stages of receipt, production, storage and dispatch **and traceable to production batches, formulation/recipes or lots**; and
- ii. Finished product is labeled to the customer specification and/or regulatory requirements.

2.6.1.2 Product identification records shall be maintained.

2.6.1.3 Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person. **The site shall control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies.**

2.6.1 Implementation Guidance

What does it mean?

To allow for effective trace back (refer to 2.6.2), recall (refer to 2.6.3) and stock control and rotation (refer to 2.4.9), materials and products at all stages of production must be labelled and identified. How the site goes about this is entirely their own choice, as long as product can be identified and tracked at every stage of production.

What do I have to do?

This element is mandatory.

The site must be able to clearly identify product upon receipt, throughout the process and when it is a finished product.

Product that is in-process may be identified in a variety of ways. The site could use bin tags, pallet tags, colors, product tags, etc. The site must be able to demonstrate how the product identification system works for incoming materials, work-in-progress and for finished product and **how it is traced back to process lots/batches.**

The finished product label needs to contain information that accurately describes the product in accordance to customer specification and/or regulatory requirements in the country of origin and intended country of destination.

Product changeover procedures need to illustrate and document that label reconciliation is maintained to match issuance/quantity of labels with those used. Label reconciliation is not required for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of packaging operations;

The site is required to prepare a procedure outlining who is responsible for maintaining the product identification system and include in the procedure the methods used to identify product.

When shipping finished product, the site must ensure the product is clearly identified and that all product identification details are accurately described on dispatch documents or otherwise included with a shipment once it leaves the business.

2.6.1 Auditing Guidance

The product identification procedure shall be reviewed initially at the desk audit and compliance to this requirement by observation, and interviews with operational staff, and review of records at each site audit. The site should expect that the auditor will select product at various stages during the process and ask for the origin of product, raw material supplier, etc. to test the identification system. Evidence may include:

- There is a documented product identification system in place;
- The product identification system is effectively implemented;
- Product is clearly identified during all stages of the process **and linked to process lots or batches as per formulation;**

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- Finished product is labeled to customer requirements;
- Finished product is labeled to regulatory requirements in the country of origin and country of destination;
- All operational staff understands and uses the product identification system.

2.6.2 Product Trace (Mandatory)

What the SQF Code says

- 2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure:
- i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back);
 - ii. Traceability is maintained where product is reworked; and
 - iii. The effectiveness of the product trace system shall be reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.3)
- 2.6.2.2 Records of raw and packaging material receipt and use, and finished product dispatch and destination shall be maintained.

2.6.2 Implementation Guidance

What does it mean?

The ability to identify and trace product is an important aspect of any food business. Food regulators, retailers, insurance companies and food manufacturers require that product be traceable. The supplier must document the method used to trace product, ensuring that it provides a link to all raw inputs used. Raw materials and other inputs shall be traceable through the process to the finished product. Records of product dispatch and destination shall be maintained. The documentation must assign responsibility for product dispatch and include the product name, when it was dispatched (sold), who was the customer (not including direct sales to consumers), the quantity and the production batch dates and details.

What do I have to do?

This is a mandatory element.

The supplier must have a process in place that enables them to trace product to their customer (one up) and back to the material supplier (one back). A written procedure must be documented to show how this is accomplished. The product trace system must account for raw materials, packaging materials and processing aids used that may impact on food safety.

For the purpose of this section, the supplier's first customer is the first location where the product is delivered after it leaves direct control. This can be a distribution center, customer location, broker, etc. It is not the requirement of the site to be able to trace past the first customer. However the supplier should also check with the requirements of their buyers.

For the purpose of the SQF Code, traceability is a "one up, one back" requirement. The supplier's procedure must include details of how all raw materials, packaging materials and processing aids are linked through to the finished product; and must outline how the supplier accounts for the reuse of reworked product. The product trace procedure must outline how the supplier traces product to a customer and who is responsible for implementing and maintaining the product trace system.

The supplier must test the effectiveness of the trace system at least annually. The auditor will request to see records of the trace test and any corrective actions taken as a result of this review.

The supplier is required to retain records of all product dispatched. Both the details of the product and where and to whom it was dispatched must be recorded.

Identifying (refer to 2.6.1) and tracing bulk materials can be problematic if there are insufficient bulk bins to store separate deliveries. Where bins/silos are continually refilled, delivery batches must still be recorded and the proportion of each delivery identified when materials are used from bulk. The processed material must, as far as possible, be linked with deliveries of raw materials.

2.6.2 Auditing Guidance

The product trace procedure shall be reviewed initially at the desk audit and compliance to this requirement

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by observation, interviews with operational staff, and review of records at each site audit. The site audit shall include a review of trace back on rework (where applicable) and the auditor may need to verify traceability requirements. Evidence may include:

- There is a product trace procedure that documents all applicable materials, work-in-progress, and finished products;
- The product trace system is effectively implemented;
- The product trace system is one up, one back;
- Finished product can be traced back to material suppliers;
- Rework is traceable back to materials and work-in-progress;
- The product trace system has been tested annually.

2.6.3 Product Withdrawal and Recall (Mandatory)

What the SQF Code says

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:

- i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall;
- ii. Describe the management procedures to be implemented including sources of legal, regulatory and expert advice and essential traceability information; and
- iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident;
- iv. SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body and notified in instances of a food safety incident of a public nature, or product recall for any reason.

2.6.3.2 Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. Testing shall include incoming materials (one back) and finished product (one up).

2.6.3.4 SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.

2.6.3.5 Records of all product withdrawals, recalls and mock recalls shall be maintained.

2.6.3 Implementation Guidance

What does it mean?

A product recall applies when a product is found to be unsafe or otherwise in breach of regulatory requirements and is withdrawn from public sale and the consumer market is advised not to use or consume that product. Recalls may be mandatory (i.e., initiated by a regulator), retailer driven, or voluntary (i.e., initiated by the supplier).

A product withdrawal applies when a dispatched product is found not to meet safety requirements, is deemed not suitable for sale and is withdrawn from the distribution chain before it has reached the consumer.

A product recall and withdrawal procedure must be prepared, implemented and regularly reviewed to ensure everyone involved in the recall process understands their role and their responsibility in the event of a recall or withdrawal.

What do I have to do?

This is a mandatory element.

The supplier must have a management committee in place to coordinate and manage recalls and must prepare a withdrawal and recall procedure describing the methods, responsibilities and procedures they implement in the event of a product withdrawal or recall. There must be senior management involvement in the recall committee, as well as departmental and division managers with the authority to make decisions.

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The procedure may contain a description of incidents specific to the supplier's product that may trigger a withdrawal or recall and must include an up-to-date list of customers, regulators and other essential contacts that need to be notified in the event of a withdrawal or recall.

The SQFI and the supplier's certification body (CB) must be included on the communication list. The supplier is required to notify the CB and SQFI in writing within 24 hours of a food safety incident of a public nature (i.e., requiring public notification) or a product recall for any reason. The SQFI contact is foodsafetycrisis@sqfi.com.

It must also outline the methods the supplier will implement to investigate the cause of a withdrawal or recall (refer to 2.5.5). The supplier shall review and test their withdrawal and recall procedure at least annually and verify that the instructions continue to be relevant, that it is effective and efficient and that everyone understands their role.

Records of any/all recalls and withdrawals must be maintained, along with the results of testing of the withdrawal and recall procedure. Records for testing must include all supporting documentation used to identify product included within the recall/withdrawal. These records may include production records, raw materials receiving records, rework records, product holds, and product storage and distribution records. The supplier should test product that has already been released so that full distribution traceability can be verified.

Non-conformances identified during the exercise must be investigated by the site and required corrective action completed, with a follow up test completed to ensure that corrective actions are effective. A recall and withdrawal exercise should be able to demonstrate linkage of raw materials through the process to the facilities first customer. This review of the system is therefore, also a review of the trace back system as outlined in 2.6.2.

The supplier must also be aware of the recall targets set by retail customers. Some may require 100% identification and quarantine of affected product within hours or recall notification. Regulatory recall requirements must also be considered.

2.6.3 Auditing Guidance

The recall and withdrawal procedure shall be reviewed initially at the desk audit and compliance to this requirement by observation, interviews with recall committee, and review of actual/mock recall records at each site audit. The SQF auditor shall review the annual test of the recall and withdrawal system, and corrective actions taken as a result of the test.

Evidence may include:

- A recall committee is established and all members understand their roles and responsibility;
- The methods and responsibilities for notifying customers, SQFI, the certification body, regulators and other essential bodies are identified;
- The recall/withdrawal system has been tested annually;
- The recall/withdrawal system meets regulatory and customer requirements;
- Communication has been tested during an actual or test recall;
- Investigations into the cause of actual recalls/withdrawals have been conducted;
- Corrective actions have been taken on identified deficiencies in the recall/withdrawal (refer to 2.5.5).

2.7 Food Defense and Food Fraud

2.7.1 Food Defense Plan (Mandatory)

What the SQF Code says

2.7.1.1 The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained.

2.7.1.2 A food defense plan shall include:

- i. The name of the senior site management person responsible for food defense;
- ii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing and storage areas through designated access points;
- iii. The methods implemented to protect sensitive processing points from intentional adulteration;

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- iv. The measures taken to ensure the secure receipt and storage of raw materials, packaging, equipment and hazardous chemicals;
- v. The measures implemented to ensure raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are held under secure storage and transportation conditions; and
- vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

2.7.1.3 The food defense plan shall be reviewed and challenged at least annually.

2.7.1.4 Records of reviews of the food defense plan shall be maintained.

2.7.1 Implementation Guidance

What does it mean?

Section 2.7 is about site security, including food defense. The supplier must document and implement a plan to assure the security of the site and the product from damage or adulteration from sabotage or terrorist-like incident.

What do I have to do?

This is a mandatory element.

The supplier must prepare, implement and maintain a food defense protocol that outlines the methods, responsibilities and criteria for preventing food adulteration caused by deliberate acts of sabotage. This plan must be reviewed, at minimum, on an annual basis. The supplier must designate a member of senior management who has responsibility for food defense. This responsible individual must assure that there are procedures in place for recording and controlling access to areas of the site by employees, contractors and visitors.

The protocol must identify how the supplier limits access to designated areas of the operation to only appropriately authorized employees. The supplier must implement steps to protect sensitive processing points from intentional contamination. The protocol should explain how the company ensures the secure storage and transportation of raw materials, packaging, equipment, hazardous chemicals and finished product.

Specific areas of program that may be addressed include:

- Employee identification;
- Visitor, contractor, tour access;
- Physical security of the site (e.g., secured doors, windows, outside storage areas);
- Secure chemical storage;
- Restricted access to sensitive areas of processing;
- Secure storage of ingredients, packaging and equipment not in use;
- Secure storage and transportation of finished product;
- Tamper proof or tamper evident packaging.

The protocol must define how these areas are to be addressed. The supplier is free to develop adequate measures to address specific areas to ensure control through a wide variety of solutions.

2.7.1 Auditing Guidance

The supplier must demonstrate to SQF auditor how their specific controls address the intent of the SQF Code requirements and any identified risk. The food defense protocol shall be reviewed initially at the desk audit and compliance will be assessed by observation, interviews with senior management, and review of actual/mock recall records at each site audit. Evidence may include:

- Responsibilities for food defense has been assigned to a senior management representative;
- A food defense plan is in place that identifies the actions required to prevent a serious incident;
- The food defense plan identifies methods to protect sensitive processing points;
- The food defense plan identifies methods to provide authorized access to products and facilities;
- The food defense plan identifies methods to secure storage of raw materials, packing materials, work-in-progress, finished product, and hazardous chemicals;

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- The food defense plan identifies methods to record and control access to the premises by employees, contractors and visitors;
- The food defense plan identifies methods to protect crops and harvesting equipment.

2.7.2 Food Fraud

What the SQF Code says

2.7.2.1 The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

2.7.2.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

2.7.2.3 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

2.7.2.4 Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.

2.7.2 Implementation Guidance

What does it mean?

In July 2014, GFSI published a discussion paper "GFSI position on Mitigating the public health risk of food fraud," in which it states "The GFSI Board recognizes that the driver of a food fraud incident might be economic gain, but if a public health threat arises from the effects of an adulterated product, this will lead to a food safety incident."

Food fraud is often described as EMA, economically motivated adulteration. However, it is more than that. As well as adulteration, food fraud includes substitution, dilution, addition, misrepresentation or tampering of food ingredients or food products. It is in fact illegal deception for economic gain.

The economic risks of food fraud to the industry are apparent. It is estimated that fraud costs the global food industry between \$US40bn - \$US50bn every year (Australian Food News, 11th July 2017). However, the public health impacts are less so. In many cases, the health impact of food fraud is not known until after the fact, when consumers become sick and the adulterant is detected.

GFSI now requires that a food fraud vulnerability assessment and mitigation plan to be incorporated into the food safety management systems in all GFSI benchmarked schemes. SQF in edition 8 now requires food fraud to be considered for the site (2.7.2), and for incoming materials and ingredients (2.4.4.5, 2.4.4.6).

What do I have to do?

Although this element is not mandatory, it is a key GFSI requirement and can only be exempted on receipt by the Certification Body (CB) of a written request from the site justifying exemption. If the justification is accepted by the CB, the element can be exempted. If not, and the site has not completed a vulnerability assessment and mitigation plan, then the CB is required to raise a major non-conformance against 2.7.2.

For many sites, food fraud is a new consideration and the hardest part is getting started. What is a vulnerability assessment? What is a mitigation strategy?

The food fraud strategy is similar to the HACCP methodology sites are familiar with. In general terms, it is:

1. Identify the risks (vulnerabilities)
2. Determine corrective and preventative actions (mitigation strategies)
3. Review and verify
4. Maintain records

The food fraud requirements talk about 'vulnerabilities' rather than 'risk'. A risk (ISO 31000 Risk Management) is something that has occurred frequently before, will occur again, and there is enough data to conduct a statistical assessment. Vulnerability is more a condition that could lead to an incident (Dr John Spink, MSU). GFSI considers an "incident" to be a "consumer health risk if not addressed."

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'Vulnerabilities' need to be identified in incoming materials and ingredients, and within the site. Not all materials and ingredients are subject to risk, and the highest risks may be from minor or infrequent ingredients that originate from sensitive geopolitical areas, or suppliers with poor past histories. Ingredients can be prioritised based on perceived risk.

Within the site, vulnerabilities may include the potential for intentional or accidental substitution, dilution, or adulteration. The question that needs to be asked is "who benefits financially from internal food fraud?"

Mitigation strategies will be developed based on the identified vulnerabilities.

Although SQF requires that the food fraud vulnerability assessment and mitigation plan to be reviewed and verified at least annually, the site should be constantly aware of their supplier history and changes in the supply chain that could impact the vulnerabilities.

SQFI recommends that suppliers initiating their food fraud strategies seek assistance from one of the many resources that are available on-line. Although SQFI lists these resources, we take no responsibility for the information they provide or the outcomes of the assistance they offer.

SQFI partners with the Food Fraud Initiative at Michigan State University (MSU) <http://foodfraud.msu.edu>. This group offers free on -line training for sites and auditors on food fraud called Massive Open On-line Courses or MOOCs.

Other resources that could be considered include the PwC food fraud vulnerability assessment, and the USP Food Fraud Database.

2.7.2 Auditing Guidance

As with suppliers, food fraud is also relatively new to auditors, and SQFI recommends that all SQF auditors seek training in food fraud strategies through the resources outlined above, or through their internal CB training.

The auditor must avoid pre-determining site's food fraud vulnerabilities or making a quick decision on 2.7.2 Food Fraud. Food fraud is a new and inexact science, and there is no prescribed methodology for determining vulnerabilities or their mitigating actions. It is based on the information that the site has available at the time.

The auditor will seek evidence of compliance to this requirement by review of documents and records, and interview. Evidence may include:

- There is awareness within senior management of the need for a food fraud vulnerability assessment and mitigation strategies.
- There is a current, documented vulnerability assessment in place that identifies key ingredient vulnerabilities including justification for their inclusion. The methodology for selecting the key ingredient vulnerabilities shall be available.
- The vulnerability assessment shall include an evaluation of the site vulnerabilities including from staff, contractors, and other associates.
- There are documented mitigation (ie prevention) strategies in place for all identified vulnerabilities, which identify what is to be done and who is responsible.
- The mitigation strategies are active, and are being reviewed for effectiveness.
- The vulnerabilities and mitigation strategies are reviewed at least annually.
- There are records available of review of the food fraud program.

2.8 Allergen Management

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

What the SQF Code says

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include:

- i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain food allergens;

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- ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch rooms, visitors;
- iii. A register of allergens which is applicable in the country of manufacture and the country (ies) of destination if known;
- iv. A list of allergens which is accessible by relevant staff.
- v. The hazards associated with allergens and their control incorporated into the food safety plan.
- vi. A management plan for control of identified allergens.

The allergen management program shall include the identification, management, and labelling of products containing gluten, where applicable.

2.8.1.2 Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in progress, rework or finished product on how to identify, handle, store and segregate raw materials containing allergens.

2.8.1.3 Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

2.8.1.4 Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible.

2.8.1.5 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.

2.8.1.6 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

2.8.1.7 The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured.

2.8.1.8 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work in progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels and verification of labels on finished product as appropriate and product change over procedures.

2.8.1.9 The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used.

2.8.1.10 Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable.

2.8.1.11 Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introducing unintended allergens through suppliers, contract manufacturers, employees and visitor activities.

2.8.1 Implementation Guidance

What does it mean?

Food allergies affect a small but growing proportion of the population. They are most common in children, although some can be life-long, and can cause mild to severe, and sometimes life-threatening, reactions. Most food allergens are proteins and are not denatured in the food manufacturing process. Their recognition, management and communication to the consumer are therefore extremely important and often required by legislation.

Allergens in food can be intentional (i.e., nuts in nut-based products, milk in milk-based products), or as a result of cross-contact, which is the term used when a residue or trace amount of an allergenic ingredient is unintentionally added to a food product. This can happen due to ingredient mixing, line change-overs or insufficient cleaning and sanitation procedures.

Some sites have high exposure to allergens that are an integral part of the product (e.g., peanuts in nut-confectionery products), but other sites may have exposure to cross-contact, or unintentional allergens, i.e., allergens that are not part of the ingredients. Other sites may have little or no allergen exposure, but must still conduct a risk assessment to ensure there is no unintentional allergen exposure.

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Sites must be familiar with the regulated allergens that apply in the country of manufacture and the country of destination if it's known. Regulated allergens differ from country to country, and product labelled for sale in other countries must meet the allergen labelling regulations in that country.

Irrespective of its inclusion in regulations, gluten must be included in the site's allergen program

Sites must also be aware of the need to correctly label products containing allergens as per regulations. Incorrect labelling is one of the major causes of recall in many countries, and can be caused by poor product changeover procedures as well as incorrect label information.

What do I have to do?

This element is mandatory for all food manufacturing sites. Irrespective of the site's considered allergen exposure, a risk analysis is required of all ingredients, materials, the workplace (canteens, locker rooms, vending machines) to determine the risk of cross-contact allergens so that action can be taken to minimise or eliminate the risk.

A management plan must be initiated for all identified allergen risks. Depending on the risk, this may include process cleaning and sanitation, validation of sanitation, ingredient and product segregation, re-work control, product scheduling.

Sites must establish the allergen status of incoming materials and ingredients and have procedures in place to isolate and control materials and products containing allergens

The product trace system must include the conditions under which allergen containing foods are manufactured and ensure full trace-back of ingredients and processing aids.

All employees must be made aware of the presence and risk of allergen contamination and receive instruction in their role in managing allergens, and in particular, cross-contact allergens.

The site must ensure that all finished product is true to label with regard to allergens. This includes ensuring labels meet the allergen labelling regulations in the country of manufacture and the country of destination, and that product change-over procedures are controlled and supervised to ensure that the correct product is in the correct label.

Appendix 2 Allergen Cleaning and Sanitation Guide of this document includes a detailed outline of allergen management requirements where intentional or cross-contact allergens are considered an identified hazard.

2.8.1 Auditing Guidance

The allergen management program shall be reviewed initially at the desk audit and compliance will be assessed by observation, interviews with senior management and operational staff, and review of storage and production records at each site audit.

Sites that are exposed to allergenic materials and do not have an adequate allergen management program in place may be subject to a critical non-conformity and a failure of their audit due to regulatory non-compliance and the public health risk.

Evidence may include:

- Regulated allergens in the country of origin and country of destination are known;
- Allergens that could impact the supplier's materials, equipment, processes and products are known, including potential cross-contact allergens;
- An allergen risk assessment has been conducted on all ingredients, materials, processing aids, and lubricants.
- An allergen risk assessment has been conducted on the workplace, including locker rooms, canteens, vending machines, etc.
- An allergen management plan is documented based on the identified risks.
- The allergen management plan is effectively implemented.
- Methods included in the allergen management plan are sufficient to prevent unintentional allergen contamination;
- Risk assessments for raw materials containing allergens have been conducted;
- A register of materials and ingredients containing allergens has been developed and is accurate;
- Allergen management is included in the food safety plan(s) (refer to 2.4.3);
- Staff involved in the receipt or handling of raw materials, work-in progress, rework or finished product have been instructed on how to identify, handle, store and segregate raw materials containing allergens.
- Cleaning, sanitation and inspection of equipment is completed prior to changeover of allergen products;
- Verification of sanitation effectiveness is carried out. Cleaning of equipment containing allergens is

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- verified prior to product changeover;
- Specific procedures have been developed for the storage of allergen containing ingredients;
- Equipment segregation for allergen control is conducted and effectively manages the risk of cross-contact allergens;
- The product identification system addresses materials, ingredients, work-in-progress and products containing allergens (refer to 2.6.1);
- The product trace system addresses materials, ingredients, work-in-progress and products containing allergens (refer to 2.6.2);
- Products containing allergens are properly labeled to identify them as allergens, and meet regulatory requirements for allergen labeling;
- Product changeover procedures are in place and properly supervised.
- Employees are aware of the risk of allergens and the allergen management procedures.

2.8.2 Allergen Management for Pet Food Manufacturing (Mandatory)

2.8.2.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include:

- A risk analysis of those inputs and processing aids, including food grade lubricants, that contain food allergens;
- An assessment of workplace-related food allergens from locker rooms, vending machines, lunch rooms, visitors;
- A list of allergens which is accessible by relevant staff.
- The hazards associated with allergens and their control incorporated into the food safety plan.

2.8.2.2 Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross contact have been identified.

2.8.2 Implementation Guidance

What does it mean?

A change in edition 8 has provided a separate Code requirement for allergen management in pet food facilities and pet food manufacturing facilities are now required to develop implement an allergen management program.

What do I have to do?

The allergen management program is to be based off a risk analysis that addresses the potential threats to the intended user and include control measures and monitoring procedures.

The site is expected to conduct a risk assessment that includes the intended population for the consumption of the finished product. It is expected that the site comply with regulatory requirements for allergen control and regularly monitor for changes in the site's policy, scientific data or regulations. Ignorance is not an excuse. Sites must establish the allergen status of incoming materials and ingredients and have procedures in place to isolate and control materials and products containing allergens.

Allergen labelling requirements are to follow company policy or regulatory requirements.

2.8.3 Allergen Management for Manufacturers of Animal Feed

2.8.3.1 Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement.

2.8.3.2 Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply.

2.8.3 Implementation Guidance

What does it mean?

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A change in edition 8 has provided a separate Code requirement for allergen management for manufactures of animal feed and, unless required by regulatory or customer requirements, an allergen management plan is not required.

What do I have to do?

If the animal feed manufacturer is required then, the requirements under 2.8.2 Allergen Management for Pet Food Manufacturing, shall apply. That means that the allergen management program is to be based off a risk analysis that addresses the potential threats to the intended user and include control measures and monitoring procedures.

2.9 Training

2.9.1 Training Requirements

What the SQF Code says

2.9.1.1 The responsibility for establishing and implementing the training needs of the organization’s personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented.

2.9.1.2 Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

2.9.1 Implementation Guidance

What does it mean?

What is considered appropriate training? All company employees that are responsible for conducting tasks related to the food safety plan, or other plan-associated roles must be trained in the procedures that relate directly to their specific responsibilities, as well as those policies that affect product safety. Training may be completed on the job by qualified technical staff or externally by recognized institutions.

What do I have to do?

A training needs analysis must be conducted to identify the skills required for each role in the SQF system. This will be based on the job descriptions (refer to 2.1.2.8), procedures and work instructions (refer to 2.1.3). It is important to ensure that all relevant positions are covered and that shift employees and relief employees are included to ensure that there are no gaps in the training requirements. Staff in supervisory, management or technical roles must also be included.

The training needs analysis will form the basis for the training program (refer to 2.9.2).

2.9.1 Auditing Guidance

Training requirements will be assessed at each site audit by interview and examination of records. Evidence may include:

- Training needs analysis has been conducted;
- Training needs analysis is based on job descriptions required within the SQF System;
- Training needs analysis includes coverage for all shifts and relief.

2.9.2 Training Program (Mandatory)

What the SQF Code says

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An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with:

- i. Developing and applying Good Manufacturing Practices;
- ii. Applying food regulatory requirements;
- iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and
- iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.

2.9.2 Implementation Guidance

What does it mean?

Once the training requirements are identified (refer to 2.9.1), the supplier must ensure that staff is trained to competently carry out their duties and responsibilities. Employees can carry out these activities if they are given clear and concise instructions regarding how, when and where to carry out the tasks and to record the information.

What do I have to do?

This is a mandatory element.

The following programs are considered the minimum required elements for employee training. They can be offered as classroom training or on-the-job training by qualified personnel. Sometimes training can be offered through team meetings. Type and depth of training will depend upon the employee's work designation. Requirements may include:

- Job/task performance
- Company food safety policies and procedures
- Good Manufacturing Practices, including regulatory compliance
- Cleaning and sanitation procedures
- HACCP overview, and specific roles within the HACCP plan
- Bio security and food defense
- Chemical control
- Hazard communication
- Foodborne pathogens
- Allergen management
- Emergency preparedness

2.9.2 Auditing Guidance

The employee training program will be assessed at the initial desk audit and compliance at each site audit by interview, observation of tasks and examination of records. Evidence may include:

- The employee training program is based on a training needs analysis (refer to 2.9.1);
- The employee training program covers all job descriptions required within the SQF System (refer to 2.1.2.8);
- The employee training program includes good manufacturing/agricultural practices (as appropriate);
- The employee training program includes pre-requisite programs;
- The employee training program includes food regulatory requirements;
- The employee training program includes hazard analysis relevant to the employees role in the food safety plan;
- The employee training program includes maintenance of food safety plan relevant to the employees role in the food safety plan;

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- The employee training program includes requirements to meet customer specifications;
- The employee training program has been effectively implemented and maintained.

2.9.3 Instructions

What the SQF Code says

2.9.3.1 Instructions shall be available in the languages relevant to the staff, explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety and process efficiency are to be performed.

2.9.3 Implementation Guidance

What does it mean?

Work instructions shall be available for all employees who carry out tasks that are part of the SQF System, e.g., contribute to meeting regulatory compliance; the food safety and process efficiency controls identified in the SQF System and customer specifications.

What do I have to do?

Instructions can be provided in a number of ways such as:

- Written work instructions may be useful when a particular task is complicated (i.e., requiring skilled operators) or repetitious (e.g., mundane work that generally results in a high turnover of staff and requires a constant training effort). These instructions can serve as a valuable training reference when staff needs to check the correct way of doing a task. Written instructions can be in the form of pre-requisite programs (refer to 2.3.1 i) and will be available (if practical) where the task is performed.
- Photos and diagrams can be particularly useful to overcome language barriers or when a task involves a number of different steps.

Instructions may be included in the food safety manual (2.1.3), and must be kept up to date as process or System requirements change.

2.9.3 Auditing Guidance

Work instructions will be assessed at the initial desk audit and compliance at each site audit by interview with key personnel, observation of tasks and examination of records. Evidence may include:

- There are specific work instructions for maintenance of food safety plan and associated tasks;
- There are specific work instructions for maintenance of pre-requisite programs and other tasks related to the SQF System;
- There are specific work instructions for adherence to customer specifications;
- Work instructions are known and applied by personnel conducting food safety tasks;
- Work instructions are updated as changes occur to the process or the SQF System.

2.9.4 HACCP Training Requirement

What the SQF Code says

2.9.4.1 HACCP training shall be provided for staff involved in developing and maintaining food safety plans.

2.9.4 Implementation Guidance

What does it mean?

Two-day (or equivalent), examinable HACCP training is required for the SQF practitioner (refer to 2.1.2.5). However other employees involved in the development of food safety plans must also be trained in HACCP. Also, staff involved in maintenance of the food safety plans must have an understanding of HACCP principles and the HACCP process, and their role in the HACCP process

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What do I have to do?

HACCP training for the SQF practitioner must be external training through a recognized training center. For other staff involved in the SQF System, training can be either/or:

- Also through a recognized external training provider;
- On-line;
- Provided internally through a qualified HACCP trainer or SQF practitioner.

Whichever method is used, participants must have a good understanding of the HACCP method and its application within their site. A record of HACCP training must be retained.

2.9.4 Auditing Guidance

The credentials of the SQF practitioner will be confirmed at the initial desk audit. HACCP training for other staff members shall be confirmed by interview and review of records at each site audit. Evidence may include:

- HACCP training has been provided for all staff associated with the development and maintenance of food safety plans;
- All staff associated with the development and maintenance of food safety plans understand HACCP principles and the HACCP method;
- All staff associated with the development and maintenance of food safety plans are aware of their roles and responsibilities.

2.9.5 Language

What the SQF Code says

2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.

2.9.5 Implementation Guidance

What does it mean?

Where employees do not have as their primary language, the language of the supplier's business, training materials and work instructions must be provided in a language or form that is understood by those employees. For example, suppliers in English-speaking countries that employ staff with English as a second language, and/or limited command of English, instruction and training must be available in a language or languages understood by all employees.

What do I have to do?

Suppliers must:

- Establish the common languages of employees working within the site;
- Consider the literacy level of all employees;
- Provide instructions (refer to 2.9.3) related to the process, food safety in the common languages of employees;
- Provide training (refer to 2.9.2) related to the SQF System in the common languages of employees;
- Ensure that the messages delivered through training and work instructions are understood by all employees;
- Ensure training materials and work instructions in other languages are updated as the primary materials are changed.

2.9.5 Auditing Guidance

Compliance to this requirement shall be confirmed by interview, observation and review of training materials

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and work instructions at each site audit. Evidence may include:

- A review of primary languages spoken within the supplier's staff;
- Review of other language work instructions and training materials available;
- Understanding of foreign language employees of the System and tasks involved.

2.9.6 Refresher Training

What the SQF Code says

2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of the organization.

2.9.6 Implementation Guidance

What does it mean?

This element relates back to 2.9.2 – Training Program. The supplier must ensure that training is current and provide refresher training as appropriate. This may be on an annual basis, start of a new season, or as changes occur to the product, process or SQF System.

What do I have to do?

The supplier must identify what refresher training is required and when and how it is to be applied. Refresher training may include:

- Review of the SQF System at the start of a new season for seasonal employees;
- Training for employees involved in a change to the process, product or procedures within the SQF System;
- Regular update training for permanent personnel.

2.9.6 Auditing Guidance

Compliance to this requirement shall be confirmed by interview, observation and review of the training program at each site audit. Evidence may include:

- The training program includes refresher training;
- The training program identifies means for achieving refresher training requirements;
- Refresher training is appropriate to the type of business and the SQF System;
- Refresher training is being applied as per training program.

2.9.7 Training Skills Register

What the SQF Code says

2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the:

- i. Participant name;
- ii. Skills description;
- iii. Description of the training provided;
- iv. Date training completed;
- v. Trainer or training provider; and
- vi. Supervisor's verification that the training was completed and that the trainee is competent to complete the required tasks.

2.9.7 Implementation Guidance

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What does it mean?

A training skills register is a file of training records. Training records must identify training applied, skills gained, and the assessment applied to ensure the competency was acquired. The training register must comply with the training program (2.9.2), which meets the requirements of the training needs analysis (2.9.1)

What do I have to do?

The supplier is required to prepare a staff training skills register and document who is trained and when they were trained to do a particular task. This may be in the form of a formal training file for permanent staff detailing training undertaken and signed and dated by the subject employee, or a training matrix may be used to keep track of large or rotational labor teams.

Whichever form is used, the training register must identify:

- The trainee participant;
- The skill or knowledge applied;
- The type of training provided;
- Date of training;
- Training provider (e.g., internal or external);
- Competency assessment (generally by the immediate supervisor).

It is also advisable to have an overall summary that links the training register back to the training needs analysis (refer to 2.9.1), so that gaps in the training program (2.9.2) can be identified and corrected.

2.9.7 Auditing Guidance

Compliance to this requirement shall be confirmed by interview and review of training records at each site audit. Evidence may include:

- The training skills register is available and up to date;
- The training skills register includes participant name, skills description, training provided, date of training, training provider, and verification of competencies;
- Individual training skills records are signed and dated by participants;
- Verification of skills are signed and dated by a supervisor or other competent person.

11.1 Site Location and Construction

11.1.1 Premises Location and Approval

What the SQF Code says

11.1.1.1 The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.

11.1.1.2 The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

11.1.1 Implementation Guidance

What does it mean?

The location and construction of food premises are to be such that neighboring buildings, farms, or factories do not introduce factors that could adversely affect the safety of food (e.g., spray drift from neighboring farms, air-borne pollutants from adjacent factories, etc.).

In most jurisdictions, the building and operation of the food premises is governed by local, state, and/or federal regulations. The supplier must be familiar with the applicable regulations and ensure that relevant permits, approvals and notifications are in place.

What do I have to do?

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The supplier must ensure the premises and its surroundings are kept free of contaminants to the products from the external environment. The supplier shall maintain structures, instructions, procedures, etc. that verifies the control of external environmental conditions and for the safety of the process and/or product produced if applicable.

For farms, this may include protection of water courses, prevention of run-off from animal farms onto crops, or measures to avoid spray drift from adjacent properties. Note that identity-preserved farm products (e.g., non-GMO) may require particular protective measures.

For food factories and storage facilities, measures may include protection of exposed products or materials from air-borne contaminants from neighboring facilities. Measures may include physical barriers, sealed factories, positive air pressure, etc.

Suppliers must check with local authorities to establish the requirements. However plans and specifications submitted to a local authority for approval may include:

- Locality map showing the site in relation to the area;
- Site plan showing all salient features of the site and a description of adjoining sites including the location of the premises north compass points, roads, storm water, waste water;
- Floor plans showing the layout of the premises, processing areas, permanent fixtures, and layout of equipment;
- Details of major items of equipment used in the processing area;
- A diagram of product/process flow;
- Specifications generally include details of construction materials, surface finishes (walls, floors, ceilings, etc.), product contact surfaces, essential services and the number of personnel;
- Refrigeration equipment and operating temperatures of cold storage rooms, storage capacity and means of loading into and out of cold stores need also be included.

All applicable certificates or inspection documents from local, state, federal or international governing agency shall be current and kept on file.

11.1.1 Auditing Guidance

Any applicable documented protection measures shall be reviewed initially at the desk audit. However, compliance to this requirement shall be reviewed by observation of adjacent facilities and land use and interviews with operational staff at each site audit. Evidence may include:

- Investigation of external environment and surrounding land-use to determine risk;
- Understanding of the supplier to the risk from the external environment;
- Physical measures in place to manage exterior environmental risks;
- Procedural measures in place to manage exterior environmental risks;
- The measures are effective in managing the exterior environmental risk.

The auditor shall be familiar with the regulatory requirements applicable to the site and check the certificates and inspection documents from the government agency.

To determine compliance, the auditor must walk around the site, inside and out to determine if there are any outside factors that would impact the certified product. This would include potential threats from neighboring facilities or other environmental conditions.

11.2 Construction of Premises and Equipment

11.2.1 Materials and Surfaces

What the SQF Code says

11.2.1.1 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food safety risk.

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11.2.1 Implementation Guidance

What does it mean?

The construction of the material and surfaces used at the site shall be constructed in a way that would be easily cleanable and prevent contamination to the finished product or the process.

What do I have to do?

The main feature of an acceptable product contact surface is that it is impervious, non-corrodible, smooth, easy to clean, light colored, nontoxic and impact resistant. Stainless steel, aluminum, hot-dipped galvanized steel, fiberglass, polyvinyl chloride and nylon are examples of approved product contact surfaces. All other surfaces must be capable of being kept clean and preferably light colored.

Documentation of product contact surfaces being in good condition can be accomplished by making this item a part of a monthly facilities checklist or other type of check list.

11.2.1 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit by interviews, observations and reviews of records. Evidence may include:

- Knowledge of local, state, and federal regulations on the construction and operation of food premises;
- The site has been approved by relevant authorities for construction;
- The site is approved by relevant authorities for production/processing/storage of the applicable products;
- Approval has been sought and given for changes to facilities or equipment.

11.2.2 Floors, Drains and Waste Traps

What the SQF Code says

11.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

11.2.2.2 Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or waste water under normal working conditions.

11.2.2.3 Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

11.2.2.4 Waste trap system shall be located away from any food handling area or entrance to the premises.

11.2.2 Implementation Guidance

What does it mean?

Floors, drains and waste traps shall be designed and constructed in such a way as to minimize the risk to product or process safety.

What do I have to do?

Drains shall be easily accessible for cleaning. Grates need to be removable for access and cleaning. Practices must be demonstrated by the supplier to assess the risks to products and to control those identified food safety risks.

Documentation of floor materials shall be included in the site plan or description of the plant/processing area. Floors shall be provided with proper drainage. Drains need to be positioned and constructed to allow the effective removal of overflow or waste water under normal working conditions. Where drainage and gradients are not ideal, a written SOP shall address the timely and effective removal of waste water to a drain.

11.2.2 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit primarily through observations. Evidence may include:

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- Food contact surfaces are constructed of materials that do not pose a food safety risk;
- Non-food contact surfaces are constructed of materials that do not pose a food safety risk;
- Floors are smooth and easy to clean;
- Floors are correctly graded to allow for water run-off;
- Floors are made of appropriate, smooth, dense, impact-resistant material;
- There are no areas of water pooling or build-up;
- Procedures are in place to deal with floor areas that are not correctly designed or constructed;
- Drain locations do not pose a safety risk;
- Drain construction does not pose a safety risk;
- Waste traps are located away from food handling areas or entrances to the site.

11.2.3 Walls, Partitions, Doors and Ceilings

What the SQF Code says

11.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish, and shall be kept clean (refer to 11.2.13.1).

11.2.3.2 Wall to wall and wall to floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

11.2.3.3 Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed to prevent the contamination of food, ingredients and food contact surfaces and allow ease of cleaning.

11.2.3.4 Pipes carrying sanitary waste or waste water that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients and food contact surfaces, and shall allow ease of cleaning.

11.2.3.5 Doors, hatches and windows and their frames in food processing, handling or storage areas shall be of a material and construction which meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction and windows shall be made of shatterproof glass or similar material.

11.2.3.6 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products.

11.2.3.7 Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.

11.2.3 Implementation Guidance

What does it mean?

This clause is concerned with the design, construction and condition of the buildings that house food processing operations – the floors, partitions, doors and ceilings. They must be designed and constructed in such a way as to minimize the risk to product safety and in some instances to offer protection to the product. The extent to which these elements are relevant will depend on the type of processes housed and whether the product is enclosed or exposed.

What do I have to do?

Walls, partitions, doors and ceilings need to be described in the site plan. Ceiling design and construction must not pose a threat of product contamination. Wall-to-ceiling, wall-to-wall and wall-to-floor junctions must be sealed and easy to clean.

Walls, partitions, doors and ceilings must be kept clean.

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Today's food premises design generally excludes windows in food processing areas. However, older plants may have glass windows. The supplier must, as part of their foreign matter control program, identify any windows that could pose a hazard to unpackaged product and primary packaging if shattered. Windows away from the immediate processing areas are generally not recognized as posing a hazard to packaged food. Windows close to processing areas and skylights that are located immediately above product processing or packaging areas can pose a hazard. Such windows must be constructed of shatterproof material or otherwise covered to prevent glass or plastic fragments from entering product or packaging. Window ledges need to be sloped downwards for ease of cleaning and to prevent their use for unwanted storage of utensils or other materials.

Doors routinely subjected to water must be of solid construction, impact-resistant, non-corrosive materials preferably with a smooth, light colored surface. Doors between processing rooms used to transport food for processing need to be protected against damage by crates, trolleys, folk lifts or similar traffic.

For efficiency and ease of cleaning, walls with cement render and smooth-finish glazed tiles, fabricated insulated panels or similar materials are examples of acceptable surfaces. Where light colored finishes do not exist, a written Standard Operating Procedure (SOP) shall address the timely and effective inspection of the adequacy of cleaning and resultant corrective actions when discrepancies are noted.

It is recommended that if light colored finishes do not exist, an inspection shall be included in the internal audit and/or cleaning sanitation schedule. Where floor junctions in facilities are not rounded to enable easy cleaning and prevent the build-up of waste, a written SOP shall address the cleaning protocol to meet acceptable hygienic standards for these areas.

Service ducting, conduit and pipes ideally need to be recessed into walls or ceilings, suspended from ceilings, housed inside drop ceilings with vertical drops to their point of use, or mounted a sufficient distance from walls or ceilings. In other words, they should be constructed to avoid build-up of debris, prevent rodent runs and allow ease of cleaning.

Drop ceilings offer some advantages and disadvantages. They can provide a clean, smooth, impervious ceiling surface in the processing area and an area for service runs. However, they can also allow for an "out of sight, out of mind" mentality and can accumulate dust and provide harborage for pests. Drop ceilings, if used, must be checked and cleaned regularly (refer to 11.2.7).

Where drop ceilings are not used, cleaning regimes and inspections must check for dust on ledges, loose fittings, glass windows, light fittings, or other areas where dust can accumulate and fall onto product.

11.2.3 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit primarily through observation. Evidence may include:

- Walls and partitions are of sound construction and made of suitable materials;
- Doors are of sound construction for the volume and type of traffic;
- Ceilings are of sound construction and made of suitable materials;
- Walls, partitions, ceilings, and doors are kept clean;
- Where a drop ceiling is used, the area is kept clean and tidy;
- Service lines are designed and constructed for ease of cleaning;
- The condition of walls, partitions, doors, ceilings, does not pose a food safety risk.

11.2.4 Stairs, Catwalks and Platforms

What the SQF Code says

11.2.4.1 Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer 11.2.13.1).

11.2.4 Implementation Guidance

What does it mean?

Stairs, platforms and catwalks shall be designed and constructed so as not to pose a contamination risk.

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What do I have to do?

All stairs, catwalks and platforms that are positioned over any portion of the processing area where product is exposed, shall be constructed so as to not present a product contamination risk. The materials used need to be rust proof and easily cleaned. Solid side (kick) plates shall be installed and the stairs shall have slip resistant tread.

Stairs, platforms and catwalks shall be kept clean and not used to store tools and equipment.

11.2.4 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit primarily through observation. Evidence may include:

- Stair design and construction does not pose a food safety hazard to the product;
- Catwalk design and construction does not pose a food safety hazard to the product;
- Platform design and construction does not pose a food safety hazard to the product;
- Stairs, catwalks, or platforms in close proximity to open product have kick boards installed;
- Stairs, catwalks, or platforms over open product are not constructed of open mesh;
- Stairs, catwalks, or platforms are kept clean and tidy, with no accumulated trash, tools or equipment.

11.2.5 Lightings and Light Fittings

What the SQF Code says

11.2.5.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

11.2.5.2 Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program.

11.2.5.3 Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.

11.2.5 Implementation Guidance

What does it mean?

Adequate light intensity is required for processing operations, cleaning and inspection tasks. However, the design and construction of lighting can pose a risk to product due to breakage or dust accumulation.

What do I have to do?

Lighting shall provide minimum lux (foot candle) intensity as prescribed by applicable legislation or in their absence, meet Good Manufacturing Best Practices appropriate to the commodity being processed. In general, processing and food handling areas are illuminated to a minimum intensity of 200 lux (18.58 ft.c.). Inspection areas require higher illumination; 500 lux (46.45 ft.c.) is generally recommended.

Light fittings in food processing and handling areas are required to be fitted with protective covers or have shatterproof lights installed. Documentation needs to be kept on file and is to include specifications from the manufacturer with a description of the product. An acceptable practice is to recess the light into the ceiling, where possible or have it fitted flush to the ceiling. Where light fittings are not able to be recessed, they must be protected from accidental damage. In circumstances where light fittings are suspended from cables, the top of the fitting needs to be sloped at an angle that permits easy cleaning. Exposed light fittings must be included in a cleaning and sanitation schedule (refer to 11.2.13).

11.2.5 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit primarily through observation. Evidence may include:

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- Lighting intensity is sufficient in food processing areas;
- Lighting intensity is sufficient at inspection stations;
- Lighting intensity is sufficient in warehousing and storage areas;
- Light fixtures are shatterproof or protected, and pose no threat to product safety;
- Light fittings are intact – there is no sign of breakage;
- Light fittings are clean and part of a regular cleaning regime.

11.2.6 Inspection/Quality Control Area

What the SQF Code says

11.2.6.1 A suitable area shall be provided for the inspection of the product if required.

11.2.6.2 The inspection control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall:

- i. Have easy access to hand washing facilities;
- ii. Have appropriate waste handling and removal; and
- iii. Be kept clean to prevent product contamination.

11.2.6 Implementation Guidance

What does it mean?

Where on-line inspection is required, a suitably equipped inspection control station is required close to the process line, but sufficient distance to prevent contamination of the product.

What do I have to do?

Inspection control areas shall be provided when online inspection is required for the commodity being processed to preclude potential contamination of the processing line and other products.

Equipment used at the inspection control station shall not pose a threat to the product. Inspected product shall not be returned to the processing line, or considered as rework. It shall be disposed of in a manner that prevents contamination of products in production and ingredients.

Hand-wash facilities shall be provided at the inspection station.

11.2.6 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit primarily through observation and interviews with inspection staff. Evidence may include:

- Online inspection is required;
- There is a suitable designated inspection control area;
- The inspection area is equipped with hand-wash facilities;
- The equipment used in the inspection station does not pose a product safety threat;
- Inspected material is suitably disposed of;
- Inspected material is not returned to production;
- The inspection station is kept clean.

11.2.7 Dust, Insect and Vermin Proofing

What the SQF Code says

11.2.7.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin, **animals** and other pests. **Guard or guide dogs are allowed if the presence of the dogs will not result in contamination of raw materials, packaging or products.**

11.2.7.2 External personnel access doors shall be provided. They shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against ingress of dust, vermin and other pests.

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11.2.7.3 External doors, including overhead dock doors in food handling areas used for product, pedestrian or truck access shall be insect-proofed by at least one or a combination of the following methods:

- i. A self-closing device;
- ii. An effective air curtain;
- iii. An insect-proof screen;
- iv. An insect-proof annex;
- v. Adequate sealing around trucks in docking areas.

11.2.7.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison rodenticide bait shall not be used inside ingredient or product storage areas or processing areas.

11.2.7 Implementation Guidance

What does it mean?

This element is closely related to *11.2.11 Management of Pest and Vermin*. This element provides the requirements for physical barriers to pest, **animals** and dust ingress into food production areas – via external doors, windows or other means. It also covers the location and use of control measures to trap pests within the premises.

What do I have to do?

Doors opening directly into processing areas must be effectively sealed to prevent dust and/or entry of pests.

Doors used for personnel access shall be self-closing unless used exclusively as a fire exit.

A procedure, included in personnel practices, will need to outline who is allowed to bring a guard or guide dog into the site or onto site grounds. Guard dogs may be part of site security and should be included in the Food Defence Plan.

All pest devices used must be approved and used per applicable legislation so as not to present a contamination risk to the product, packaging containers or equipment.

In 11.2.7.4, "bait" refers to poison baits or glue boards. Indicator baits that conform to local regulations may be used inside processing areas.

11.2.7 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit primarily through observation, and records of pest activity (refer to 11.2.11). Evidence may include:

- Windows are closed or protected and sealed against dust or pests;
- Doors are closed or adequately protected against dust or pests;
- Personnel doors have self-closing devices or other method to ensure effective protection;
- External doors are adequately fly-proofed;
- Sealing around trucks in docking areas is adequate;
- Insect devices are located so as not to pose a threat to product, tools or equipment;
- Poison baits or glue boards are not used in processing areas.

11.2.8 Ventilation

What the SQF Code says

11.2.8.1 Adequate ventilation shall be provided in enclosed processing and food handling areas.

11.2.8.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.12, to prevent unsanitary conditions.

11.2.8.3 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features:

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- i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over the cooker(s);
- ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and
- iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

11.2.8 Implementation Guidance

What does it mean?

Poor ventilation can result in condensate build-up in cooking areas or other areas where heat or steam are applied, and can result in contamination due to condensate dripping onto product or food-contact surfaces. Also, in high-risk processing areas, positive air pressure must be maintained to prevent airborne contaminants being drawn into the area.

What do I have to do?

Cooker/washer steam shall be adequately ventilated to the outside. Ventilation in enclosed food processing areas must meet applicable design and construction legislation and prevent condensation over food and surfaces of food contact equipment. Vents and exhausts must be screened to prevent ingress of flying insects.

Positive air pressure must be maintained in high risk processing areas to prevent airborne contaminants being drawn into the area.

11.2.8 Auditing Guidance

Compliance to this requirement shall be reviewed at each site audit primarily through observation and interview. Evidence may include:

- Food processing areas have adequate ventilation;
- Cooking areas are adequately exhausted;
- There is no condensation present over product or food contact surfaces in cooker areas;
- Exhaust vents are adequately fly-proofed;
- Positive air pressure exists in high risk processing areas.

11.2.9 Equipment, Utensils and Protective Clothing

What the SQF Code says

11.2.9.1 Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented. **The equipment specifications shall ensure that they can consistently produce product that meets specifications its capable of operating satisfactorily within the operating limits required by the process.**

11.2.9.2 Equipment and utensils shall be designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products. **Equipment shall include those used in automated, mechanical, or electronic systems.**

11.2.9.3 Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious and free from cracks or crevices.

11.2.9.4 Product containers, tubs, bins for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned as per 11.2.13. Bins used for inedible material shall be clearly identified.

11.2.9.5 Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system, and to meet local regulatory requirements.

11.2.9.6 Protective clothing shall be manufactured from material that will not contaminate food and is easily cleaned.

11.2.9.7 Racks shall be provided for the temporary storage of protective clothing when staff leaves the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

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11.2.9.8 All equipment, utensils and protective clothing shall be cleaned after use or at a frequency to control contamination and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination. **Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) shall be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that protects against contamination.**

11.2.9 Implementation Guidance

What does it mean?

A new Code requirement, 11.2.9.1, has been included in edition 8 that requires specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented.

This is a general provision covering the condition and use of equipment, including utensils, benches, tables, bins, and protective clothing, so that they do not pose a threat to product safety.

This also includes the provision that requires specifications for equipment, utensils, and protective clothing new to the site or being repaired or modified. Written procedures are required for the purchasing of equipment new to the site or being repaired or modified and the procedures are to be documented and implemented.

What do I have to do?

Food processing equipment shall be designed, constructed and maintained in accordance with manufacturer and/or industry standards. Metal frames, supports and brackets supporting sinks, wash basins, benches, tables and shelves are generally constructed of solid materials such as hot dipped galvanized iron, stainless steel or aluminium and securely fixed to the walls or on metal frames. Equipment shall be smooth-finished, free from angles, ledges and crevices and easy to clean. The open ends of tubular legs or rails must be sealed to prevent the accumulation of process waste and residues.

Where equipment is dismantled for cleaning, it is to be designed free of loose bolts or nuts or other objects that could inadvertently find their way into a food product or provide points for accumulation of food waste.

Containers (e.g., tubs, bins, etc.) used for inedible food or materials must be clearly identified (i.e., color-coded or labelled). Containers previously used for pesticides, insecticides or other deleterious materials must not be re-used for product handling (refer 11.2.11.7).

Where protective clothing (e.g., gloves, face shields, etc.) is provided and used, it must be made of a material that is food-safe and is easily cleaned. There must be a cleaning regime in place for protective clothing.

Price should not be the only factor when purchasing equipment, utensils and protective clothing. Site's need to consider the role of the new item and choose the right item to do the job.

Written specifications are to be developed that includes the detailed description or features of the item. The goal of the specification is to outline all the technical details and requirements that the site has in mind for the purchased item.

Some things that may be considered for the specification document may include, but is not exclusive to the following:

- What is needed for the equipment and how the equipment will be used;
- Specific features, capabilities, or construction materials that are needed for that equipment;
- Durability of the item;
- Regulatory requirements;
- Manufactured and designed for use in a food site;
- **Suitability in meeting production and process controls for consistent application of formulation/recipes;**
- Any required certifications or approvals (i.e., NSF, UL);
- Ease and use of cleaning;
- A receiving document to verify delivery and installation instructions;
- The type of power source;

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- Quantity needed;
- Plumbing needs;
- Drainage requirements;
- Special options or features (ventilation, etc.);
- Service or maintenance requirements;
- Warranty;
- Energy rating;
- Freight and delivery requirements;
- Tear down and installation requirements; and
- Cleaning limitations or requirements.

Written procedures for the purchasing of equipment are also to be developed. This procedure is to outline the process in which equipment is identified, purchased and installed on the site. The procedure will assist in the purchasing decisions and choosing the right equipment to handle the required task. Some things that may be considered for the purchasing procedure may include, but not inclusive to the following:

- Regulatory requirements;
- The conditions and requirements when purchasing refurbished equipment;
- Members that are to be on the purchasing committee such as QA, sanitation, engineering; maintenance, etc.
- Conditions; and
- Confirmation from equipment vendors on acceptance of specification prior to manufacturing, modification or repair and confirmation of any installation specifications that may affect food safety.

11.2.9 Auditing Guidance

This element shall be reviewed at each site audit through observation and interview with operational staff. Evidence may include:

- Food processing equipment is properly designed;
- Food processing equipment is properly maintained;
- Food contact utensils are properly designed;
- Food contact utensils are properly maintained;
- **Single service articles are stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that protects against contamination.**
- Containers for inedible materials are correctly labeled;
- Waste water and overflow from tanks and tubs is properly drained;
- Protective clothing is provided that is fit for purpose;
- Protective clothing is provided that is made of material that will not contaminate food and is easily cleaned;
- There is a cleaning process in place for protective clothing;
- Properly designed racks are provided for protective clothing;
- Protective clothing is stored in an area accessible to staff.

11.2.10 Premises and Equipment Maintenance

What the SQF Code says

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11.2.10.1 The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and implemented in a manner that minimizes the risk of product, packaging or equipment contamination.

11.2.10.2 Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded.

The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety.

11.2.10.3 Failures of plant and equipment in any food processing, handling or storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule.

11.2.10.4 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer 11.3.1, 11.3.2, 11.3.3, 11.3.4).

11.2.10.5 All maintenance and other engineering contractors required to work on site shall be trained in the site's food safety and hygiene procedures, or shall be escorted at all times, until their work is completed.

11.2.10.6 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling or storage area.

11.2.10.7 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times.

11.2.10.8 Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

11.2.10.9 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed and a pre-operational inspection conducted prior to the commencement of site operations.

11.2.10.10 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product.

11.2.10.11 Paint used in a food handling or contact zone shall be suitable for use and in good condition and shall not be used on any product contact surface.

11.2.10 Implementation Guidance

What does it mean?

Maintenance activities – both planned and breakdown – can have a major impact on food safety, if not effectively implemented. Maintenance procedures must be carefully planned, designed, documented and implemented to avoid contamination of product, materials or equipment and to ensure that maintenance staff, including contractors, have an understanding of the safety implications of maintenance activities.

What do I have to do?

The protocol must outline that maintenance staff and service contractors engaged to complete work in food production areas must observe all personnel and process hygiene requirements. Service contractors must be provided with protective clothing, as required. The procedures must describe the practices under which repairs are to be completed in any product handling or storage areas including the following requirements that maintenance staff must observe:

- Maintenance of equipment or building structures must be completed in a manner that does not pose a risk to the product, materials (including packaging materials) or equipment;
- The maintenance supervisors must ensure they are notified by all contractors engaged to complete work in any product handling areas. They must ensure that all service contractors are aware of the supplier's personnel hygiene requirements and that they are provided with any necessary protective clothing, or that protective clothing meets the same requirements as those of the supplier staff;
- Maintenance staff and service contractors must ensure that they account for and remove all tools and debris from any maintenance activity once it has been completed in any product handling area and inform the area supervisor so appropriate sanitation can be completed;
- Service contractors are to inform the maintenance supervisor if any required work poses a potential threat to product, packaging or equipment safety (i.e., pieces of electrical wire, damaged light fittings, loose fittings overhead, etc.). When necessary, maintenance must be conducted outside processing times;

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- Service contractors shall notify the maintenance supervisor in the event of any breakage or damage that could expose products, packaging or equipment to contamination;
- Service contractors must notify the maintenance supervisor when work has been completed;
- Plant supervisors and operators must ensure appropriate and effective clean up measures are taken once all maintenance or service contractor activity is completed and prior to the commencement of plant operations.

It is essential that supplier staff, maintenance personnel and service contractors adhere to the correct procedures when completing maintenance on all equipment. As part of maintenance procedures, repaired equipment must be inspected for missing parts (nuts, bolts, springs, etc.) prior to use.

Those responsible for reporting and completing repairs and cleaning the equipment after repairs must be specified in maintenance procedures.

The use of temporary fasteners such as string, wire or tape is not permitted (refer to 11.7.5.1).

Where machinery that exists over product lines or food contact surfaces requires lubrication, only food grade lubricant is to be used. Even then, food-grade lubricant is still a quality hazard and must be used sparingly to avoid contact with product.

Where paint is used on equipment, roofs, walls or floors, it must be in good condition and suitable for use. Paint must not be used on food contact surfaces.

11.2.10 Auditing Guidance

Maintenance schedule and procedures shall be reviewed at the initial desk audit. Subsequently, compliance to this requirement and the supplier maintenance schedule and procedures shall be reviewed at each site audit through observation, review of records and interview with operational, maintenance staff and contractors. Evidence may include:

- There is a planned maintenance schedule;
- The maintenance schedule includes critical equipment and areas of the site;
- There are maintenance procedures that include food safety issues;
- The planned maintenance schedule is being followed;
- Maintenance procedures afford no risk to product safety and integrity;
- Maintenance procedures are known by maintenance personnel and contractors;
- Maintenance procedures are being followed;
- Maintenance procedures include food safety and hygiene practices;
- Maintenance staff follow food safety and hygiene practices;
- Maintenance contractors follow food safety and hygiene practices;
- Preventative maintenance activities are documented;
- Plant and equipment failures are documented;
- The maintenance schedule is adjusted for plant and equipment failures;
- Operating staff and supervisors are notified when repairs are made/completed;
- All tools, parts and debris are removed from repair areas;
- Sanitation activity occurs after maintenance repair in food processing areas;
- Notification occurs when potential risk to product is evident through maintenance activities or breakdowns;
- food grade lubricant is used in food contact zones, conveyors, and on all motors over food contact surfaces;
- Food grade lubricant is used sparingly and does not come into contact with food product, materials, or food contact surfaces;
- Paint is not used on product contact surfaces;

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- Maintenance records are available and complete.

11.2.11 Calibration

What the SQF Code says

11.2.11.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite program, food safety plans and other process controls, or to demonstrate compliance with customer specifications shall be documented and implemented. **It shall ensure:**

- Equipment is adequate in number for their designated uses;**
- Instruments or controls are repaired or replaced when they cannot be adjusted to agree with the reference standard.**
- Appropriate controls for automated, mechanical, and electronic equipment (including software for a computer controlled process) are validated as appropriate, functioning and for their intended use by authorized personnel.**

11.2.11.2 Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.

11.2.11.3 Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.

11.2.11.4 Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.

11.2.11.5 Calibration shall be performed:

- According to regulatory requirements and/or to the equipment manufacturers recommended schedule;
- Before first use; and**
- At routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument and control.**

11.2.11.6 Calibration records shall be maintained.

11.2.11 Implementation Guidance

What does it mean?

The accuracy of measuring, and inspection equipment that is used to test food safety parameters (e.g., temperature, pH, product weight) **and process controls that effect formulation and recipe accuracy**, is essential in ensuring that product meets regulatory, legal and customer requirements. The equipment itself must itself be tested to ensure correct information is provided to make operational decisions.

What do I have to do?

Test equipment used to confirm regulatory requirements (e.g., weight scales) must be calibrated against a national or international standard.

In cases where a national or international standard does not exist or is not arranged, a reference standard can be purchased or created and/or a standard method (often supplied by the equipment supplier) used.

- pH meters are calibrated against reference buffer solutions according to the manufacturer instructions.
- Thermometers can be calibrated against boiling water or ice-water if these approximate the temperatures the thermometer is required to measure when in use.

To ensure that measuring equipment gives reliable results, the site must:

- Identify all the equipment that requires calibration (e.g., thermometers, scales, pH meters, etc.).
- Ensure the equipment, once calibrated, is protected so that measurements remain accurate.
- Ensure the equipment is only operated by authorized personnel and using approved methods.

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- Determine how accurate the measurements need to be. Does the site need to comply with industry or national standards? If the calibration is designed to check measurements implemented to improve a process the site may determine the level of measurement required and apply calibration parameters to ensure consistent measurement.
- Calibrate equipment regularly. The calibration frequency will vary depending upon the type of equipment and its usage. Calibration frequency must be adjusted in light of experience or manufacturer's instructions. Validation of software, for example software used to control manufacturing lines, or other equipment, is to be scheduled and performed according to provider's recommendation (s).
- Develop a procedure to address products produced between the time equipment "out-of-calibration" is discovered and the last calibration check with normal tolerances recorded.
- Clearly identify who is responsible for undertaking calibration, recording the results of all calibrations and labelling equipment to indicate when it was last calibrated and when recalibration is due.
- **Be validated as being appropriate, functioning and for the intended use by qualified quality or food safety personnel.**

11.2.11 Auditing Guidance

Calibration procedures shall be reviewed at the initial desk audit. Subsequently, compliance to this requirement and the site calibration procedures shall be reviewed at each site audit through observation, review of records and interviews with operational staff responsible for calibration. Evidence may include:

- All measuring, test and inspection equipment is identified;
- Calibration standards are known and followed;
- Calibration methods and frequency are documented for all available measuring, test, and inspection equipment;
- Calibration methods and frequency meet national or international standards where appropriate;
- Calibration methods and frequency meet customer requirements where appropriate;
- Calibration and/or validation methods and frequency meet manufacturer's instructions where appropriate **and are approved by qualified personnel;**
- Methods for calibration of equipment include responsibility for conducting calibration;
- Authorized personnel understand the methods for conducting calibration;
- There are procedures in place to address disposition of potentially affected product **and for repair or replacement of the affected equipment;**
- Potentially affected product is adequately disposed of;
- Calibrated equipment is protected from damage;
- Calibrated equipment is not subject to unauthorized adjustment;
- Calibration records are available and complete.

What the SQF Code says

11.2.12.1 The methods and responsibility for pest prevention shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.

11.2.12.2 Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging.

11.2.12.3 Food products, raw materials or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

11.2.12.4 The pest prevention program shall:

- i. Describe the methods and responsibility for the development, implementation and maintenance of the pest prevention program;
- ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications;
- iii. Outline the methods used to prevent pest problems;
- iv. Outline the pest elimination methods;
- v. Outline the frequency with which pest status is to be checked;
- vi. Include on a site map the identification, location, number and type of bait stations set;

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- vii. List the chemicals used (they are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available);
- viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station;
- ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and
- x. Measure the effectiveness of the program to verify the elimination of applicable pests.

11.2.12.5 Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present.

11.2.12.6 Records of all pest control applications shall be maintained.

11.2.12.7 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

11.2.12.8 Pest contractors shall be:

- i. Licensed and approved by the local relevant authority;
- ii. Use only trained and qualified operators who comply with regulatory requirements;
- iii. Use only approved chemicals;
- iv. Provide a pest prevention plan (refer to 2.3.3) which will include and maintain a site map indicating the location of bait stations traps and other applicable pest control/monitoring devices;
- v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and
- vi. Provide a written report of their findings and the inspections and treatments applied.

11.2.12.9 The site shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that:

- i. Empty chemical containers are not reused;
- ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and
- iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.

11.2.12 Implementation Guidance

What does it mean?

Formerly 11.2.11, Management of Pest and Vermin, 11.2.12 in edition 8 is now titled as "Pest Prevention" to emphasize the prevention practices that are to be in place. Edition 8 provides two new requirements (11.2.12.1 and 11.2.12.2) regarding how pests are handled when identified onsite.

Pest prevention incorporates the site's integrated pest management (IPM) program as a holistic approach that integrates a range of practices to minimize the incidence of pest activity.

The Food and Agriculture Organization (FAO) of the United Nations defines IPM as "the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment."

In other words, a range of integrated measures are required to minimize pest populations, including mechanical preventions (e.g., sealed doors and windows, air curtains, etc.), mechanical controls (e.g., baits, traps, etc.), waste minimization, appropriate use of pesticides, etc.

This element covers primarily traditional pest management activities, including pesticide application. However it is related to 11.2.7 Dust, fly, and vermin proofing, which is also part of an overall IPM approach.

What do I have to do?

A fully maintained pest prevention program is essential to the safe function of any general processing operation. The pest prevention program must:

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- Record sightings and frequency of pest activity to identify the target pest (s) for each pesticide application;
- Outline the frequency with which pest status is to be checked;
- Identify the location of bait stations, traps and chemical sites for ease of checking;
- Outline the methods used to prevent pest problems (the recommendation is to be proactive);
- Outline the methods used when pests are found;
- Maintain licenses and credentials of the pest control operator (s);
- List the chemicals used;
- Assure chemicals used are approved by the relevant authority and that SDS are accessible; and
- Outline the requirements for staff awareness and training in the use of chemicals.

The location of internal and external pest control devices must be completed based on the risk to the site and the product. Factors that can affect this include product type, processing type, location of site, surrounding environment, types of facilities, external storage of equipment (such as equipment graveyards), neighboring facilities and land use. The site and surrounding areas must be kept free of waste, redundant equipment and associated debris to minimize harborage for vermin.

Pest control devices should be located at all product storage, material and packaging storage facilities in addition to the main processing facilities. Inspections for pest activity must take place on a regular basis, the results recorded and the actions taken if pests are present. This can be incorporated into the operation's internal audit program.

Examples of records of pest control applications include service reports, pesticide usage logs, pest sighting logs, corrective action reports and trending of activity by the service provider.

In addition to the pests most commonly seen in food product manufacturing facilities (i.e., flies, mice, rats, roaches, etc.), pest management procedures need to also consider and control domestic and feral animals and birds where applicable.

Any type of pest activity, including but not limited to flies, mice, vermin, insects, etc., identified within the site shall not pose a risk to the food products or packaging material. Any products that have been found to be contaminated shall be disposed of according to the site's policy. All activity is to be documented with the records clearly identifying the results of the disposal, investigation and outcomes and resolution.

Personnel handling pest control chemicals must be trained and authorized to do so. Where external pest management contractors are used, they must be licensed by the relevant local authority and use only approved pest control chemicals. Chemicals must be stored appropriately and separate from any food materials or products (refer 11.6.4.1), and used chemical containers disposed of correctly.

11.2.12 Auditing Guidance

Pest prevention procedures shall be reviewed at the initial desk audit. Subsequently, compliance to this requirement and the supplier pest prevention procedures shall be reviewed at each site audit through observation, review of records and interviews with operational staff and possibly the pest contractor (if applicable). Evidence may include:

- The potential pests are known;
- There is a documented pest management program that integrates a number of preventative as well as control measures;
- The documented pest management program targets all known pests;
- The documented pest management program includes responsibilities for pest management;
- The documented pest management program targets includes methods to eliminate or minimize all known pests;
- The pest management program includes frequencies for checking pest status;
- The pest management program includes the exterior or surrounding areas of site;
- The methods, frequencies and responsibilities identified in the pest management program are effectively implemented;
- External areas are kept clear and free from waste and debris;

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- There are no observed pest harborage areas observed within the site or in the immediate surrounds;
- There is a site map of pest control devices;
- Pest control devices meet regulatory requirements;
- There is a list of approved pest control chemicals;
- Only approved pest control chemicals are used;
- SDS sheets are available for all pest control chemicals;
- Pesticides are correctly labeled;
- Empty or redundant pest control chemical containers are correctly disposed of;
- Pest control contractors are trained, licensed and approved;
- Pest control inspections are thorough and conducted at the correct frequency;
- Supplier's staff are aware of pest control devices;
- Appropriate corrective action is taken in response to pest control inspections;
- Pest control records are current and maintained.

11.2.13 Cleaning and Sanitation

What the SQF Code says

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to:

- i. What is to be cleaned;
- ii. How it is to be cleaned, **including disassembly of equipment and utensils as necessary;**
- iii. When it is to be cleaned, **including before use and after interruption, as necessary for continuous or batch operations where wet washing occurs;**
- iv. Who is responsible for the cleaning;
- v. Methods used to confirm the correct concentrations of detergents and sanitizers, and
- vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

surfaces dry before use and sanitizer used if wet washing occurs

before use and after interruption and as necessary for continuous or batch operations

11.2.13.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

11.2.13.3 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required.

11.2.13.4 Cleaning in place (CIP) systems where used shall not pose a chemical contamination risk to raw materials, ingredients or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored and recorded (e.g., chemical and concentration used, contact time and temperature). CIP equipment including spray balls shall be maintained and modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

11.2.13.5 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential areas are clean **and dry** before the commencement of production. **If wet washing is in use then a sanitizer shall be applied and dried before the commencement of production.** Pre-operational inspections shall be conducted by qualified personnel.

11.2.13.6 Staff amenities, sanitary facilities and other essential areas shall be inspected by qualified personnel to ensure the areas are clean, at a defined frequency.

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11.2.13.7 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.

11.2.13.8 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labelled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure:

- i. The site maintains a list of chemicals approved for use;
- ii. An inventory of all chemicals purchased and used shall be maintained;
- iii. Detergents and sanitizers are stored as outlined in element 11.6.4;
- iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and
- v. Only trained staff handles sanitizers and detergents.

11.2.13.9 Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.

11.2.13.10 The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that:

- i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use;
- ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and
- iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor.

11.2.13.11 A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

11.2.13 Implementation Guidance

What does it mean?

Edition 8 includes two new elements: 11.2.13.4 regarding the requirements for clean in place (CIP) equipment and; 11.2.13.9 regarding the mixing of detergents and sanitizers.

Cleaning and sanitation methods will vary depending on the nature of the operation, and the microbiological and allergen risk. Some food facilities (e.g., flour milling operations) require a dry clean, whereas dairy and beverage facilities will utilize clean-in-place (CIP) and high-risk facilities will have very stringent cleaning and sanitation regimes. This element covers cleaning and sanitation protocols generically but specifies the correct use and type of cleaning detergents, sanitizers (also referred to as disinfectants) and the requirement for post-clean inspections.

It is important to stress that, irrespective of the type of production and risk, all food facilities require an appropriate documented and implemented cleaning program. The program must be verified to ensure its effectiveness.

What do I have to do?

A written cleaning program shall be in place and fully implemented that includes provisions for effective cleaning of equipment, facilities, utensils, amenities and external areas. The cleaning program shall identify the what, how, when and who for every item of equipment and part of the site. Responsibilities shall be identified, including responsibility for the visual or test inspection, and the verification of cleaning methods.

For small items of equipment such as tools, knives, tubs, cutting boards, etc., a wash area shall be provided with sufficient hot and cold running water, a suitable detergent and sanitizer for cleaning and when necessary, suitable racks for draining/drying equipment, utensils, and protective clothing. These areas shall be identified and constructed so they do not present a hazard to other food processing operations. Protective clothing racks (refer to 11.2.12.6) provide temporary storage for gloves, aprons and other items when staff needs to leave the processing area for meals or other short breaks. Used disposable protective clothing must be immediately disposed of in an appropriate manner. Non-disposable protective clothing shall be cleaned according to the written procedures.

The cleaning and sanitation protocol shall include the following detail:

- List all the areas and equipment to be cleaned;

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- The frequency for cleaning and sanitizing different areas of the premises and all associated equipment including pre-operative cleaning and cleaning between breaks;
- A full description of the cleaning and sanitation procedures for each piece of equipment or area of the operation. This should include:
 - **Assembly and disassembly instructions;**
 - Physically remove solid particles by sweeping or wiping;
 - Apply a suitable detergent in the correct concentration to remove grease and other food residues;
 - Rinse off residual food residue and detergent;
 - Apply a suitable sanitizer in the correct concentration to reduce or eliminate microbiological contaminants;
 - Rinse to remove residual sanitizer, if indicated on product label;
 - Dry, as indicated, in a manner that will prevent recontamination.
 - Ensure operators involved in cleaning, including contract cleaners, are fully trained in cleaning and sanitation procedures;
 - Chemicals must be approved for use by the appropriate authority; maintain on file Safety Data Sheets (SDS) for each chemical used. Describe the chemicals used, their dilution rate and method of application;
 - Chemical cleaners and sanitizers must be used and stored in an approved manner (refer 11.6.4);
 - Evaluation of cleaning. Monitor the effectiveness of cleaning and keep records of all inspections implemented to verify the effectiveness of the cleaning program;
 - Maintain an inventory of chemicals purchased and used;
 - Outline requirements for the disposal of unused compounds and empty containers in accordance with regulatory requirements.

Clean-in-place (CIP) is a method of cleaning the interior surfaces of processing equipment, filters, valves, pipes, fittings, etc. in food and beverage facilities without the need to breakdown the equipment. There are many benefits to using CIP systems such as faster cleaning, less risk of chemical exposure to the employee, consist cleaning, and is overall less labor intensive. CIP systems use time, temperature, chemicals and mechanical force to intensify the cleaning effectiveness. The main system component to the CIP system is the use of spray balls or other types of spray to create agitation and circulation of detergent to remove soil.

Where CIP systems are used, the use and design shall not pose a contamination risk to the raw or finished product. The design of the CIP system for any operation shall include parameters critical to ensuring the effective cleaning of the equipment. The identified parameters such as flow rate, chemical usage, concentration, contact time and temperature are to be monitored and recorded. Equipment is to be maintained and any modifications to the equipment, including the spray balls shall be validated.

Employees that operate, maintain or are otherwise engaged with the CIP system shall be properly trained. Training should be included in the training registers and refresher training to include when any updates or modifications are made to the system.

Chemicals and sanitizers, used at the site, that are mixed to proper concentration levels shall be mixed according to the manufacture directions. Mixed chemical solutions shall be stored in appropriate containers that are labelled and clearly identified. Verification of the mixed concentration shall be verified and results shall be recorded.

To verify the effectiveness of sanitation, a visual pre-operational inspection of equipment and site is to be conducted prior to the start of operations, after a sanitation activity or the beginning of a shift. For high risk operations and allergen cleaning verification (refer to 2.8.2.1), a more thorough swabbing program shall be implemented to verify the integrity of the cleaning regime.

To verify the site is operating in a sanitary manner throughout the shift, sanitation shall be monitored and documented regularly by the shift supervisor or a designated employee.

Any corrective actions taken when inspection reveals a problem must be recorded.

11.2.13 Auditing Guidance

Cleaning and sanitation procedures and schedule shall be reviewed at the initial desk audit.

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Subsequent compliance to this requirement and the site cleaning and sanitation procedures shall be reviewed at each site audit through observation, review of records, and interviews with operational staff and cleaning contractors if applicable. Evidence may include:

- The site has an effective and appropriate cleaning program in place;
- All critical equipment and areas of the site are covered in the cleaning program;
- Cleaning methods include what is to be cleaned, how it is to be cleaned, **assembly/disassembly instructions**, frequency of cleaning and responsibility for cleaning;
- The cleaning program includes measures for verification of the effectiveness of sanitation;
- The cleaning of processing equipment is effective;
- The cleaning of utensils and protective clothing is effective;
- The cleaning of buildings, surrounds, and amenities is effective;
- Cleaning of utensils is carried out in an area separate from processing operations;
- Racks and areas for storing cleaned utensils are provided and appropriate;
- Pre-operational inspections are completed to ensure cleanliness;
- All critical areas of the site are included in pre-operational inspections;
- Personnel conducting pre-operational inspections are trained and qualified;
- A sanitation verification schedule is available;
- Methods are established for verification of sanitation;
- Responsibility is established for verification of sanitation;
- An inventory of purchased chemicals is available and is current;
- Detergents and sanitizers meet local regulatory requirements;
- SDS sheets are available for all cleaning chemicals purchased;
- Personnel handling cleaning chemicals are properly trained;
- Cleaning chemicals are disposed of as per regulatory requirements;
- Empty cleaning chemical containers are labeled and securely stored;
- Records of cleaning and sanitation activities are maintained and complete;
- Mixed concentration levels are to be mixed to manufacturer instructions, tested for verification and recorded.
- Records of hygiene inspections are maintained and complete.

Auditors are to check that the CIP system is in proper working order and parameters critical to the cleaning and sanitizing process are established, monitored and recorded. Any modifications to the system are to be validated and employees that are engaged in the process are to be trained and retrained. Training should be included as part of the training register in 2.9.1.7.

11.3 Personnel Hygiene and Welfare

11.3.1 Personnel

What the SQF Code says

11.3.1.1 Personnel who are carriers or are known to have been carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food, or enter storage areas where food is exposed. **Employees will be trained to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition that could result in microbial contamination of any raw materials, contact surfaces or products.**

11.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means.

In the event of an injury which causes spillage of bodily fluid, properly trained employee shall ensure that all affected areas including handling and processing areas have been adequately cleaned and that all materials and products have been quarantined and disposed of.

11.3.1.3 Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing.

11.3.1.4 Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of water is permissible only under conditions that prevent contamination or other food safety risks from occurring.

Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging or equipment.

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11.3.1 Implementation Guidance

What does it mean?

In many jurisdictions, personnel requirements in food plants are covered by food safety legislation. Where this applies, the legislative requirements must underpin the requirements of 11.3.1. This element covers the basic personal hygiene requirement for working in a food manufacturing site.

What do I have to do?

Medical screening of staff and contractors must be undertaken to detect carriers of infectious diseases. Staff identified as carriers of infectious diseases are not to be permitted to handle raw materials, work in progress, or finished product.

Employees must be aware of risks to the food products from the potential transmission of pathogens from ill employees. The site's employee hygiene plan will address both the prevention and control of product exposed to ill employees and bodily fluids. An example of a control program could be the removal of an employee from direct food contact to non-food contact activities when the employee reports potential illness or injury. Ideally, an employee will not be penalized for reporting illness to the site. This will be supported by introductory training with all employees on reporting illnesses and injury **to their supervisor(s)** and a questionnaire on illnesses for visitors. Procedures and training will outline how to address exposure and contact of ingredients, packaging and product.

Staff with exposed cuts, sores or lesions is not permitted to handle products unless suitable protective coverings are applied. These coverings must be monitored regularly by responsible personnel to ensure they remain effective. Bandages are to be brightly colored to ensure they can be easily seen and include a metal strip for ease of detection, if the site uses metal detection.

Dressings on hands and fingers are required to be covered with a suitable glove.

Smoking, eating, chewing and drinking are not permitted in production areas. A risk analysis for drinking water must be conducted and controls must be developed by the site to minimize the risk to the safety of the product if it is provided in a production area. If water is consumed in the processing area, it is recommended that employees wash hands before returning to their station, or, at a minimum, hand sanitizer needs to be applied prior to returning to their workstation, if permitted by regulation.

11.3.1 Auditing Guidance

Medical screening and personal hygiene policies and procedures shall be reviewed at the initial desk audit, and the effective implementation checked at each site audit through observation, review of records and interviews with staff. SQF auditors will question employees on hygiene practices to ensure they are understood and applied. Evidence may include:

- Medical screening and personal hygiene program, policies and procedures are in place;
- Medical screening and personal hygiene program, policies and procedures are effectively implemented;
- The policies and procedures for the prevention and control of bodily fluids are in place;
- The policies and procedures for the prevention and control of bodily fluids are effectively implemented;
- Employees notify the business **and/or supervisor(s)** of illness and injury according to policy;
- Personnel who are engaged in product handling and exhibit signs of illness are redeployed to low risk tasks;
- Personnel who are known to have been ill with an infectious illness are not involved in food processing;
- Personnel sores or cuts on hands are redeployed to low risk tasks or have cuts suitably bandaged and gloved;
- Bandages provided to staff are brightly covered and have a metal strip (where metal detection is used);
- There is no smoking, eating or drinking in food product processing or handling areas.
- Drinking water in production areas is in clear, covered containers, and stored in a designated area away from raw materials, packaging or equipment.

11.3.2 Hand Washing

What the SQF Code says

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- 11.3.2.1 Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.
- 11.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with:
- i. A potable water supply at an appropriate temperature;
 - ii. Liquid soap contained within a fixed dispenser;
 - iii. Paper towels in a hands free cleanable dispenser; and
 - iv. A means of containing used paper towels **to ensure it is handled, dispensed, used, and disposed of in a manner that protects against contamination of raw materials, contact surfaces and products.**
- 11.3.2.3 The following additional facilities shall be provided in high risk areas:
- i. Hands free operated taps; and
 - ii. Hand sanitizers.
- 11.3.2.4 A sign instructing people to wash their hands, and in appropriate languages, shall be provided in a prominent position.
- 11.3.2.5 Personnel shall have clean hands and hands shall be washed by all personnel, including staff, contractors and visitors:
- i. On entering food handling or processing areas;
 - ii. After each visit to a toilet;
 - iii. After using a handkerchief;
 - iv. After smoking, eating or drinking; and
 - v. After handling wash down hoses, dropped product or contaminated material.
- 11.3.2.6 When gloves are used, personnel shall maintain the hand washing practices outlined above.

11.3.2 Implementation Guidance

What does it mean?

In all food manufacturing facilities, employees, contractors and visitors must have clean hands upon entering food handling or processing areas; after each visit to a toilet; after using a handkerchief; after smoking, eating or drinking; and after handling wash down hoses, dropped product or contaminated material. Hand wash stations must therefore be correctly equipped and available at convenient locations for use.

What do I have to do?

Hand wash basins must be provided in close proximity to pedestrian entry points at each area of the site, with instructions for all staff, contractors and visitors to wash hands immediately before entering the processing area. Additional hand basins are required where hands could become contaminated prior to working with product.

Potable water at a suitable temperature, liquid soap, single-use paper towels and a means of disposing of used paper towels need to be provided at each station **to ensure they are handled, dispensed, used, and disposed of in a manner that protects against contamination of other employees, raw materials, contact surface and products.** Hands-free operated taps and hand sanitizers are also required for high risk operations. Hands-free operated taps can include foot, knee or elbow operated handles, auto-sensing devices or any other method that does not require the user to touch the handle with their washed hands to turn it off.

Hand sanitizers for low risk processes are optional.

Where alternative methods of hand-drying are preferred (e.g., high-speed air dryers), their use must be justified and their effectiveness validated (refer to 2.4.2.2).

Hand-wash basins are to be constructed of stainless steel or similar non-corrodible material. Hand-wash basins constructed of porcelain or similar materials must be located at a distance from food handling areas.

11.3.2 Auditing Guidance

The location and construction of hand-wash stations and their use by staff, contractors and visitors shall be reviewed at each site audit. Evidence may include:

- Hand wash basins are available for staff, contractors, and visitors;

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- Hand wash basins are located at personnel access points and areas where hands could become contaminated;
- Hand wash basins are constructed of an appropriate material;
- Hand wash basins have potable water supplied at appropriate temperatures;
- There is liquid soap available at hand wash stations;
- There are paper towels available at hand wash stations;
- There are containers for used paper towels at hand wash stations;
- There is signage near hand wash stations instructing people to wash their hands;
- There are hands-free taps at hand wash stations in high risk areas;
- There is hand sanitizer at hand wash stations in high risk areas;
- Personnel in food handling areas have clean hands **by following handwashing instructions thoroughly**;
- Personnel wash their hands on entering processing areas;
- Personnel wash their hands on leaving toilet areas;
- Personnel wash their hands on leaving the lunch room;
- Personnel wash their hands after handling food products, hoses or waste;
- Personnel wash their hands after eating, drinking or smoking;
- Personnel who use gloves also follow hand washing requirements.

11.3.3 Clothing

What the SQF Code says

11.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination.

11.3.3.2 Clothing worn by staff engaged in handling food shall be maintained, stored, laundered and worn so as not to present a contamination risk to products.

11.3.3.3 Clothing including shoes, shall be clean at the commencement of each shift and maintained in a serviceable condition.

11.3.3.4 Excessively soiled uniforms shall be changed or replaced where they present a product contamination risk.

11.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged. **Gloves shall be of an impermeable material.**

Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment.

11.3.3 Implementation Guidance

What does it mean?

Uniforms, including footwear, and hair coverings that are provided to employees in food manufacturing sites are primarily for the protection of materials, work-in-progress (WIP), finished product and food-contact surfaces; however, buttons, snaps, pockets and the like can pose risk if the clothing item is not properly vetted, and head, face and body hair pose both potential biological and physical hazards that must be analyzed. Clothing must therefore be designed to prevent contamination and maintained in a clean and serviceable condition. A risk analysis will identify which items are appropriate for the personnel, product and process.

What do I have to do?

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Employees and visitors must wear clean clothing, footwear, and hair covering, if identified as a risk, while in the processing area. The site must conduct a risk analysis to identify clothing needs and the risk posed by the clothing choices. Employees and visitors with excessively soiled clothing are not to handle products or packaging materials. Employees working in high risk areas must not wear processing uniforms off site. Employees engaged in low risk processes can wear uniforms off site provided they are properly cleaned at the beginning of their work operation.

Clothing includes outer garments such as work clothes, overalls, boots, shoe coverings, head coverings, hair nets, smocks, frocks, beard snoods and coats. When required, gloves and aprons shall be kept in an intact and sanitary condition when used. When not in use, gloves and aprons shall be stored in a designated area (e.g., such as a rack or in sealed containers within lockers), not on products, packaging or equipment.

Disposable gloves shall **be made of an impermeable material and** removed before each break, changed upon re-entry into the processing area and when damaged. Employees must comply with hand washing practices even when gloves are used.

Any disposable clothing must be changed between breaks, upon entry into processing areas and when damaged. This includes aprons, frocks, smocks, boots, gloves, etc. When clothing is to be reused, it must be properly cleaned and stored on racks or hangers. It cannot be stored on boxes, product or packaging materials. Hairnets and beard snoods are to be worn by employees working on the packing or processing line or who work around exposed product.

11.3.3 Auditing Guidance

Company choices for clothing, including uniforms, gloves, hairnets, snoods and footwear shall be based on a risk analysis and reviewed at the initial desk audit. Clothing worn by staff, contractors and visitors (where appropriate) shall be reviewed at each site audit through observation and interview. Evidence may include:

- A risk analysis has been conducted to determine clothing needs and choices;
- Company policies on clothing including uniforms, gloves, hairnets, snoods and footwear are in place and are appropriate for the type of operation;
- Company clothing policies are implemented by all staff;
- Clothing provided to staff is appropriate and properly maintained;
- Clothing worn by staff is clean;
- Clothing worn by staff in high risk areas is not worn off-site;
- There is clean or temporary clothing available for staff in high risk areas;
- Items such as hair nets, snoods and disposable gloves are available at accessible locations;
- Clothing designations (e.g., color coding) for high risk/low risk areas are fully implemented;
- Clothing requirements for contractors and visitors are followed:
- Staff clothing is clean at the start of each shift;
- Staff clothing is changed when excessively soiled;
- Disposable gloves and hairnets are correctly disposed of;
- Non-disposable gloves and/or aprons are properly cleaned between uses.

11.3.4 Jewelry and Personal Effects

What the SQF Code says

11.3.4.1 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.

If hand jewelry cannot be removed, it shall be covered by material that is maintained in an intact, clean, and sanitary condition.

11.3.4 Implementation Guidance

What does it mean?

Loose pieces of jewelry can fall into exposed food products and cause a choking hazard. Also, pathogenic bacteria can multiply in the warm, humid areas under watchbands, rings and bracelets.

The application of the jewelry policy in food manufacturing is therefore dependent on the risk to the product and exposure to the product. In high risk processes, or those where product is exposed,

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company policies shall require the removal of all jewelry and loose objects prior to entering the processing areas.

What do I have to do?

Jewelry and other loose objects, including watches, worn or carried, must comply with local regulatory authority and proper employee hygiene practices. If such hand jewelry cannot be removed, it may be covered with material which can be maintained intact, in a clean and sanitary condition and which effectively protects against the contamination by these objects to the food, food-contact surfaces or food-packaging materials. Facilities can adjust their good employee hygiene practices based on customer requirements, risk to their product, product exposure and processing conditions.

11.3.4 Auditing Guidance

As with clothing, company policies on jewelry shall be reviewed at the initial desk audit, and the implementation of that policy reviewed at each site audit through observation and interview. Evidence may include:

- The jewelry policy is appropriate to the risk, product exposure and processing conditions;
- The jewelry policy is effectively implemented for staff, contractors and visitors.

11.3.5 Visitors

What the SQF Code says

11.3.5.1 All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.

11.3.5.2 All visitors shall be required to remove jewelry and other loose objects.

11.3.5.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.

11.3.5.4 Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements.

11.3.5.5 All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing or handling areas, or shall be escorted at all times in food processing, handling and storage areas.

11.3.5 Implementation Guidance

What does it mean?

A visitor is considered a non-employee of the company or site. Examples of visitors would be vendors, service providers, contractors, truck drivers, tours and guests. Some sites may define visitors to include anyone who does not work in the site, thus, corporate or sister plant personnel could be considered visitors.

Visitors pose the same risk to product safety as site staff and in some cases a greater risk because they may not understand the operation or food hygiene requirements.

What do I have to do?

The requirements for visitors in food manufacturing are dependent on the risk to the product, exposure to the product and the proximity of visitors to the process. In high risk areas, or those where product is exposed, visitors must follow exactly the same provisions as staff.

The site shall have specific good hygiene practices for visitors, contractors and tours; have a means to communicate those expectations to visitors, contractors and tours; and monitor visitors, contractors and tours to ensure all visitors are in compliance with the company's good hygiene practices. All visitors must be suitably trained in hygiene policies prior to entering ingredient storage areas, processing, and packing areas; if this is not possible or feasible, for example for short-term visits, visitors must be escorted while in the processing, handling, and storage areas. All visitors are required to wear clean clothing and foot wear, and must remove jewelry and other loose objects, including watches that may fall into equipment.

Visitors shall enter and exit product packing and processing areas through designated staff entrance points and must comply with all hand washing and personal requirements. Visitors must not be permitted to handle any product or equipment.

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Visitors shall sign in the visitor log and shall be accompanied at all times by a site employee. For their personal safety, as well as the security of the product and process, they cannot be untrained or unsupervised.

11.3.5 Auditing Guidance

The site policy on visitors shall be reviewed at the initial desk audit and the implementation of that policy reviewed at each site audit through observation and interviews. As someone external to the site, the auditor will be able to partly ascertain compliance by their personal experience on entering the site. Evidence may include:

- The visitor policy is appropriate to the risk, product exposure and processing conditions and the type and number of visitors visiting the site;
- The visitor policy is effectively implemented for contractors, and visitors.

11.3.6 Staff Amenities

What the SQF Code says

11.3.6.1 Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.

11.3.6 Implementation Guidance

What does it mean?

This is a header element, which leads to the further descriptions in 11.3.7 – 11.3.10 addressing change rooms, laundry, restrooms, and lunch rooms.

What do I have to do?

Provide adequate lunchroom and restroom facilities, as appropriate for the number of employees in the operation based on applicable legislation relevant to the commodity being processed.

Provided amenities must have adequate lighting and ventilation.

11.3.6 Auditing Guidance

This element will be audited as part of each site audit through observation and interviews with operational staff. Evidence may include:

- Amenities are provided commensurate with the type of operation and the number of employees;
- Amenities are available for all employees who handle product;
- Staff amenities have adequate lighting;
- Staff amenities have adequate ventilation.

11.3.7 Change Rooms

What the SQF Code says

11.3.7.1 Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.

11.3.7.2 Change rooms shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled.

11.3.7.3 Provision shall be made for staff to store their street clothing and personal items separate from food contact zones and food and packaging storage areas.

11.3.7.4 Where required, a sufficient number of showers shall be provided for use by staff.

11.3.7 Implementation Guidance

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What does it mean?

Provide a designated area (i.e., locker room) for employee and visitor garments and personal items.

What do I have to do?

Change rooms (i.e., locker rooms) must be provided with lockers for staff and visitors when they are required to change from street clothing to protective clothing to enter the food processing operation. The areas shall be designed so materials and personal items cannot be stored on top of the lockers. The area around and under lockers if not fully sealed, must be able to be easily cleaned. It is generally recommended that lockers be fitted flush with the ceiling and placed on stands raised off the floor to allow ease of cleaning.

See also the reference to high risk processes in 11.7.4.

Showers are only required for those food processing plants required by legislation to have such facilities available or if the supplier's risk assessment indicates the facilities are required for high risk processes. The number is to be based on the maximum number of staff likely to use the facilities at one time.

11.3.7 Auditing Guidance

This element will be audited as part of each site audit through observation and interview with operational staff. Evidence may include:

- Change rooms are provided commensurate with the type of operation and the number of employees;
- Change rooms are available for all employees who work in high risk areas;
- Change rooms are designed to avoid storage on top of lockers, and ease of cleaning;
- There are sufficient showers for staff working in high risk areas or areas where clothing can become heavily soiled;
- There are facilities for staff to secure personal items.

11.3.8 Laundry

What the SQF Code says

11.3.8.1 Provision shall be made for the laundering and storage of clothing worn by staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.

11.3.8 Implementation Guidance

What does it mean?

In high risk areas or facilities where clothing can be heavily soiled, provision must be made for the laundering of uniforms.

What do I have to do?

Laundering of uniforms can be on-site or off-site, but must ensure that clean uniforms are available for staff at shift commencement, or when uniforms become soiled.

Change rooms (refer to 11.3.7) are required when clean, laundered uniforms are brought on site and staff have to change into them. Restrooms are not adequate to be used as change rooms for this purpose.

11.3.8 Auditing Guidance

This element will be audited as part of each site audit through observation and interview with operational staff. Evidence may include:

- Provision is made for laundering of protective clothing worn by staff;
- Provision is made for laundering of uniforms of staff working in high risk areas;
- Sufficient numbers of clean, laundered uniforms are available.

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11.3.9 Sanitary Facilities

What the SQF Code says

11.3.9.1 Toilet rooms shall be:

- i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations;
- ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room;
- iii. Sufficient in number for the maximum number of staff;
- iv. Constructed so that they can be easily cleaned and maintained;
- v. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and
- vi. Kept clean and tidy.

11.3.9.2 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance in regulations.

11.3.9.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.

11.3.9 Implementation Guidance

What does it mean?

Sufficient restrooms/toilets are required to accommodate the number of staff. Their location and design must be such that they do not cause a contamination risk to product, food contact surfaces, areas where product is exposed or to food handlers.

What do I have to do?

Restroom/toilet facilities must be located so that they do not open directly into the processing area. In existing facilities where they are in close proximity to areas where product is exposed, an airlock vented to the exterior must be maintained (negative pressure). Staff shall enter toilet rooms from processing areas through either an intervening change room or air lock which is ventilated to external air.

Where exhaust fans are fitted, they must be exhausted to the outside and not into a food production area. The light and exhaust fan can be inter-wired to create negative pressure as an option or the light and exhaust fan can be left on continuously.

To eliminate the risk of air flow from restrooms into the processing room, exhaust fan off-switches may be on timer delay. The light and exhaust fan may be on a single switch located on the outside of the restroom.

Separate toilet rooms shall be provided for each gender and are typically located adjacent to and separate from the change room. The number of toilet cubicles to be provided depends on the number of staff or is based on applicable legislation. Suppliers must be aware of local legislation, but as a guide:

Persons of the same sex	No. of bowls
1-15	1
16-35	2
36-55	3
56-80	4
>80 for each additional 30 persons	1

In male toilets, urinals can substitute for up to one-third of the total number of bowls.

Employee restrooms shall be properly equipped with hand wash facilities (refer 11.3.2). Hands-free taps are preferred, particularly in high risk facilities and include those than can be operated by foot, knee or elbow or turned on/off via electronic sensing devices.

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Signage may consist solely of icons (such as those published by the International Association for Food Protection) to accomplish these requirements, with exception of restroom signage, where other regulatory requirements must be applied.

Sanitary drainage must be kept separate from drainage from food production areas.

11.3.9 Auditing Guidance

This element will be audited as part of each site audit through observation and interviews with operational staff. Evidence may include:

- There are sufficient toilets available for each gender and the number of employees;
- Toilets do not open directly into processing areas;
- Toilets can be easily cleaned;
- Toilets are clean and tidy;
- Sufficient hand wash basins are available near the toilets;
- Sanitary drainage is separated from processing site drains.

11.3.10 Lunch Rooms

What the SQF Code says

11.3.10.1 Separate lunch room facilities shall be provided away from a food contact/handling zone.

11.3.10.2 Lunch room facilities shall be:

- i. Ventilated and well lit;
- ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting;
- iii. Equipped with a sink serviced with hot and cold potable water for washing utensils;
- iv. Equipped with refrigeration and heating facilities enabling them to store or heat food and to prepare non-alcoholic beverages if required; and
- v. Kept clean and free from waste materials and pests.

11.3.10.3 Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for introduction of contamination including pests to the site.

11.3.10.4 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch rooms and at lunch room exits, and in outside eating areas, if applicable.

11.3.10 Implementation Guidance

What does it mean?

Employees, contractors and visitors are not permitted to eat or drink in food handling areas (refer to 11.3.1.3). Designated lunch rooms must therefore be available for staff to take breaks and eat meals. These areas must be physically separated from food handling areas.

What do I have to do?

The supplier may provide additional outdoor lunchroom facilities (e.g., picnic tables) where they do not pose a dust or pest hazard to the processing area of the site. Covered facilities and sealed paths are one way to address these hazards. Where hazards presented by such facilities are minimal, the supplier may employ alternative controls such as routine cleaning of tables and steps to minimize dust on non-sealed paths.

Foot baths also provide another means to ensure that foot traffic does not bring dust or other contaminants into the processing area, if practical to do so.

Each site shall be equipped with a ventilated and well-lit lunch/break room for employees. The room must be equipped with a sink serviced with hot and cold potable water, a refrigerator and a microwave. The area must be kept clean.

11.3.10 Auditing Guidance

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This element will be audited as part of each site audit through observation and interviews with operational staff. Evidence may include:

- Separate lunch facilities are provided;
- Lunch room facilities are adequate for the number of staff;
- Lunch facilities are separated from processing, product storage or handling areas;
- Lunch room facilities are properly ventilated;
- Lunch room facilities are well lit;
- Lunch room facilities include a sink with hot and cold running water;
- Lunch room facilities are clean and tidy;
- Proper heating or cooling facilities are provided in lunch facilities;
- Hand wash signage is available at the exit of the lunch facilities;
- Hand wash signage at the exit of lunch facilities is in appropriate languages.

11.4 Personnel Processing Practices

11.4.1 Staff Engaged in Food Handling and Processing Operations

What the SQF Code says

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices:

- i. Personnel entry to processing areas shall be through the personnel access doors only;
- ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/package is required;
- iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor;
- iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate;
- v. Wearing outer garments in a manner that protects against the contamination;**
- vi. Maintaining adequate personal cleanliness;**
- vii. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2;
- viii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food;
- ix. Hair restraints are used where product is exposed.

11.4.1.2 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the site shall implement proper controls and procedures to ensure:

- i. Food safety is not compromised;
- ii. Sensory evaluations are conducted by authorized personnel only;
- iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations;
- iv. Sensory evaluations are conducted in areas equipped for the purpose; and
- v. Equipment used for sensory evaluations is sanitized, maintained and stored separate from processing equipment.

11.4.1.3 All wash down hoses shall be stored on hose racks after use and not left on the floor.

11.4.1 Implementation Guidance

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What does it mean?

Proper product handling practices combined with sanitary conditions result in:

- Extended storage life of product;
- Reduced risk of product contamination; and
- Fewer product returns or complaints.

While management has overall responsibility for ensuring that sanitary processing practices are adopted, and for establishing hygiene procedures, line operators have a responsibility for ensuring these procedures are carried out properly and effectively.

What do I have to do?

Management must develop a list of good hygiene practices of “dos and don’ts.” This list must be consistent with sections 11.3 and 11.4 of the SQF Code. This will be part of the documented procedures and work instructions. All staff, contractors, and visitors (where applicable) must be made aware of these requirements before entering the site.

The site shall have designated access points for personnel to enter and exit. This is particularly important in high risk areas where product is exposed and when specific entry conditions apply (e.g., change of uniforms, foot baths, etc., refer 11.3.3.2).

Access points are defined as dock doors, pedestrian doors, office doors and any door that enters into the site from the outside or from a lower risk area. Doors that are opened for ventilation must be screened. All processing areas must have areas for employees to be able to wash their hands upon entry into processing and exposed food handling areas.

Appropriate containers for waste storage are containers that are considered easily cleanable, properly labelled, not absorbable and designed for the purpose. No packaging container is to be used for the storage of waste or scrap. Waste containers are to be clearly labelled or designated as waste in languages relevant to the employee workforce.

Where sensory analysis is conducted within processing area, the site is to develop specific hygiene practices that are intended to control food safety risks to the product and be consistent with those defined within this section.

11.4.1 Auditing Guidance

Good hygiene practices will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each site audit through observation and interviews with operating personnel.

Evidence may include:

- Good hygiene practices have been developed;
- Staff are aware of the company’s good hygiene practices;
- Staff adhere to the company’s good hygiene practices;
- All exterior doors have protective controls in place;
- Doors or access points between low risk and high risk areas have no protective controls in place;
- Hand wash stations are available at designated access points;
- Employees, contractors and visitors wash their hands at designated access points;
- Employees, contractors and visitors follow hygiene protocols when entering high risk areas;
- Employees do not wear false fingernails, false eyelashes, eyelash extensions, fingernail polish or have long fingernails in food handling areas;
- Employees are wearing hairnets in food handling areas;
- Food products or ingredients are stored in appropriate containers and not on the floor;
- Packaging materials are stored appropriately and not on the floor;
- Waste containers are properly identified;
- Waste is not left to accumulate in waste containers and is removed at appropriate intervals;
- Sensory evaluations are conducted as per company protocols;
- Sensory evaluations do not compromise food safety or product integrity;
- Sensory evaluation equipment is cleaned and sanitized after use;
- Wash down hoses are stored correctly and not left on the floor.

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11.5 Water, Ice, and Air Supply

11.5.1 Water Supply

What the SQF Code says

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.

11.5.1.2 Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.

11.5.1.3 The delivery of water within the premises shall ensure potable water is not contaminated.

11.5.1.4 The use of non-potable water shall be controlled such that:

- i. There is no cross contamination between potable and non-potable water lines;
- ii. Non-potable water piping and outlets are clearly identified; and
- iii. Hoses, taps, or other similar sources of possible contamination are designed to prevent back flow or back siphonage.

11.5.1.5 Where water is stored on site, storage facilities shall be adequately designed, constructed and maintained to prevent contamination.

11.5.1 Implementation Guidance
<p>What does it mean?</p> <p>Potable water supply at the correct temperature and pressure prescribed by applicable legislation must be of sufficient capacity for all scheduled production needs and meet cleaning and sanitation requirements (refer to 11.2.13).</p> <p>What do I have to do?</p> <p>Potable water, or drinking water, is water that is safe enough to be consumed by humans or used with low risk of harm. In most developed countries, sufficient quantities of potable water are delivered to food manufacturing facilities for operational purposes. In some countries however, and some regions in developed countries, the potability of municipal water cannot be relied on. The supplier must ensure the availability of sufficient supplies of water both as a processing ingredient and for cleaning purposes.</p>
11.5.1 Auditing Guidance
<p>This element will be audited as part of each site audit through observation, review of records and interviews with operational staff. Evidence may include:</p> <ul style="list-style-type: none">• Water used in processing is from a potable source;• Potable water availability is adequate for processing needs;• Potable water availability is adequate to meet cleaning requirements;• Hot water is available for cleaning purposes.

11.5.2 Water Treatment

What the SQF Code says

11.5.2.1 Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment.

11.5.2.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.

11.5.2.4 Water used in as an ingredient in processing, or in cleaning and sanitizing equipment, shall be tested, and if required, treated to maintain potability (refer 11.5.2.1).

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11.5.2 Implementation Guidance

What does it mean?

In many facilities, chemical treatment of water is required to maintain the correct pH or chemical balance for use in boilers, heaters or as an ingredient. Treatment must be controlled and carefully monitored where the above are required. Any water used in the manufacturing or sanitation process must be verified as potable.

What do I have to do?

Water and boiler (water heater) treatment chemicals must be approved for such use and properly stored (refer to 11.6.4).

Procedures must be written and implemented for all water testing used within the premises. Additionally, procedures must be in place defining treatment methods used to when water tested does not meet potability.

Where in-plant chlorination of water is required for washing, rinsing or cleaning purposes, a free residual chlorine level of 0.25 ppm after 20 minutes of contact time (or equivalent at the point of use) is recommended. In-line chlorination that provides higher levels of free residual chlorine at specific points is also acceptable. Regular sampling and testing of residual chlorine is implemented to ensure a safe water supply. Other methods of bactericidal treatment such as UV lighting may be used. In all cases, a program of regular microbiological testing of water is required to verify in-plant effectiveness of all water treatments (refer 11.5.6).

11.5.2 Auditing Guidance

Water treatment procedures (where applicable) will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Water treatment is performed as per written instructions;
- Water treatment that is carried out is appropriate;
- Water treatment is carried out using approved chemicals;
- Water treatment equipment is regularly monitored;
- Treated water is regularly monitored.

11.5.3 Ice Supply

What the SQF Code says

11.5.3.1 Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.4.1.

11.5.3.2 Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.

11.5.3 Implementation Guidance

What does it mean?

Where ice is required for processing or storage of product, it must be made from potable water and under hygienic conditions. Ice storage rooms and containers must be designed and constructed of suitable materials and be maintained in good condition.

What do I have to do?

Ice used as an ingredient or processing aid or ice that comes into contact with food or food contact surfaces or equipment must meet potable water requirements, microbiological standards as required. Ice storage areas, equipment and dispensing tools shall be easy to clean.

11.5.3 Auditing Guidance

This element will be audited as part of each site audit through observation, review of records and

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interviews with operational staff. Evidence may include:

- Ice is made from potable water;
- Ice is made under hygienic conditions;
- Ice is properly protected during manufacture, storage and use;
- Ice in contact with food product complies with national or customer standards;
- Ice storage areas are properly designed and constructed;
- Ice storage areas are maintained in good condition.

11.5.4 Water Quality

What the SQF Code says

11.5.4.1 Water shall comply with local, national or internationally recognized potable water microbiological standards as required when used for

- washing, thawing and treating food;
- handwashing
- to convey food;
- as an ingredient or food processing aid;
- cleaning food contact surfaces and equipment;
- the manufacture of ice; or
- the manufacture of steam that will come into contact with food or used to heat water that will come in contact with food.

11.5.4.2 Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning, or from within the site. The frequency of analysis shall be risk-based, and at a minimum annually.

11.5.4.3 Water and ice shall be analyzed using reference standards and methods **and records of analysis maintained.**

11.5.4 Implementation Guidance

What does it mean?

Even though the water supply may come from the town or regional water supply in which the water is treated, safety tested and maintained by the local authority, it is required that food processors implement their own testing to ensure the safety of the potable water used within the site.

Any water that is used in the process that could come in contact with the product must be verified to be in compliance with local and national standards. In the US and Australia for example, the potability standard for drinking water is <1 coliform / 100 mL water and membrane filtration is the preferred method. However, standards also apply for *Salmonella* spp, *Shigella* spp, enterovirulent *E.coli*, *Vibrio cholera*, *Yersinia enterocolitica*, *Campylobacter jejuni*, and protozoa.

What do I have to do?

This element identifies the areas where potable water must be used, e.g., washing of food product, as an ingredient, cleaning and the manufacture of ice or steam that comes into contact with food product or food contact surfaces.

The site must be aware of the national and/or international potable water standards and any microbiological or chemical water standards imposed by customers. Analysis (refer to 11.5.6) must be conducted to ensure water continues to meet the required standard.

The monitoring may involve one or a number of the following:

- Regular testing of water (e.g., pH, turbidity);

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- Checking filtration apparatus and changing it as required (refer to supplier specifications);
- Regular cleaning of water holding tanks and reservoirs;
- Regular monitoring of sanitizer levels in water (levels normally tested at various sites in the food handling and processing areas).

The rate at which water is tested should, ideally, be based on risk, owing to the potential for seasonal variations in the supply, but at minimum, water should be tested at least annually for potability and any additional quality or safety attribute. Utilize recognized guidance or hire a suitably qualified external resource to collect samples. When utilizing an outside laboratory, seeking a laboratory that is properly accredited to complete the desired analysis is required. The water must be retested any time the water source is changed or when equipment is added to treat the water system.

If ice is supplied by an outside source, the site must have a current analysis of potability on file. Any treatment of water on-site, either prior to usage or as a treatment of waste water, the treatment needs to have applicable analysis verifying the efficiency of the treatment.

Records of all analysis used to support the compliance of water used to regulatory limits are maintained.

11.5.4 Auditing Guidance

Water testing procedures will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- There is a documented water testing procedure in place, including frequency and test method;
- Water (and ice, where applicable) are microbiologically tested to verify cleanliness of the supply;
- Water (and ice, where applicable) are microbiologically tested to verify the effectiveness of treatment methods;
- Appropriate standards are used to collect and analyze water or ice;
- Where external laboratories are used, the laboratories are accredited to offer water testing services; and
- **Records of all analysis performed on water are maintained.**

What the SQF Code says

11.5.5.1 Compressed air or other gasses (e.g., nitrogen, carbon dioxide) that contacts food or food contact surfaces shall be clean and present no risk to food safety.

11.5.5.2 Compressed air systems, and systems used to store or dispense other gasses used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

11.5.5 Implementation Guidance

What does it mean?

This applies to compressed air that comes into contact with exposed food product (e.g., pneumatic conveying), food contact surfaces and interior surface packaging. It does not apply to air that does not come into contact with food or food contact surfaces.

Purity means absence of contaminants that could cause a food safety hazard. Pure air means the air is free of risk for contamination of the products. Essentially, the air must not contribute any contamination to the product.

What do I have to do?

11.5.7.1

Compressed air can be a source of chemical and microbiological contamination. Potential contaminants can include particulates, including dirt (microorganisms, atmospheric dirt and solid particulates, rust and pipe scales), water (water vapor, condensed liquid water and water aerosols) and oil (oil vapor, liquid oil and oil aerosols).

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Food operations must verify and validate that the compressed air used is appropriate and does not serve as a source of contamination. When compressed air comes in contact with exposed product or direct product contact surfaces, the air compressor must use food grade oil.

Preventive maintenance programs need to ensure that an appropriate filtration program is in place at the point of use and the filters are cleaned or changed at a frequency appropriate to the product and process or following any maintenance to air supply source or equipment. Any maintenance must be done in a hygienic manner.

Wherever the compressed air comes in contact with the food, either directly or indirectly, high efficiency filters are to be in place at point-of-use where the air enters the final section of tubing (not in the compressor room). This will significantly reduce the risk of microbial contamination of the food from the air. The recommended final stage of filtration in these food contact areas should have a rating of 0.01 micron with an efficiency of 99.999% (or as determined by appropriate risk analysis). Sufficient filtration is to be in place directly upstream of the final stage to protect the final stage from oil and water aerosols.

Nozzles and air hoses are to be in good condition, properly repaired and maintained in a hygienic state (e.g., cleaned and sanitized). Hoses and nozzles are to be kept off the ground.

It is generally advisable to locate the filtration as close as practically possible (near the "point of use," or the point where air contacts the food), so as to not have long lengths of piping/tubing between the microbial removal filter and the air/food contact point.

11.5.7.2

Testing can be conducted to validate the compressed air-filtration control system's effectiveness based on the risk to the product; however, testing must be conducted at a minimum of once a year. Testing can be done in-house or by a contracted party. Test requirements and number of samples will be based on the risk to the product and process. Microbiological testing can include testing for aerobic plate count and/or indicator organisms as appropriate to the operation. Testing for moisture is to be considered if moisture is a potential risk to the product (e.g., dry operations).

Aseptic sample collection needs to be used. There are a wide variety of measures available, including the use of air sampling equipment, use of sterile sponges, membrane filtration and others.

The site may consider the following controls for particulates

- i. Intake filters to remove atmospheric dirt and solid particulates.
- ii. Microorganisms – A point-of-use filter, minimum 0.01 micron, prevent pathogenic microorganisms from contaminating food. An effective PM program should be in place to maintain the integrity of the filter. Validation from the filter manufacturer is often considered adequate validation.
- iii. Water, including vapor, liquid, condensed. A dryer in the compressed air system provides effective control. An effective PM program should be in place.
- iv. Oil, including vapor, liquid and aerosols. The presence of coalescing filters in the compressed air system effectively removes contamination. An effective PM program should be in place to maintain the integrity of the filter.

Industry Standards of Reference:

For general compressed air quality standards within a food plant, ISO 8573-1 standards are a very good reference. These standards provide a good baseline for quantifying compressed air quality relative to moisture, oil content (carryover from compressor), as well as general particulate contamination. ISO 8573-1 does not, however, provide guidance for microbial contamination. For areas where the compressed air comes in direct contact with food or food contact surfaces, ISO 8573-7 provides a standardized method for collecting compressed air samples for microbial testing; however, it leaves the user to determine the acceptable type and level of CFU content.

11.5.5 Auditing Guidance

Air quality program and test procedures will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- The condition of air compressors and compressed air used to transport product, or otherwise to come into contact with exposed product, product contact surfaces or packaging materials;
- Compressed air that is in contact with food is filtered in accordance with the site's risk

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- assessment or otherwise treated;
- Filters are checked or changed at a frequency based on the air quality program;
 - The site has a standard for microbiological purity of compressed air that contacts foods as well as a process for testing;
 - Maintenance staff has the data specification sheet for the filter housing;
 - Follow up with preventative maintenance and SSOPs;
 - Performance characteristics of the filter in place must match the risks identified in the site's assessment.
 - Identification of the level of filtration at the point-of-use for commercially sterile air.
 - Compressed air that is in contact with food is checked for purity using methods and at a frequency based on the air quality program and test procedures.

11.6 Storage and Transport

11.6.1 Storage and Handling of Goods

What the SQF Code says

11.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, **retention samples**, packaging materials, equipment, and chemicals.

11.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

11.6.1.3 Procedures shall be in place to ensure that all ingredients, materials, work-in-progress, rework, and finished product are utilized within their designated shelf-life.

11.6.1.4 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.

11.6.1.5 Where goods described in 11.6.2 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety.

11.6.1.6 Records shall be available to validate alternate or temporary control measures for the storage of raw materials, ingredients, packaging materials, equipment, chemicals, or finished products.

11.6.1 Implementation Guidance

What does it mean?

This element addresses how raw materials, ingredients, work in progress, rework, finished product, **retention samples** and packaging materials, do not get lost, damaged or contaminated in the process and, along with stored equipment and chemicals, are safely identified, utilized, rotated stored to maintain the safety, and integrity of the item.

What do I have to do?

The control of stock is not necessarily as simple as "first in, first out" (FIFO). The program must be designed to manage product safety, shelf life and codes based on risk, customer specifications, conditions of the product, storage locations and inventory management.

Materials used in the construction of storage rooms must comply with 11.2.1.1 and light fittings in storage areas must comply with 11.2.5.2.

Equipment storage rooms may be adjacent to equipment cleaning areas but kept separate to ensure there is no commingling of dirty and cleaned tools, utensils and equipment.

Racks are to be provided to ensure tools and equipment are not stored on the floor.

Where temporary or overflow storage is used, a risk analysis must be undertaken to ensure the stored product is not at risk or pose a risk to products, processes or personnel. The risk analysis must be documented and be available every time overflow storage is applied.

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In particular:

- Frozen or refrigerated product must be held at the required temperature and in clean and sanitary conditions;
- Dry ingredients, and packaging materials must be held in a dry, clean area that is free from pests;
- Chemicals must be stored in a safe secure area that complies with relevant regulations and does not pose a risk to personnel or other products.

11.6.1 Auditing Guidance

The storage plan shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview and review of records at each site audit. Evidence may include:

- Storage plan is documented, implemented and effective;
- Review of stock rotation procedure;
- Review of stock records;
- Understanding of personnel responsible for inventory management;
- Visual confirmation of raw material, ingredient, packaging, work in progress, and finished product stock in storage;
- There is a dedicated storage area for clean tools, utensils and equipment;
- The equipment storage area allows access for cleaning;
- The equipment storage area protects equipment during storage;
- Alternative storage is being used;
- Risk analysis has been conducted for alternate storage;
- Materials or products are not being stored continuously in temporary storage;
- There is no risk of product contamination from the use of temporary storage;
- Records validate the safe alternate or temporary storage control measures.

11.6.2 Cold Storage, Freezing, and Chilling of Foods

What the SQF Code says

11.6.2.1 The site shall provide confirmation of the effective operational performance of freezing, chilling and cold storage facilities. Chillers, blast freezers and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and easily accessible for inspection and cleaning.

11.6.2.2 Sufficient refrigeration capacity shall be available to chill, freeze, store chilled or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

11.6.2.3 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.

11.6.2.4 Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible. **They shall also be fitted with an automated device for regulating temperature or an automated alarm system to indicate a significant temperature change when temperature adjustments are a manual operation.**

11.6.2.5 Loading and unloading docks shall be designed to protect the product during loading and unloading.

11.6.2 Implementation Guidance

What does it mean?

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Freezing and cold storage apply to the process of Individually Quick Frozen (IQF) product down to sub-zero temperatures and storage of the product at that temperature for preservation. Ideally, frozen food is stored at less than -18°C (0°F).

Chilling refers to the process of reducing the temperature of a high risk food to 0 - 5°C (32 - 40°F), and storing within that temperature range, to minimize pathogen growth and extend shelf-life.

In both cases, the equipment required to chill, freeze or store product must be effective and cater for the maximum throughput.

Controlled atmosphere storage for seasonal fruit and vegetable products in which oxygen, carbon dioxide and nitrogen concentrations are controlled and must also meet the requirements of 11.6.1 as well as temperature and humidity.

What do I have to do?

Refrigeration equipment shall have the capacity to maintain an ambient temperature at or below 5°C (40°F) except when loading or unloading product from the cooler unless other temperatures are prescribed by legislation. During these operations, the ambient temperature must return to 5°C (40°F) within a short time after access doors are closed.

Freezing and cold storage equipment shall have the capacity to maintain a product temperature below -15°C (5°F) and must be maintained during loading and unloading.

A description of the refrigeration capacity needs to be included in the site plan. Verification may be demonstrated through historical temperature recordings.

Refrigeration facilities will be capable of reducing temperatures of product at rates suitable to maintain food safety and/or quality or as prescribed by legislation appropriate to the commodities being processed.

Documentation of floor materials shall be included in the site plan or description of the plant/processing area. A written SOP shall address the timely and effective removal of water or excessive ice build-up. Dense waterproof concrete is the material generally used for flooring and needs to be smooth and graded to reduce water accumulation.

The tops of refrigerated rooms are to be covered with a rodent-proof material. Inaccessible cavities need to be sealed to prevent the access of rodents or other pests. Storage racks and shelving need to be constructed of a non-corrosive material and easily cleanable. The product on these racks or shelves should be at least 30 cm (twelve inches) from walls and 150 mm (6 inches) off the floor to prevent contamination and allow for adequate air circulation around the product (refer to 11.2.3).

Condensation from cooling equipment must be piped to the plant drainage system or to the exterior of the building in a manner which does not create pools or standing water. When defrosting refrigeration units in a processing area, it is necessary that the timing of the defrosting be such that it does not pose a threat to the sanitary conditions of the area or product.

Monitoring and validation of the cooler temperature shall be done in accordance with the site's Food Safety Plan or similar document. The site shall be able to verify and validate cooling or storage temperatures prescribed by legislation. Manual monitoring of cold storage rooms on a predetermined frequency is acceptable provided there is a justification in place for the frequency and documentation is kept on file with corrective actions, if applicable.

The regulating of temperature can be automated or manual. If it is manually adjusted the storage rooms must be fitted with an alarm mechanism.

Where open docks exist, products are to be loaded and unloaded in a manner which protects the premises, the product and/or packaging from inclement weather, pests and temperature abuse.

11.6.2 Auditing Guidance

Cold storage, freezing, and chilling procedures (SOPs) and temperature validation procedures will be reviewed as part of the initial desk audit. Subsequently, they will be audited as part of each site audit through observation, review of records and interviews with refrigeration mechanics and operating personnel. Evidence may include:

- SOPs exist for chilling, freezing and cold storage;
- SOPs exist for validation of chilled and frozen temperatures and times;
- Site can confirm the effective operation of the chillers/freezers;
- Site can confirm the effective operation of the chilled and cold storage rooms **including**

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automated adjustments and/or alarms;

- Cold storage rooms are properly designed and constructed;
- Cold storage rooms are easily cleaned;
- Cold storage areas are easily accessible for inspection;
- There is adequate refrigeration capacity;
- There is adequate freezer capacity;
- There is no condensation in the cold storage area;
- There is no frost or ice build-up in the cold storage area;
- Defrost water is discharged appropriately.
- Temperature monitoring is adequate;
- Temperature records are retained;
- Loading/unloading docks are adequately designed to protect product and product temperature.

11.6.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

What the SQF Code says

11.6.3.1 Rooms used for the storage of product ingredients, packaging, **finished products** and other dry goods shall be located away from wet areas and constructed and designed to protect the product from contamination and deterioration **and to ensure adequate separation and identification of the different materials being stored.**

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

11.6.3.3 Vehicles used in food contact, handling or processing zones or in cold storage rooms shall be designed and operated so as not to present a food safety hazard.

11.6.3 Implementation Guidance

What does it mean?

Rooms where materials, ingredients, packaging, **finished products** and other dry goods - apart from hazardous chemicals, (refer to 11.6.4) are stored, must be clean, dry and accessible **and ensure adequate separation of different types of materials and products.**

What do I have to do?

Ingredients, raw materials, packaging, packing materials **and finished products** must be stored in designated storage areas which protect the materials from contamination and deterioration. **Materials used as inputs to processing** shall be stored only in dry areas of the processing room when staged for use during processing or packing. Ensure that packaging storage areas are adequately protected from the elements, rodents and other pests. Packaging materials which become food contact surfaces must be protected from dust and other contaminants while in storage. This can be accomplished by the use of plastic wrap or other means to protect the packaging material.

Sites must also be aware of the need to segregate identity preserved products (refer to 2.8.1) and in particular materials and products containing allergens (refer to 2.8.2). These materials may require separate, dedicated storage rooms. **Other materials and products must be adequately separated to minimize contamination and also reduce the risk to misuse.**

Materials used in the construction of storage rooms must comply with 11.2.1.1 and light fittings in storage areas must comply with 11.2.5.2.

The racks provided for the storage of packaging shall be constructed of impervious materials and designed to be easy to clean. The site must limit the use of wooden racks for storage of packaging and packing materials to dry areas only. Stands and the lower shelves of stands should be at least 150 mm (6 inches), or as required by applicable regulation above floor level to facilitate proper cleaning.

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Fork lifts, hand-forks and other vehicles used in storage areas must be safe to use, hydrocarbon emissions must be controlled and operated in a manner that does not cause damage to product and equipment.

11.6.3 Auditing Guidance

This element will be audited as part of each site audit through observation and interviews with operational staff. Evidence may include:

- Product storage rooms are located away from wet processing areas;
- Storage rooms are adequately designed to protect product, ingredients, materials, or packaging materials **from contamination or misuse**;
- Packaging racks are made of materials that is easily cleanable;
- Packaging racks allow access to floor/wall junction for cleaning;
- Vehicles used in food processing, storage or cold storage areas release hydrocarbon emissions or present a hazard to food product, ingredients, materials or packaging materials.

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

What the SQF Code says

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported.

11.6.4.2 Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

11.6.4.3 Daily supplies of chemicals used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or surfaces in food contact zones, may be stored within or in close proximity to a processing area provided access to the chemical storage site is restricted to authorized personnel.

11.6.4.4 Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers, or in clearly labelled and suitable secondary containers if allowed by applicable legislation.

11.6.4.5 Hazardous chemical and toxic substance storage facilities shall:

- Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals;
- Be adequately ventilated;
- Be provided with appropriate signage indicating the area is a hazardous storage area;
- Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic substances;
- Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff;
- Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage site;
- Have suitable first aid equipment and protective clothing available close to the storage area;
- In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and
- Be equipped with spillage kits and cleaning equipment.

11.6.4 Implementation Guidance

What does it mean?

Cleaning chemicals, pesticides, agricultural chemicals, lubricants, oil, grease, boiler chemicals, etc. plus any other toxic substances must be stored in designated separately secure storage areas.

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What do I have to do?

There must be clearly visible means of separation of these groups of chemicals or toxic substances. They must not be stored on the same shelf or above each other on the same rack. Pest management chemicals shall be stored separate from cleaning chemicals and separate from engineering chemicals. Bulk containers of hazardous chemicals or toxic substances must have sufficient spill-proof procedures that ensure that no cross-contamination can occur. There must be signage indicating this area is a hazardous chemical storage area.

Chemical delivery systems installed in manufacturing areas will be clearly labelled to identify their use and all chemical containers connected to these systems will remain connected while in use and identified through proper labels. Only personnel who have been properly trained in the use of the system will be authorized for access and use of the system.

Chemical storage areas must comply with local or national regulations, be designed to contain spillages, and be ventilated, secure and lockable. Only approved and authorized chemicals are to be stored. An inventory of stored chemicals must be available at all times.

Chemicals must be stored in their original containers or transferred to specifically designed bulk storage units that are correctly labelled.

Utensils, tools or equipment used for food product must not be stored in the same room as hazardous chemicals.

The supplier must ensure that Safety Data Sheets (SDS) are readily available and accessible to personnel handling or coming into contact with hazardous chemicals. The supplier must also ensure that personnel have been trained in the safe handling and use of all hazardous chemicals in use on site as required by legislation.

Please refer to 11.2.11.5 for pest control chemicals and 11.2.13.6 for cleaning chemicals.

11.6.4 Auditing Guidance

This element will be audited as part of each site audit through observation and interviews with operators, cleaners and pest control personnel. Evidence may include:

- There is one or more designated storage rooms for storing of chemicals;
- Chemical storage rooms are correctly designed and constructed, and meet regulatory standards;
- Chemical storage rooms are ventilated, secure and lockable;
- There is a detailed inventory of stored chemicals;
- The inventory agrees with the actual stock in store;
- Only authorized chemicals are stored;
- There is appropriate signage indicating the area as a hazardous storage area;
- The chemical storage areas are separate from food production areas;
- There is spill control and spill kits available in the chemical storage rooms;
- There are no food processing tools, utensils or equipment stored with hazardous chemicals;
- Daily/shift supplies of chemicals are stored correctly;
- Packaging is not stored in an area used to store hazardous chemicals;
- Sanitizers and detergents are not stored with pesticides or other toxic chemicals
- Chemicals are stored in original containers;
- There are instructions on safe handling of chemicals available.

11.6.5 Loading, Transport and Unloading Practices

What the SQF Code says

11.6.5.1 The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported and unloaded under conditions suitable to prevent cross contamination.

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11.6.5 Implementation Guidance

What does it mean?

The duty of assuring food safety

of the supplier's product continues from when ingredients and materials are first unloaded at the site through when the finished product is placed into storage and loaded ready for distribution. Loading, unloading and distribution procedures must be documented and implemented.

What do I have to do?

Conditions for storage, loading and unloading will vary depending on the type, nature and temperature of the commodity. Documented procedures must cover each type (e.g., bulk, bagged, packaging, refrigerated and frozen) of product delivered into or out from the site.

Some suppliers have their own transport, some suppliers use contract transport. Where contract services are used, the transport protocol will be referenced in the contract with the provider (refer to 2.3.3).

11.6.5 Auditing Guidance

Transport (i.e., loading, unloading and distribution) procedures will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Methods used to load and unload materials and products are documented;
- Methods used for the transportation of products are documented;
- The documented methods adequately protect the product;
- The documented methods are effectively implemented.

11.6.6 Loading

What the SQF Code says

11.6.6.1 Vehicles (e.g., trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.

11.6.6.2 Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity during loading and transport.

11.6.6.3 Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon, acceptable device or system.

11.6.6 Implementation Guidance

What does it mean?

Loading practices shall be documented as per 11.6.7. They shall include conditions and inspections for outbound refrigerated and ambient trucks and trailers.

What do I have to do?

Prior to loading, vehicles carrying refrigerated product must be pre-chilled. Refrigerated units need to be capable of cooling and maintaining finished product at ambient temperature of 5°C (40°F) or below at the point of origin. Inspections must ensure the ability to cool and maintain temperatures (where applicable) on all outbound trucks/trailers. Inspections must verify the setting of the refrigeration unit of the trailer (when applicable).

For all outbound trucks and trailers a visual inspection must be conducted for cleanliness, pest infestation and structural conditions and to verify that all trucks/trailers are free of offensive odors. All inspection findings are to be maintained in records.

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11.6.6 Auditing Guidance

This element will be audited as part of each site audit by observations, review of records and interview with warehouse operators and drivers Evidence may include:

- Pre-shipment reviews are conducted on transportation vehicles for cleanliness, maintenance, and suitability;
- The requirement for pre-shipment inspection is included in the transport protocol (refer 11.6.6) and the transport contract (refer to 2.3.3);
- Loading and staging of product does not expose product to potential abuse or contamination.

11.6.7 Transport

What the SQF Code says

11.6.7.1 Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures recorded at regular intervals during loading as appropriate.

11.6.7.2 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature checked at regular intervals during transit.

11.6.7 Implementation Guidance

What does it mean?

This element refers to loading practices for refrigerated (i.e., chilled or frozen) goods and specifies practices that shall be included in the transport protocol (refer to 11.6.6), if applicable. It will generally apply to outgoing finished product.

What do I have to do?

Temperature abuse during delivery and transport can occur if the process is not controlled. The transport and delivery protocol shall cover those aspects necessary to ensure refrigerated product is protected during transport.

On all transport journeys, the driver must ensure that the refrigeration unit is operational at all times. Facilities may choose to verify refrigeration with regular monitoring of temperature during transport by means of devices similar to a time-temperature recorder (TTR).

The supplier must use clean equipment when taking core product temperatures and open outer packaging to access units in the middle of larger cartons. In circumstances where it is difficult to core test product, or if core testing destroys the serviceability of the packaging, alternative methods of determining a products temperature can be used.

Prior to loading, refrigeration units must be pre-chilled. Food is to be transported at its appropriate storage temperature. It is recommended that the air temperatures of the refrigeration units are recorded at regular intervals during shipment and this can be accomplished by the use of data logger temperature recording devices. Appropriate temperature requirements for chilled food range between 0 – 4°C (32 – 40°F) and for frozen foods ≤ -18°C (≤ 0°F).

11.6.7 Auditing Guidance

This element will be audited as part of each site audit through observation, review of records and interviews with warehouse operators and drivers Evidence may include:

- Loading protocols for refrigerated vehicles are documented;
- Loading protocols for refrigerated vehicles are implemented;
- Pre-ship review of refrigerated transport vehicle include temperature checks;

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- Loading and staging of refrigerated product includes monitoring product temperatures;
- Refrigerated vehicles are capable of maintaining the product at the correct temperature;
- Data loggers indicate that the refrigeration units are kept on at all times;
- Door seals are checked during transit;
- Product temperatures are recorded;
- Core product temperatures indicate that product remains within the required range;
- Corrective action is taken if core product temperatures are outside the required range.

11.6.8 Unloading

What the SQF Code says

11.6.8.1 Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

11.6.8.2 Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity. **Practices shall include a visually examine each immediate container or delivery designated as a shipment that the site receives for appropriate content label, container/vehicle damage, or broken seals**

11.6.8 Implementation Guidance

What does it mean?

This element refers to unloading practices for refrigerated (i.e., chilled or frozen) goods, and specifies practices that shall be included in the transport protocol (refer to 11.6.6) if applicable. It will generally apply to incoming ingredients and raw materials but may also apply to the delivery of finished product to the customer warehouse, if under the responsibility of the supplier.

The site must have procedures in place to minimize the risk of tampering or other malicious, criminal, or terrorist action when shipping and receiving product.

What do I have to do?

The site must verify all incoming shipments are from approved suppliers or are being shipped under prior arrangements made by site management.

Visual inspection and documentation of all incoming shipments of raw materials is required. The site must verify that all incoming carriers are in good repair, clean and free of offensive odors. Proper securing of all shipments shall be checked when delivered.

Sites shall apply seals to all tankers, trucks, or containers being shipped and maintain a logbook of seal assignments. All incoming shipments/deliveries shall be sealed and ensure that the seal number and trailer numbers are recorded on shipping documents for verification prior to entry to the site. The site shall maintain records of all seal activity.

All seal numbers shall be recorded on shipping documents before the seal is broken. The site must record receiving temperatures and supplier codes for traceability purposes and inspect all incoming materials.

11.6.8 Auditing Guidance

This element will be audited as part of each site audit through observation, review of records and interviews with warehouse operators. Evidence may include:

- Unloading protocols for refrigerated vehicles are documented;
- Unloading protocols for refrigerated vehicles are implemented;
- Prior to opening the doors, the refrigeration units on incoming refrigerated vehicles are checked;
- Unloading and receiving of refrigerated product include monitoring product temperatures;

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- All incoming materials are inspected prior to receiving;
- **All incoming materials are verified as being secured during transport through seal integrity checks and shipping documentation review;**
- All incoming materials are transferred to appropriate storage as required to maintain the temperature and integrity of the product;
- Core product temperatures indicate that product remains within the required range;
- Corrective action is taken if core product temperatures are outside the required range;
- Corrective action is taken if inspection of incoming materials finds damage, infestation or product contamination.

11.7 Separation of Functions

11.7.1 Process Flow

What the SQF Code says

11.7.1.1 The process flow shall be designed to prevent cross contamination and organized so there is a continuous flow of product through the process. **Equipment shall be placed in an orderly manner to facilitate maintenance, cleaning operational efficiency.** The flow of personnel shall be managed such that the potential for contamination is minimized **through designation of high risk areas and adequate spacing between work areas, equipment and walls.**

11.7.1 Implementation Guidance

What does it mean?

The layout of process and packing lines must be designed to minimize the potential for contamination from materials, premises, other processes, other parts of the same process, vehicle (e.g., forklift) traffic and pedestrians (e.g., employees, contractors or visitors).

What do I have to do?

The layout of food manufacturing processes must consider the risks of product contamination and be designed to minimize or eliminate those risks. This is particularly relevant in processes where there is a kill-step or other CCP, and the potential for post-CCP contamination must be considered and avoided.

Process flow considerations may include, but is not limited to:

- Avoiding u-shape, or circular processes where the "clean" or high-risk end of the process can be contaminated by the raw material or "dirty" end of the process (refer 11.7.4.1.i);
- Controlling pedestrian walkways to avoid employees walking from the "dirty" to "clean" end of the process;
- **Placement of equipment and work areas in an orderly manner that facilitates proper maintenance, cleaning and operations.**
- Avoiding where possible overhead platforms, catwalks or stairways where debris can fall into the process line (refer to 11.2.4)
- Ensuring separation of allergenic materials (refer to 2.8.2);
- Covering exposed product tanks, bins and conveyors to avoid airborne contamination;
- Avoiding equipment bottlenecks, corners or areas where product can be held up or accumulate.

11.7.1 Auditing Guidance

This element will be audited as part of each site audit through observation. Evidence may include:

- Process flow has been designed to minimize the risk of cross contamination;

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- The flow of personnel is designed to minimize the risk of cross contamination;
- **Observations on personnel activities such as maintenance and cleaning to determine orderly placement of equipment; and**
- Post kill-step parts of the process are well protected.

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

What the SQF Code says

11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross contamination.

11.7.2 Implementation Guidance

What does it mean?

This element relates to 11.6.1 (cold storage), 11.6.2 (storage of dry ingredients, packaging) and 2.4.5 (incoming goods and services). Dry ingredients, raw materials and packaging need to be received and stored separately from frozen and chilled products.

What do I have to do?

All raw materials and work in progress shall be kept in appropriate conditions as to the type of material (refer to 11.6.1 and 11.6.2).

Special consideration must also be given to identity preserved materials (refer to 2.8.1) and materials/ingredients containing allergens (refer to 2.8.2).

Materials shall be kept dry and free from contamination which may lead to waste of materials and potential hazards in the final product.

11.7.2 Auditing Guidance

This element will be audited as part of each site audit through observation. Evidence may include:

- Dry materials and packaging are received separately from chilled/frozen materials;
- Dry materials and packaging are stored separately from chilled/frozen materials.

11.7.3 Thawing of Food

What the SQF Code says

11.7.3.1 Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose.

11.7.3.2 Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature does not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor.

11.7.3.3 Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.

11.7.3.4 Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.

11.7.3 Implementation Guidance

What does it mean?

Where food is required to be thawed for processing (e.g. fish blocks), thawing must be conducted under controlled conditions to ensure consistent and even thawing, including water thawing and air thawing.

What do I have to do?

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Thawing of food (where performed) must be undertaken in a room and on equipment designed and dedicated for that purpose. The room must be located in close proximity to cold storage to prevent surface thawing before entering the thawing room.

Thawing may be by water or air. In both instances, the flow must be regulated to ensure an even and consistent thawing process in an environment that does not pose a product risk or expose the food to deterioration. Where water is used, overflow must be directed to drain.

Time and temperature of product thawing must be established and validated, as must the shelf life of the food prior to use after thawing.

11.7.3 Auditing Guidance

This element will be audited as part of each site audit through observation. Evidence may include:

- Time and temperature of the thawing process have been established and validated;
- Thawing is a controlled process in a custom-designed room;
- Food is thawed in a way that does not pose a food safety risk;
- Water used in water thawing of food is properly disposed of;
- Water used in water thawing is properly cooled;
- Food temperature is monitored during the thawing process;
- Used packaging from thawed food is properly contained and disposed of.

11.7.4 High Risk Processes

What the SQF Code says

11.7.4.1 The processing of high risk food shall be conducted under controlled conditions such that sensitive areas in which high risk food has undergone a “kill” step, a “food safety intervention” or is subject to post process handling, are protected/segreated from other processes, raw materials or staff who handle raw materials to ensure cross contamination is minimized.

11.7.4.2 Areas in which high risk processes are conducted shall only be serviced by staff dedicated to that function.

11.7.4.3 Staff access points shall be located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.

11.7.4.4 Staff engaged in high risk areas shall change into clean clothing or temporary protective outerwear when entering high risk areas.

11.7.4.5 Product transfer points shall be located and designed so as not to compromise high risk segregation and to minimize the risk of cross contamination.

11.7.4 Implementation Guidance

What does it mean?

High risk processes are those in which high risk foods are handled, exposed, stored, processed or packed.

High risk food is food that may contain pathogenic microorganisms and will support the formation of toxins or growth of pathogenic microorganisms, and has a significant likelihood of growth causing illness or injury to a consumer if not properly produced, processed, distributed and/or prepared for consumption. It may also apply to a food that is deemed high risk by a customer, declared high risk by the relevant food regulation or has caused a major foodborne illness outbreak (refer SQF Code, Appendix 2: Glossary).

This element outlines the specific conditions required in areas where high risk foods are processed or handled.

What do I have to do?

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The process flow is particularly relevant for high risk processes where the product is subject to handling or exposure after a "kill-step." This includes (refer to 11.7.1) segregation of the post-process end from the raw material end of the process; controlling pedestrian walkways to avoid personnel contamination; dedicated tools and equipment post-process; dedicated staff servicing the post-process end; and dedicated uniforms for staff working post-process.

The reference to the environmental monitoring program is self-explanatory, but is worth repeating as it is considered mandatory for areas in which high risk food is processed, handled or exposed. Failure to have an effective environmental monitoring program will result in a major non-conformance.

An environmental monitoring program (EMP) is a program which includes pathogen swabbing to detect risk in the sanitary conditions of the processing environment and is a verification of the effectiveness of the pathogen controls that a management site has in place for high risk foods (refer Appendix 2: Glossary of Terms).

Swabbing must include not only the smooth, accessible parts of the process, but also the transfer points, bearings, etc., where product is likely to build up.

11.7.4 Auditing Guidance

Control procedures for high risk areas shall be reviewed as part of the initial desk audit. Subsequently, high risk processes will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- There are control procedures in place for high risk processes;
- Control procedures are effectively implemented for high risk processes;
- High risk areas are adequately segregated from raw material handling areas;
- High risk areas are only serviced by staff dedicated to that function;
- Post-process areas are not at risk from pedestrian walkways;
- Protective clothing is provided in high risk areas;
- Dedicated tools and equipment are available in high risk areas;
- Product transfer between equipment and between high risk areas and other areas poses no risk to product;
- An effective environmental monitoring program (EMP) is in place;
- The EMP includes a sampling schedule and responsibility for sampling;
- Swabbing includes transfer points and joints in equipment;
- Swabbing records are maintained.

11.7.5 Control of Foreign Matter Contamination

What the SQF Code says

11.7.5.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.

11.7.5.2 Inspections shall be performed to ensure plant and equipment remains in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.

11.7.5.3 All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location.

11.7.5.4 Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones.

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.

11.7.5.6 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

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11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.

11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

11.7.5.9 Knives and cutting instruments used in processing and packaging operations shall be controlled, and kept clean and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

11.7.5 Implementation Guidance

What does it mean?

Foreign matter can originate from:

- External sources such as pests, raw material and packaging material (e.g., plastic and/or cardboard embedded in product by the supplier);
- Internal sources of foreign matter include the building (e.g., rust, insects and insulation), surface coatings (e.g., flaking paint, damaged render), equipment (e.g., nuts, pins, screws, washers, etc.), metal swarf, glass (e.g., from windows, or utensils) and wood (e.g., from pallets or brooms or other equipment).

In all cases, where there is risk for potential foreign matter contamination, procedures must be in place to eliminate or minimize the risk of foreign materials entering the product. The supplier needs to be aware of potential sources of foreign matter contamination, however, customer complaints (refer to 2.1.5) may provide an indication of the prevalence and priority.

What do I have to do?

The foreign matter (including glass) protocol must outline the sources of foreign materials, the methods of control and the responsibility for taking action when foreign materials or glass are detected in the manufacturing environment.

The protocol shall include removal of all tools and machine parts from the processing areas when maintenance has been completed (refer to 11.2.9.2 v1) and this shall be implemented and supervised. Plant and equipment must be inspected regularly to ensure it remains in good condition so that nothing has detached, damaged or deteriorated. Personnel must be encouraged to report all recognized sources of potential contaminants. This includes potential deterioration of e.g., metal blades in mixers and other areas where metal/metal wear can cause metal swarf to tear off.

Fabricated equipment covers shall be used wherever possible to prevent potential contamination from nuts, bolts, etc. Temporary repairs shall not be utilized within general processing facilities. The use of plastic, tape, string, cardboard or other non-permanent materials as a means to repair or alter the operation or equipment must be avoided. The site shall have included within its maintenance process (refer to 11.2.9) control measures to be taken when repairs are needed during process to protect product from foreign materials that could impact food safety. Containers, equipment and other utensils made of glass, porcelain, ceramics or other like material must not be permitted in any processing or food handling area.

Quality assurance staff must replace all laboratory glass containers with plastic containers if possible and avoid using glass instruments in processing areas. Regular inspections must be made to ensure that these areas are free of glass and staff must be made aware of their responsibility to adhere to the company foreign matter and glass protocol. All overhead lighting must be protected and shielded (refer to 11.2.5).

The risk assessment of foreign material contamination and preventative controls shall be included within the food safety plan (2.4.3) development. Each site must assess its risks of foreign material contamination to product and develop specific controls within its environment.

Wooden pallets are part of the food industry and are not expected to be banned from processing environments. Depending on the type of operation and the products being produced, the types of controls for the management of pallets can vary from one site to another. At a minimum, all general processing facilities should have a pallet management program in place where pallets undergo inspection for broken slats or wood pieces protruding which could pose a risk to products. If pallets are stored for prolonged periods outdoor, then the pallets may need to be cleaned and inspected for vermin prior to entry into the processing area.

For high-risk operations and wet processing environments, the use of clean slip sheets or plastic pallets may be utilized to help to minimize the risk of foreign material or microbiological contamination to the products.

Knives and cutting instruments must be counted and controlled and kept clean to avoid cross-contamination.

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11.7.5 Auditing Guidance

Foreign matter control (including glass) procedures shall be reviewed as part of the initial desk audit. Subsequently, foreign matter control procedures will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Foreign matter control procedures are documented;
- Foreign matter control procedures identify all potential sources of foreign matter contamination;
- Foreign matter control procedures are effectively implemented;
- Foreign matter control procedures include responsibility for foreign matter control;
- Foreign matter control procedures are communicated to staff;
- Inspections are conducted to prevent foreign material contamination of product;
- Temporary repairs are not used within the processing areas or where food is handled or stored;
- A glass register has been developed;
- The glass register is complete, and covers all glass located at the site;
- The glass register includes brittle plastic and other materials;
- Glass inspections are conducted regularly including instrument dial covers and thermometers;
- Wood used in processing / handling area well maintained and clean;
- There are no loose materials on processing equipment;
- Knives and cutting instruments are clean and sanitized.

11.7.6 Detection of Foreign Objects

What the SQF Code says

11.7.6.1 The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect foreign matter shall be documented and implemented.

11.7.6.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

11.7.6.3 Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections.

11.7.6 Implementation Guidance

What does it mean?

Foreign matter detectors can include metal detectors, x-ray, color sorters, screens, sieves and filters. They must be designed and installed to detect and/or trap foreign objects that have been identified in a detailed risk assessment. Their management, control, and calibration must be documented in procedures and work instructions which include responsibility and frequency.

What do I have to do?

Specific work instructions must be written on the monitoring of foreign material detection and prevention devices. The frequency of monitoring such devices, the criteria used in monitoring, and the corrective actions to take when foreign materials are discovered, or issues are discovered with the effectiveness of the prevention device must be defined within the methods. For example, if a metal detector must reject three wands (2.0 Fe, 2.5 non Fe, 3.0 SS) to pass, then when all three wands are not rejected, the site must have defined criteria for how such an incident will be handled including product identification and disposition (i.e., if the detector should fail, all product since last good check is placed on hold and must be re-run through a working metal detector).

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Some examples of frequency of monitoring may be hourly metal detector checks, screen checks once per shift, tailings check daily and filter check once per shift or once per load.

Metal detectors, x-ray, color sorters (if used for defects or foreign material) and all other detection devices must be validated to ensure that they can effectively detect a foreign object within the packaged product that is passed through the device. The passing of wands through the device to ensure that it is working is verification. An example of a means for validation of a metal detector could be the placing of a piece of metal within the package of product (product would be marked to ensure it does not enter market). All types of packaging and sizes of product that are passed through the device must be validated as well as all new packaging or size of product.

11.7.6 Auditing Guidance

Procedures for foreign object detection devices shall be reviewed as part of the initial desk audit. Subsequently, procedures will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Methods are documented for the monitoring, maintenance or calibration of filters and screens;
- Responsibility is assigned for the monitoring, maintenance or calibration of filters and screens;
- Methods are effectively implemented for the monitoring, maintenance or calibration of filters and screens;
- Methods are documented for the monitoring, maintenance or calibration of physical contaminant detection devices;
- Responsibility is assigned for the monitoring, maintenance or calibration of physical contaminant detection devices;
- Methods are effectively implemented for the monitoring, maintenance or calibration of physical contaminant detection devices;
- Physical contaminant detection technology is routinely monitored;
- Physical contaminant detection technology is validated;
- Records are maintained of foreign body inspections;
- Records are not maintained of the validation of foreign body detection equipment.

11.7.7 Managing Foreign Matter Contamination Incidents

What the SQF Code says

11.7.7.1 In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed of.

11.7.7.2 In circumstances where glass or similar material breakage occurs, the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a suitably responsible person prior to the commencement of operations.

11.7.7 Implementation Guidance

What does it mean?

The site must have established criteria for the identification, isolation and disposition of product affected when a foreign material issue is detected. The supplier must manage the incident with established procedures consistent with element 2.5.5 (Corrections and Preventative Actions).

What do I have to do?

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The supplier must have a procedure in place to identify, isolate, inspect and rework or dispose of product that is known to be at risk of foreign matter contamination. This shall include isolation, labeling, quarantine of affected product, and depending on the nature of the suspected contaminant, further inspection or examination of the product to determine the source and extent of the contamination so that a decision can be taken on its disposition.

Where a glass or similar breakage occurs, the procedure (refer 11.7.6) must include a glass clean-up process that covers the footprint of the tramp glass. For example, breakage on high speed beverage bottling lines can spray glass over a wide area. The procedure must include a shut-down of the whole area, and a thorough clean-up to eliminate all broken glass. Brooms, brushes, vacuums and footwear must be included in the clean-up. The area must be thoroughly inspected before recommencing operations.

11.7.7 Auditing Guidance

The foreign matter control (including glass) procedures shall be reviewed as part of the initial desk audit. Subsequently, the procedure including glass clean-up protocols will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Isolation and rework/disposition is included in the foreign matter control procedure;
- Isolation and rework/disposition is effectively implemented;
- Glass breakage procedure is included in the foreign matter control procedure;
- Glass breakage procedure includes clean-up of footwear, tools, brooms, brushes and other equipment;
- Glass breakage procedure is effectively implemented.

11.8 On-Site Laboratories

11.8.1 Location

What the SQF Code says

11.8.1.1 On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.

11.8.1.2 Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory waste water outlet shall as a minimum be down stream of drains that service food processing and handling areas.

11.8.1.3 Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.

11.8.1 Implementation Guidance

What does it mean?

On site laboratories are an option based on cost and needs of the supplier. In many cases, outsourcing laboratory services is applicable and reduces the risk of having on-site laboratories. In most instances, testing for monitoring purposes may be carried out in an on-site laboratory, while validation activities are outsourced to an accredited laboratory.

What do I have to do?

This guidance is specific to on-site laboratories only. Laboratories must be located away from any food processing or handling activities or food contact surfaces to avoid contamination. Raw materials, ingredients, work-in-progress, packaging or exposed product shall not be exposed to laboratory waste.

Signage shall be posted at laboratory entrance(s) restricting access to trained, authorized personnel. Signage may consist solely of icons such as those published by the International Association for Food Protection to accomplish these requirements, and other local regulatory requirements must be applied.

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It is not necessary for the internal laboratory to be accredited to ISO 17025 or equivalent; this is required in the Code for only external laboratories (refer to 2.5.6.1.iv); however the testing methods used must be justified and proficiency against an accredited laboratory is recommended to validate the testing methods.

Laboratory waste must be labeled, stored and disposed of separately from food waste. This applies to contained waste and waste flushed to drain.

11.8.1 Auditing Guidance

This element will be audited as part of each site audit through observation. Evidence may include:

- The on-site laboratory is separated from food processing and handling areas;
- Laboratory access is restricted to only authorized personnel;
- Laboratory waste is properly treated prior to disposal;
- Laboratory waste is adequately contained and separated from general food waste;
- Adequate signage is available for the laboratory.

11.9 Waste Disposal

11.9.1 Dry and Liquid Waste Disposal

What the SQF Code says

11.9.1.1 The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented. **Methods shall provide for:**

- Minimizing the development of odors;**
- Minimizing the potential for the trash to attract, harbor, or become a breeding place for pests;**
- Protection against contamination of raw materials, packaging materials, in-process materials, finished products, water supplies, and grounds surrounding the site; and**
- Control of hazardous waste.**

11.9.1.2 Waste shall be removed on a regular basis and not build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

11.9.1.3 Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition and cleaned and sanitized regularly so as not to attract pests and other vermin.

11.9.1.4 Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging.

11.9.1.5 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

11.9.1.6 Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing.

11.9.1.7 Waste held on site prior to disposal shall be stored in a separate storage site and suitably insect proofed and contained so as not to present a hazard.

11.9.1.8 Adequate provision shall be made for the disposal of all liquid waste from processing, food handling areas **and sanitary waste**. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard. **Sewage shall be disposed into an adequate sewage system or through other adequate means.**

11.9.1.9 Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.

11.9.1 Implementation Guidance

What does it mean?

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The procedures for storage and disposal of all types of waste – dry and liquid – must be documented and implemented. The procedure will include how waste is contained in appropriate, covered and labeled containers; the frequency of disposal; how it is disposed of; and who is responsible for it. Customer requirements, local regulations and community expectations concerning recycling, waste **and sewage disposal** and transport must also be considered.

What do I have to do?

As with solid waste, the disposal of any liquid waste from production and handling areas is essential to the maintenance of a clean and safe working environment. Procedures are to be in place to monitor the effective removal of liquid and solid wastes per written plant procedures.

On-site incinerators, compactors or other waste collecting/disposal equipment need to be designed, sited, constructed and operated so as not to create a hazard to product or the surrounding environment. Compactors and other waste storage areas must not be sited adjacent to any area where food product is exposed.

Cafeteria/lunch room food waste shall be stored separately from packaging waste in covered pest-proofed containers and emptied on a basis that prevents the attraction of pests.

The site must have a plan, where appropriate, to address the proper disposal or destruction of trademarked materials, whether ingredients, finished product, or packaging, taking note of that provided by customers. If contracted disposal is used, the site must take measures to verify disposal procedures are followed and that the services of the contracted service provider is documented as per 2.3.3.

If food waste is designated for feed, the site must have in place a plan to safely handle, hold, store and/or transport the waste according to any customer or regulatory requirements.

At the end of the each shift or day (depending on the site and operation), all office trash, processing trash, packaging material trash, etc. needs to be removed by designated employees and disposed of in the external trash receptacle. All trash generated in the manufacturing and handling areas must be separated for recycling where possible.

Empty chemical drums shall be collected and transported to secured storage (refer to 11.2.11.7 and 11.2.13.7).

Exterior waste containers need coverage or lids to prevent attracting flies or vermin. It is also advisable to secure waste containers in regards to site security requirements (refer to 2.7)

Review of the waste collection and handling system should be incorporated as part of the internal audit program of the site (refer to 2.5.7).

Liquid waste handling systems need to either remove such waste (processing and sewage) immediately into appropriate regulated systems or have temporary storage locations that are properly designed to avoid leaks, odors and contamination with food material or products.

11.9.1 Auditing Guidance

Waste handling, storage and disposal procedures shall be reviewed as part of the initial desk audit. Subsequently, waste storage and removal will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Waste handling, storage and disposal procedures are documented;
- Waste handling, storage and disposal procedures include how waste is contained in appropriate, covered and labeled containers; frequency of disposal; how it is disposed of; and who is responsible for waste handling and disposal;
- Waste handling, storage and disposal procedures are fully implemented;
- Waste handling, storage and disposal procedures adequately dispose of waste without risk of product contamination;
- Waste is regularly removed from processing and food handling areas;
- Waste collection and storage areas are maintained and cleaned;
- Containers for waste are properly maintained and cleaned;
- Trolleys, vehicles and equipment used for waste are properly cleaned;
- Daily inspections are conducted to monitor handling of waste;
- Records are maintained of waste disposal;
- The waste system is included in the internal audit program.

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11.10 Exterior

11.10.1 Grounds and Roadways

What the SQF Code says

11.10.1.1 Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed.

11.10.1.2 The grounds and area surrounding the premises shall be maintained to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin.

11.10.1.3 Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises.

11.10.1.4 Paths, roadways, loading and unloading areas shall be adequately drained to prevent ponding of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

11.10.1.5 Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises.

11.10.1.6 Paths from amenities leading to site entrances are required to be effectively sealed.

11.10.1 Implementation Guidance

What does it mean?

Unkempt surroundings (including the accumulation of unused equipment, pallets, bins, drums, pooling water or waste) can provide harborage for vermin and other pests and, in turn, pose a serious hazard to the hygienic operation of a food premises.

What do I have to do?

The provision of lawn and landscaping is effective for sealing large traffic areas. High vehicle traffic areas are also required to be effectively sealed to prevent dusty conditions.

To prevent such a hazard, proper and purposeful measures for separation of drains and the site draining system shall be implemented. Additionally, these areas shall be kept clear of debris build up in and surrounding such areas.

Exterior construction projects that impact sealed areas should be reviewed, and controls established on a temporary basis during the project timeline.

Where employee amenities are external to the site, the access to the amenities must be sealed, and should be covered to allow for weather conditions.

11.10.1 Auditing Guidance

This element shall be reviewed as part of each site audit. Evidence may include:

- Exterior grounds are maintained, tidy and uncluttered and do not provide pest harborage areas;
- Exterior grounds are managed to minimize dust or other hazards;
- Exterior grounds are kept free of waste;
- Exterior paths and roadways are managed to minimize dust or other hazards;
- Exterior loading and unloading areas are maintained to minimize hazards;
- Grass and vegetation is kept under control in surrounding areas;
- Equipment that is stored outside is protected from the weather;
- External paths from amenities to the site are sealed.