General Guidance for Developing, Documenting, Implementing, Maintaining, and Auditing an SQF System

Module 2: System Elements

SQF Code, Edition 7.2

JULY 2014

SQF Institute is a division of the Food Marketing Institute (FMI).

Preface

This document provides general guidance for SQF suppliers, consultants and auditors when implementing and auditing module 2 of the SQF Code, edition 7 and can be used where no specific industry sector guidance is available.

The purpose of SQF Code implementation is not only to achieve certification, but to assure constant and continual validate and review of a supplier's SQF System for currency and completeness.

Effective implementation of the SQF Code requires the commitment of the site management and the constant involvement and participation of site staff to maintain the safety and quality of SQF certified products. The results of effective SQF implementation are not only the protection of public health and company brands, but real improvement in margins by reduction of waste, recalls and withdrawals, and improved productivity through "doing it right the first time."

The SQF Institute is grateful to the SQF Institute's Technical Advisory Council and SQF stakeholders for their assistance in reviewing and contributing to this document.

Table of Contents

Section 1. Introduction

1.1   Purpose of the Guidance Documents

The purpose of this series of SQF Guidance Documents is to assist suppliers with designing, developing, documenting, implementing and maintaining an SQF System using the SQF Code, edition 7, and to assist SQF registered auditors in auditing the SQF Code, edition 7.

The relevant Code version number is identified in the document header. Terms used in these documents are defined in Appendix 2: Glossary of the SQF Code edition 7.

Guidance is intended to support the SQF Code, but does not replace it. It is not an auditable document, nor is it definitive and applicable in every situation. Suppliers, consultants, and auditors are required to understand the food safety (and quality, where applicable) risks in a given industry sector and are able to apply the SQF Code to effectively control those risks.

1.2   Layout of the SQF Code

The SQF Code, edition 7 consists of two parts and three appendices. Part A contains the criteria for implementing and maintaining the SQF Code. Part B, the heart of the SQF Code, is made up of modules. Within each module are clauses or elements, which the supplier must implement as their SQF System. In module 2, the clauses encompass the system elements. Each element outlines where procedures need to be documented, where record keeping is required or where actions must be taken. Modules 3-15 are the Good Agriculture, Aquaculture, Manufacturing and Distribution Practices (GAP/GMP/GDP) requirements applicable to various food industry sectors. Producers and suppliers must meet the requirements of the module or modules applicable to their food industry sector. Module 16 describes the requirements of the SQF multi-site programs managed by a central site.

The three appendices in the SQF Code provide additional information needed to implement an SQF System:

o   Appendix 1: SQF Food Sector Categories

o   Appendix 2: Glossary of Terms

o   Appendix 3: SQF Quality Shield and Logo Rules of Use

Section 2. The SQF Certification Process

The steps for the process of preparing for SQF certification are shown below. Optional steps or other options are indicated in parenthesis. This process is outlined in section 1 of Part A of the SQF Code, edition 7.

Step 1
- Learn about the SQF Code
- (SQF Implementation Training)

Step 2
- Select the relevant SQF modules

Step 3
- Register in the SQF assessment database

Step 4
- Designate an SQF practitioner

Step 5
- Select the certification level - 1, 2, 3

Step 6
- Document and implement the SQF Code

Step 7
- Select a certification body

Step 8
- (Conduct a pre-assessment audit)
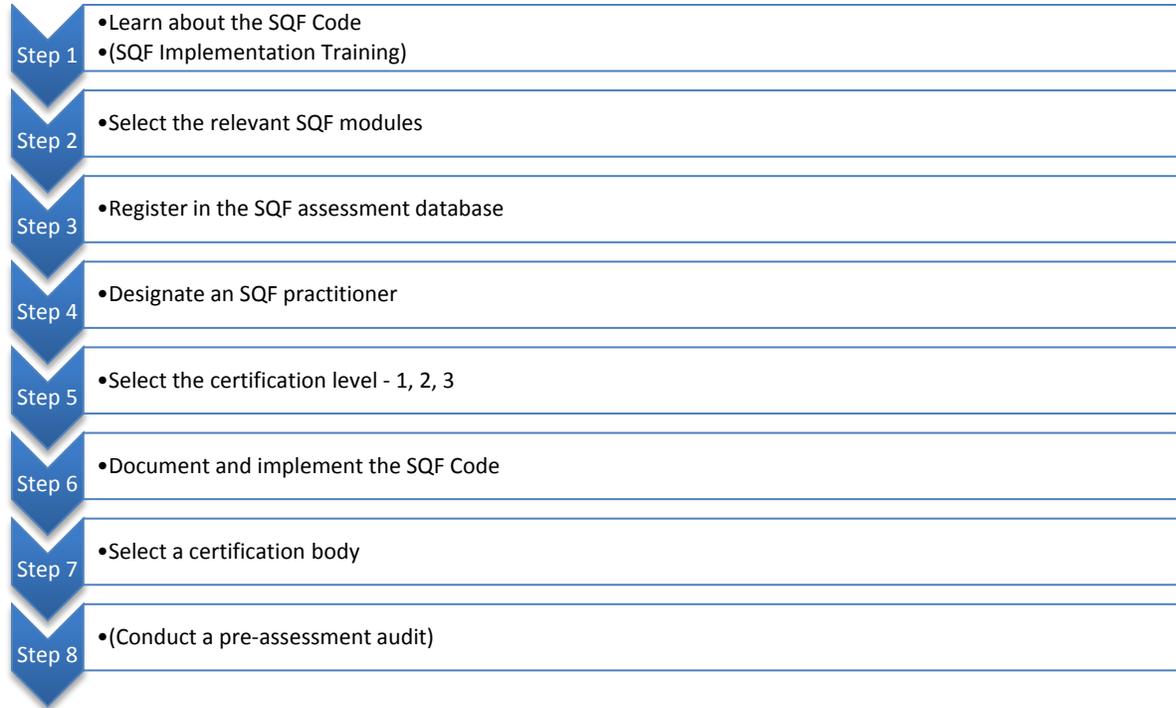
The first step is for the supplier to learn about the SQF Code. The SQF Code suggests several options for doing this, including completing an "Implementing SQF Systems" training course either online or through a licensed SQF training center. Be sure to download the SQF Code, available free of charge from the SQFI website (sqfi.com).

In step 2, select the relevant modules to be implemented by the supplier. To aid in doing this, Table 1 SQF Food Sector Categories and Applicable Modules and Appendix 1: Food Sector Categories are available in the SQF Code for reference. Keep in mind that certification to the SQF Code is site and product specific.

Please note that module 2 is applicable to all industry sectors and will need to be implemented by all suppliers.

The third step is to register the supplier's company or site in the SQF assessment database. For new users, the registration link is housed on the SQFI website (sqfi.com). Choose the "Suppliers" tab from the home page, and then select "New Users." Suppliers must register with SQFI prior to achieving certification and must remain registered at all times to retain their certification.

In step four, the supplier will need to designate an SQF practitioner to oversee the development, implementation, review and maintenance of the SQF System. The requirements for an SQF practitioner are described in elements 2.1.2.4 and 2.1.2.5 in module 2 of the SQF Code.

The fifth step is for the supplier to select a certification level – 1, 2 or 3 based on the needs of customers and the stage of development of the food safety and quality management system.

At the sixth step, the supplier must document and implement the relevant modules of the SQF Code in their SQF System. This step will be explained further in the next section.

In step seven, the supplier will choose a certification body. Certification bodies are licensed by SQFI to conduct SQF audits and issue the SQF certificate. A current list of licensed certification bodies is

available on the SQF website (sqfi.com) and includes their countries of operation. Certification bodies are also listed on the SQF assessment database and suppliers can request a quote or select a certification body online once they have registered.

In the final step, the supplier may wish to conduct a pre-assessment of their systems, procedures and protocols already in place to determine existing gaps requiring action in order to reach the level of SQF certification desired. This assessment, while voluntary is essential to the development of the SQF System and may be conducted by a consultant, a certification body or by the supplier's staff under direction of an SQF practitioner.

Section 3. The SQF Implementation Process

To achieve SQF certification, the supplier must document and implement the relevant modules of the SQF Code, at the level required. It's also important to provide evidence of the System in the form of documents and records. The implementation process is shown below.
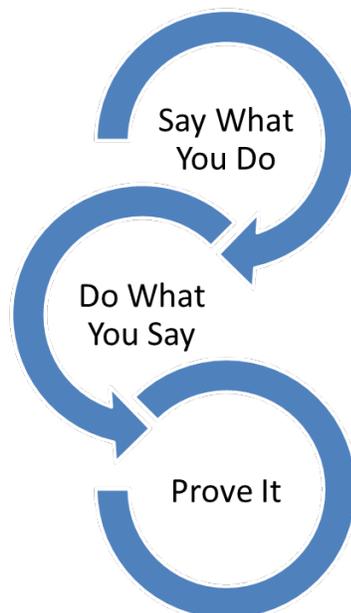
Document the SQF System – prepare policies, procedures, work instructions and specifications that address the relevant modules of the SQF Code. In other words "say what you do."

Implement the SQF System – put into place the prepared policies, procedures, work instructions and specifications. In other words, "do what you say."

Provide records the SQF System – keep records to demonstrate compliance to the relevant modules of the SQF Code. These records provide evidence of the function and control of the System. In other words, "prove it."

Section 4. Introduction to this Guide

1.   Purpose and Scope of this Guide

The purpose of this series of SQF Guidance Documents is to assist suppliers with designing, developing, documenting, implementing and maintaining an SQF System using the SQF Code, edition 7, and to assist SQF registered auditors in auditing the SQF Code, edition 7.

The relevant Code version number is identified in the document header. Terms used in this document are defined in Appendix 2: Glossary of the SQF Code, edition 7.

This particular guide covers the requirements of *Module 2: SQF System Elements.* All suppliers seeking certification to the SQF Code, edition 7 must document, implement and maintain module 2 of the SQF Code, irrespective of their industry sector.

Guidance is intended to support the SQF Code, but does not replace it. It is not an auditable document, nor is it definitive and applicable in every situation. Suppliers, consultants, and auditors are required to understand the food safety (and quality, where applicable) risks in a given industry sector and are able to apply the SQF Code to effectively control those risks.

Module 2 can be applied at any one of three levels:

SQF Level 1 – Food Safety Fundamentals

Level 1 is an entry level for new and developing businesses that requires the supplier to demonstrate how their operations comply with relevant food safety legislation, and to apply those fundamental food safety controls are essential to providing a sound foundation for the growth, production or facilitation of a safe product. Level 1 requirements are located in the far left-hand column in module 2 of the SQF Code, edition 7.

SQF Level 2 – Food Safety Plan

Level 2 incorporates all Level 1 requirements, but also requires the supplier to first, identify hazards that can impact product safety; second, conduct a food safety hazard analysis of the product (s) and its process (es); and third, identify actions to eliminate, prevent or reduce identified hazards to an acceptable level. These steps must be achieved using an approved HACCP methodology (refer to section 2, below). Level 2 requirements are found in the center column in module 2 of the SQF Code, edition 7.

SQF Level 3 – Food Quality Plan

Level 3 incorporates all Level 1 and Level 2 System requirements. At this level, the supplier is also required to use and approved HACCP methodology to identify and assess food quality hazards and document the action (s) taken to eliminate, reduce or prevent their occurrence. Quality hazards and their controls can be included in the same HACCP study as performed for food safety hazards, or can be documented separately. However, if incorporated food safety hazards and their controls must be clearly distinguished from food quality hazards.

The HACCP methodology must be used to identify and control quality to achieve Level 3 certification.

Level 3 requirements are found in the right hand column in Module 2 of the SQF Code, edition 7.

This guide focuses on the requirements for Level 3 implementation of the SQF Code, edition 7.

2.   The Structure of the SQF Code, Edition 7

The SQF Code is a process and product certification standard that uses Hazard Analysis Critical Control Points (HACCP) as its foundation. HACCP is a food safety management system based on the principles defined in either:

- The CODEX Alimentarius Commission HACCP principles and guidelines, or
- The National Advisory Committee on Microbiological Criteria for Food (NACMCF)

The main feature of the SQF Code is its emphasis on the systematic application of HACCP to identify, monitor and control food safety hazards as well as food quality hazards in the process flow to manage identified food safety risks and/or quality threats.

This guide references the HACCP (Hazard Analysis and Critical Control Point) technique but does not explain the HACCP method in any detail. It requires that those implementing and auditing an SQF System to have completed HACCP training as defined in *Appendix 2: Glossary* of the SQF Code, edition 7 and have extensive knowledge of the HACCP guidelines of either of the above documents, the application of the HACCP principles and experience in implementing HACCP systems. It is not meant to deliver prescribed, absolute rules for implementation, but to be utilized by suppliers, SQF consultants and SQF auditors as recommendations on practical applications for implementation and certification of the SQF Code.

3.   The Structure of an SQF System

An SQF System is a risk management system documented and implemented by a supplier of food (or related) products to control food safety risks (and food quality risks at Level 3) using the SQF Code, edition 7. It can be audited and certified by an SQF licensed certification body.

The process of how to document and implement the SQF Code, edition 7 and achieve SQF certification can be found in the most current version of Part A of the SQF Code, edition 7.

Module 2 defines the core elements of the SQF Code that provide protection and assurance and are required to be implemented by all suppliers seeking SQF certification. It forms the foundation of the supplier's SQF System. It includes the commitment of site management to maintain a safe, quality food supply and the management processes that must be in place to do so; the HACCP plan(s) that identify and control hazards; the HACCP food quality plan (s) that identifies quality threats and defines their control; product traceability and recall; control of foods containing allergens and other foods requiring identity preservation; and staff training requirements.

It also points to the industry specific pre-requisite programs that are found in modules 3 through 15 of the SQF Code. Module 2 must be paired with implementation of the relevant GAP/GMP/GDP module for SQF Certification to occur.

The elements of Module 2 that the supplier must address in their SQF System are as follows:

2.1 Management Commitment

2.2 Document Control and Records

2.3 Specification and Product Development

2.4 Attaining Food Safety (and Food Quality at level 3)

2.5 SQF System Verification

2.6 Product Identification, Trace, Withdrawal and Recall

2.7 Site Security

2.8 Identity Preserved Foods (including food containing known allergens)

2.9 Training

4. Module 2 Mandatory Elements

The SQF Code recognizes that every business is different and that some SQF System Elements may not apply to some food businesses. However, it is expected that the majority of the elements of module 2 apply to the majority of food businesses, and where they are applicable, must be documented and implemented.

A number of the elements in module 2 are indicated as "mandatory" and must be implemented and audited for certification to be granted. During an SQF audit, these elements cannot be reported as "not applicable" or "exempt" by the auditor. They are marked with an (M) in the heading of the clause. The mandatory elements are listed in Part A, 2.9 of the SQF Code, edition 7 and are as follows:

2.1.1 Management Policy

2.1.2 Management Responsibility

2.1.3 Food Safety and Quality Management System

2.1.4 Management Review

2.2.1 Document Control

2.2.2 Records

2.4.1 Food Legislation

2.4.2 Food Safety Fundamentals

2.4.3 Food Safety Plan (at Level 2, 3)

2.4.4.1 Food Quality Plan (at Level 3)

2.4.8 Product Release

2.5.2 Validation and Effectiveness

2.5.4 Verification and Monitoring

2.5.5 Corrective and Preventative Action

2.5.7 Internal Audit

2.6.1 Product Identification

2.6.2 Product Trace

2.6.3 Product Withdrawal and Recall

2.7.1 Food Defense

2.9.2 Training Program

Suppliers should not consider the mandatory elements as the only elements to be implemented. All applicable elements within module 2 must be implemented and will be audited. For example, allergen management is not considered to be a mandatory element because some low risk food businesses do not have an allergen risk. However, every facility that does have an allergen risk must have an allergen management program that meets 2.8.2, and will be audited against that element.

5.   Format of the Module 2 Guidance

The following section explains the elements and sub-elements of the SQF Code, edition 7 at Level 3 and provides guidance on what a supplier needs to do to develop, document and implement an SQF System at this level, and provides information on what the auditor may be looking for to confirm compliance.

The following format is used throughout:

Element Number and Name

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

This section will describe what the SQF Code, edition 7 requires at Level 3. 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
What does it mean?   This will include the interpretative comments of what the sub-element requires or definitions of the terms used.   **What do I have to do?**   This will include suggestions of what is required to be done by the supplier 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.

Auditing Guidance
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.

Section 5. Module 2: SQF Systems Elements

"Food" can also be taken to mean "feed," "pet food," or "food contact packaging materials." "Food safety" can be taken to mean "feed safety," or "pet food safety." "Food safety plan" can be taken to mean "feed safety plan" or "pet food safety plan" and "food quality plan" can also mean "feed quality plan," or "pet food quality plan."

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 facility that encourages a pro-active attitude amongst staff towards food safety and (at Level 3) quality.

The requirements detailed in 2.1 provide an important measure of the level of leadership within the supplier's facility.

2.1.1   Management Policy (M)

What the SQF Code says

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

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

2.1.1.2 The policy statement shall be:

  i.   Signed by senior 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 and quality.

"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 and quality manual (refer 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 and/or quality responsibility under the SQF System;

  • outlines how the supplier will achieve and maintain food safety and quality;

  • 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 during the first and subsequent facility 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 and quality objectives; reviewing food safety and quality objectives on a regular (at least annual) basis; and continually improving their SQF food safety and quality management System.

- The currency of the policy statement.

- The availability of the policy statement to all staff within the facility. This includes confirming employee understanding of the policy statement.

- Food safety and quality objectives are established and realistic.

- Activities within the facility meet regulatory and customer expectations.

- Activities within the facility reflect established food safety and quality objectives. The auditor may seek company food safety meeting minutes and check if management participated in these meetings.

- The policy statement, including food safety and quality 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 (M)

What the SQF Code says

2.1.2.1 The organizational reporting structure describing those who have responsibility for food safety and quality and their interrelationship shall be defined and communicated within the organization.

2.1.2.2 The senior management shall make provision to ensure fundamental food safety and quality practices are adopted and maintained.

2.1.2.3 The senior management shall ensure adequate resources are available to achieve food safety and quality objectives and to support the development, implementation and maintenance and ongoing improvement of the SQF System.

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

i.   Oversee the development, implementation, review and maintenance of the SQF System, including food safety fundamentals outlined in 2.4.2, the food safety plan outlined in 2.4.3 and the food quality plan outlined in 2.4.4;

ii.   Take appropriate action to maintain the integrity of the SQF System; and

iii. 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:

i.   Be employed by the supplier as a company employee on a full-time basis;

ii.   Hold a position of responsibility in relation to the management of the supplier's SQF System;

iii. Have completed a HACCP training course;

iv.   Be competent to implement and maintain HACCP based food safety plans and food quality plans; and

v.   Have an understanding of the SQF Code Level 3 and the requirements to implement and maintain SQF System relevant to the supplier scope of certification.

2.1.2.6 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 product, legality, safety, and quality shall be defined and documented.

2.1.2.7 All staff shall be informed of their responsibility to report food safety and quality problems to personnel with authority to initiate action.

2.1.2.8 Job descriptions for those responsible for food safety and quality shall be documented and include provision to cover for the absence of key personnel.

2.1.2.9 The senior management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.

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 and food safety and quality objectives, are available. Resources are often scarce in many organizations. Regardless, management must demonstrate that employees understand their responsibility for food safety and quality 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 supplier's facility, each employee will know his/her role in assuring food safety, quality 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 and quality objectives.

This element also includes the requirements for, and responsibilities of, the SQF practitioner. This is a key role within the supplier's facility, being the person designated by senior management to manage the development, implementation, daily operation, validation and verification of the SQF System.

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 quality. The organisational structure provides a snapshot of how these positions interact and share that responsibility.

Senior management must convey this to every employee. This will be written into job descriptions for all roles within the facility that impact food safety and quality. 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 and quality problems to personnel with the authority to initiate actions.

Senior management must also document how they will provide resources to achieve food safety and quality objectives. 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 and Quality 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 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.

The commitment of management to ensuring that employees are trained and assessed as competent to carry out job functions pertaining to food safety and quality must be documented. The job descriptions must reflect the competencies required of each employee to carry out their food safety and quality responsibilities and the training that is necessary to assure those competencies (refer 2.9).

Also, management must be able to demonstrate that the goal is not simply to achieve SQF Certification, but that they have processes in place to continuously improve their food safety and quality processes (refer 2.1.4). They must have measures in place to monitor the effectiveness of their SQF System and have programs and activities in place to improve the outcomes. Measures may include, but are not limited to:

- customer complaints (2.1.5),
- audit results (2.5.7),
- product analysis (2.5.6),
- corrective actions (2.5.5), and
- product withdrawal and recall (2.6.3).

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 facility 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 shall be confirmed at each facility 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 quality, and their interrelationship, and is agreed by senior management.

- Job descriptions are in place for positions within the supplier's facility that have responsibility for food safety and quality. 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 and quality objectives and the requirements of the SQF System. This includes coverage for all operational shifts and absences.

- Employees within the facility with responsibility for food safety and quality 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 quality 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 facility's programs.

- There is a designated SQF practitioner who manages the implementation and maintenance of the SQF System 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 take appropriate corrective actions when necessary; and communicates to relevant employees any information necessary to maintain or improve the System.

- Senior management has processes in place to measure the effective implementation of the SQF System and initiate, resource and review improvement programs.

2.1.3   Food Safety and Quality Management System (M)

What the SQF Code says

2.1.3.1 A food safety and quality manual shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the organization will use to meet the requirements of this standard, be made available to staff and include:

   i.   A summary of the organization's food safety and quality policies and the methods it will apply to meet the requirements of this standard;

   ii. The policy statement and organization chart;

   iii. The scope of the certification; and

   iv. A list of the products covered under the scope of certification.

2.1.3.2 A food safety manual shall be documented, maintained, made available to relevant staff and include or reference the written procedures, pre-requisite programs, food safety plans and other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

2.1.3.3 A quality manual shall be documented, maintained, made available to relevant staff and include or reference the written procedures, standard operating practices, work instructions, and food quality plans and other documentation necessary to support the development and the implementation, maintenance and control of the SQF System. The quality manual may be combined and integrated with the food safety manual.

2.1.3   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 and quality manual is the documented system ("saying what you do") that must be implemented ("doing what you say").

The food safety and quality manual must be practical, usable, and available to all employees with a responsibility for food safety and quality. It can be stored electronically or in hard copy, and the currency and security of the manual must be controlled (refer 2.2.1). The form and structure of the manual is determined entirely by the supplier. 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 supplier must prepare a food safety and quality manual that documents the policies, procedures, pre-requisite programs, Food Safety and Quality Plan(s), specifications and work instructions necessary to support the development, implementation, maintenance and control of the SQF System.

The manual will include the company policy statement and an organizational chart. It will include the HACCP Food Safety Plan(s) (refer 2.4.3) for all products included in the supplier's scope of certification. It will also include, at Level 3, the HACCP Food Quality Plan (s) (refer 2.4.4) for all products included in the supplier's scope of certification.

There is no prescribed format for how the manual (s) is/are to be constructed. Format is determined by the supplier. It can be divided into a policy manual, food safety manual and quality 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 supplier'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.

2.1.3   Auditing Guidance

The food safety and quality 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 facility 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 facility audit. The auditor shall review changes and conduct checks of the documentation, including specifications or procedures that may impact on food safety and quality. The content of Food Safety Plans and Food Quality 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 2.1.1) and organizational structure and job descriptions (refer 2.1.2)

- The manual includes a summary of the supplier's food safety and quality 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 supplier's scope of certification.

- The manual includes specifications for all products included within the supplier's scope of certification.

- The manual includes the HACCP Food Safety Plan(s) for all products included in the supplier's scope of certification, and at Level 3, the HACCP Food Quality Plan(s) for all products included in the supplier's scope of certification.

- The manual is current, concise, available, and usable by employees within the supplier's facility.

2.1.4   Management Review (M)

What the SQF Code says

2.1.4.1 The senior 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; and
  iv.   Customer complaints and their resolution and investigation.

2.1.4.2 The SQF System in its entirety shall be reviewed at least annually.

2.1.4.3 Food safety fundamentals, food safety plans and food quality plans shall be reviewed when any changes implemented have an impact on the supplier's ability to deliver safe, quality food.

2.1.4.4 Changes to food safety fundamentals and food safety plans and food quality plans that have an impact on the supplier's ability to deliver safe, quality food are to be validated.

2.1.4.5 Records of all reviews and reasons for amending documents, validations and changes to the SQF System shall be maintained.

2.1.4   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 and/or quality. 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.

Ideally, the SQF System is reviewed on a regular basis as part of a management review of all operational activities. However at a minimum, a full review of the SQF System must be completed annually by senior management.

What do I have to do?

This element is mandatory. Senior management must ensure the entire SQF System is reviewed. This should be conducted on a regular basis, however as an absolute minimum, annually. This review 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 and quality manual. The review must be conducted by senior management with the objective of ensuring the continued integrity of the food safety and quality management system.

The review shall measure the effectiveness of the SQF System against the food safety and quality 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) and Food Quality 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 quality food shall trigger a review of the Food Safety Plan and/or the Food Quality Plan in addition to the annual review. Any major changes to Food Safety or Quality Plans shall be validated and verified before implementation.

2.1.4   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 and quality manual.

- The extent to which changes in materials, process or products have been validated.

- Records of product and process changes and their validation.

2.1.5   Complaint Management

What the SQF Code says

2.1.5.1 The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities shall be documented and implemented.

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

2.1.5.3 Corrective action shall be implemented commensurate with the seriousness of the incident and as outlined under 2.5.5.

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

2.1.5   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 supplier 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, edition 7 requires the supplier 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 suppliers NOT to have any customer complaints.

The supplier 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.

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.

2.1.5   Auditing Guidance

Customer complaints may be the first record that an auditor asks to review when beginning the facility audit. 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 facility 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 2.5.5);

- Investigation of the interface between a corporate reporting function and facility knowledge and investigation of customer complaints (where applicable);

- Investigation of outcomes of corrective actions taken as a result of customer complaint investigations (refer 2.5.5).

2.1.6   Business Continuity Planning

What the SQF Code says

2.1.6.1 A business continuity plan based on the understanding of known threats to a business shall be prepared by senior management outlining the methods and responsibility the organization will implement to cope with a business crisis that may impact on the ability of the supplier to deliver safe, quality food.

2.1.6.2 The business continuity 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 to a crisis does not compromise product safety and quality;
   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;
   vii. Sources of legal and expert advice; and
   viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

2.1.6.3 The business continuity plan shall be reviewed, tested and verified at least annually.

2.1.6.4 Records of reviews and verification of the business continuity plan shall be maintained.

2.1.6   Implementation Guidance

What does it mean?

A "business continuity plan" is often confused with a "product withdrawal and recall plan" (2.6.3). They are two separate functions and programs. A business continuity plan is a crisis management plan that 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, quality 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 and quality limits, is distributed and has to be recovered from the market (refer 2.6.3).

For some smaller suppliers, the business continuity 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, quality food supply.

What do I have to do?

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, quality 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 and quality 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 business continuity 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 business continuity 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.

2.1.6   Auditing Guidance

The business continuity 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 facility 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 business continuity plan is in place and has been tested at least annually;

- The business continuity 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 business continuity plan includes identification of the individual (s) responsible for communication, including communication within the facility;
>
> - Where the annual review of the business continuity plan has identified non-compliances or areas requiring improvements, corrective actions (refer 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   Document Control (M)

What the SQF Code says

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

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

2.2.1.3 Documents shall be safely stored and readily accessible.

2.2.1   Implementation Guidance

What does it mean?

This element relates back to *2.1.3 Food Safety and Quality Management System*. All management system documents (e.g., policies, procedures, specifications, food safety plans, food quality 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, food quality 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.

2.2.1   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.

2.2.2   Records (M)

What the SQF Code says

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

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

2.2.2.3 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.

2.2.2   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 so as to not be 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.

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 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 supplier 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 and quality 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 and quality records sign and date each record they review as part of their verification activities (refer 2.5.4). These responsibilities and actions must be documented in the procedure.

Electronic records are acceptable. The supplier must have the means to manage electronic security of records, electronic signatures of monitors and reviewers and the means for electronic review.

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, suppliers must retain records beyond the next recertification audit, as a minimum.

2.2.2   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 facility 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 monitor critical control points and other activities necessary to maintain food safety and quality, 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.

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 facility 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 and food quality 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 or quality.

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 and quality of products escalated from bench/pilot scale production to full commercial production. This will include a food safety and quality 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 facility 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.

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 or food quality risks associated with new conditions. These risks must be assessed, and adjustments made to food safety and food quality plans prior to implementation.

Any adjustments to food safety or food quality plans 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 facility 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, food quality 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 and quality shall be documented and kept current.
2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation.
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 and quality is not compromised and the material is fit for its intended purpose. Validation of raw materials and ingredients shall include certificate of conformance; or certificate of analysis; or sampling and testing.

2.3.2.5 Validation 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 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?

This element links with *2.4.5 Incoming Goods and Services.* Before an approved supplier program can be implemented, specifications must be in place for all materials that could impact product safety and quality. This relates to raw materials, ingredients, packaging materials, processing aids, additives and chemicals used within their facility including cleaning compounds. The supplier 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 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 and the food safety risk to the finished product.

Quality related detail included in material specifications could include information such as color, grade, nutritional data, size, weight, type of packaging, etc. Quality requirements may be determined by customers.

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 and quality are identified and controlled. Raw and packaging materials should be included in the HACCP Food Safety Plan (refer 2.4.3) and Food Quality Plan (refer 2.4.4) 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 and quality 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 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, allergen declarations, and in particular, in-country labelling requirements (refer also 2.4.1).

All current specifications for materials that could impact food safety and quality 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 facility 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 also 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 quality 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 finished product safety and quality shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of contract personnel.

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

2.3.3   Implementation Guidance

What does it mean?

Many duties within the food production or processing facility 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 or quality, but could still indirectly affect the product or facility. For example, construction engineers may not have direct contact with food manufacturing, but their work and presence in a food handling facility can indirectly impact food safety and quality.

This element of the Code addresses how the services from these outside organizations are controlled monitored and verified to ensure that food safety and product quality 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 and quality 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 facility 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, quality and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.

2.3.4.2 The supplier shall:

i. Verify compliance with the SQF Code 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 supplier or other third party agency to confirm compliance to the SQF Code and agreed arrangements; and

ii. 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?

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 facility. In other cases, a contract manufacturer may only be used intermittently to fulfill or supplement the supplier's production.

Whatever the situation, any contract facility 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 contact manufacturer meets their customer specifications and the requirements of the SQF Code. Control of the food safety and quality management system in an external facility 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, food quality plans and all other food safety and quality 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 facility 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 facility, the auditor may require a visit to that facility to confirm compliance to the Code and the agreed arrangements.

2.3.5   Finished Product

What the SQF Code says

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

 i.   Microbiological and chemical limits;
 ii.   Labeling and packaging requirements; and
 iii. Product quality attributes.

2.3.5.2 A register of finished product specifications shall be maintained.

2.3.5   Implementation Guidance

What does it mean?

A written finished product specification must be provided for all products covered under the supplier'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 supplier 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 supplier 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 must be updated as required. The supplier 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.) and the packaging specifications for the product.

The supplier needs to ensure that the annual review of the SQF System (refer 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 will normally provide finished product specifications and if this is the case, it is advisable that both the supplier and their customers agree the specification is achievable and agree on the quality and safety attributes of the product to be supplied. For stock items that are not customer specific, the supplier 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 and quality manual, and will initially be reviewed at the desk audit. At each facility audit, the auditor will ensure that all specifications exist for all products included in the scope of certification and that the facility 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 and quality of the product;

- Current versions of specifications are available to all relevant staff;

- The supplier has methods and criteria for sampling and testing finished product (refer 2.5.6) to ensure compliance with finished product specifications;

- The supplier has processes in place to ensure that product released (refer 2.4.8) meets specifications;

- Specifications are reviewed as part of the management review process (refer 2.1.4.2).

2.4   Attaining Food Safety

2.4.1   Food Legislation (Regulation) (M)

What the SQF Code says

2.4.1.1 The organization 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 its origin and destination. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, trade weights and measures, packaging, product description, nutritional, allergen and additive labeling, and to relevant established Industry codes of practice.

2.4.1.2 The methods and responsibility for ensuring the organization is kept informed of changes to relevant legislation, scientific and technical developments 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 24 hours upon identification of a food safety event that requires public notification (e.g. receipt of a regulatory warning letter).

2.4.1   Implementation Guidance

What does it mean?

Food legislation (regulations) always applies and underpins the SQF Code. Suppliers MUST meet all applicable food regulations in the country, state, or region that the product is processed (i.e., where the supplier's facility 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, 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 supplier is required to know and keep up-to-date with all applicable legislation. A larger supplier may employ a regulatory affairs person with that responsibility. For a smaller supplier, 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 supplier 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 supplier 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 2.3.5) and be tested for (refer 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, allergen declarations and in particular, in-country labeling requirements (refer2.3.2).

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 supplier must ensure compliance and be able to cite registration/approval documentation.

It is important to note here that where a supplier 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 (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 facility audit. Evidence may include:

- Review of the procedure to maintain and update legislative requirements;

- Applicable legislative requirements have been incorporated into specifications (refer 2.3.2, 2.3.5);

- Applicable legislative requirements are being applied and being inspected and/or tested (refer 2.5.6);

- Compliance with legislation is checked as part of internal audits (refer 2.5.7) and the management review (refer 2.1.4.2).

- Confirmation that SQFI and the Certification Body have been notified in writing in the event of a food safety incident requiring public notification.

2.4.2 Food Safety Fundamentals (M)

What the SQF Code says

2.4.2.1 The property, buildings and equipment shall be located, constructed, designed and maintained to facilitate the hygienic production, manufacture, handling, storage and/or delivery of safe, quality food.

2.4.2.2 The supplier shall ensure the food safety fundamentals described in the relevant subsequent modules of this Code (i.e. modules 3 through 15) are applied, or exempted according to a risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that food safety and quality are not compromised.

2.4.2.3 Those pre-requisite programs applicable to the scope of certification that outline the means by which food safety is controlled and assured shall be documented and implemented.

2.4.2.4 The effectiveness of the pre-requisite programs shall be verified as described in 2.5.4.

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, quality 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 facility 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;

- 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 (M)

What the SQF Code says

2.4.3.1 A food safety plan shall be developed, effectively implemented, and maintained and outline the means by which the organization controls and assures food safety. The food safety plan shall:

i.   Be prepared in accordance with the steps identified in the Codex Alimentarius Commission or NACMCF HACCP guidelines. Primary producers and feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

ii.   Cover a product or product group and the associated processes.

iii.   Describe the methodology and results of a hazard analysis conducted to identify food safety hazards associated with all inputs and process steps including rework. Animal feed and pet food safety plans must include hazards associated with animal safety as well as the safety of consumers of animal products.

iv.   Prescribe those measures taken to apply the controls implemented that are critical to assuring, monitoring and maintaining food safety.

v.   Process controls at control points in production to monitor product safety, identify when a process is deviating from set parameters and make corrections to keep a process under control; and

vi.   Include documented Standard Operating Procedures (SOPs) and Work Instructions (WI) applicable to the organization's scope of certification.

2.4.3   Implementation Guidance

What does it mean?

The HACCP Food Safety Plan is the foundation of the supplier's SQF System. The Food Safety Plan (FSP) 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. Either the Codex or NACMCF HACCP model can 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 supplier, meaning the supplier 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 supplier must be, in the words of the GFSI Guidance Document, sixth edition "systematic, comprehensive, and thorough."

There are two elements only in module 2 where primary producers are separated out and dealt with independently. One is 2.4.3.1 i and the other is 2.4.6.1 iv. SQFI allows for HACCP plans for primary producers to be based on templates prepared by trade organizations, regulators, buyers or other responsible authority. Where a template is used, the HACCP plan must still be adapted or customized to suit the supplier's business. This only applies to primary

producers. All other businesses must fully develop and implement their own HACCP systems.

What do I have to do?

This element is mandatory. The supplier must develop and fully implement a Food Safety Plan using the Codex or NACMCF 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 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 product specifications (refer 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 supplier 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.

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 may be, 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 2.5.2), 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 2.5.5). 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 manual (refer 2.1.3.1) and controlled as per 2.2.1. Records of monitoring, corrective actions and verification activities must be secured and retained according to 2.2.2.

The HACCP Plan is not a static document. Critical limits must be re-validated at least annually (refer 2.5.2.1 v) by the SQF practitioner, and the entire 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 2.1.4.3).

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 supplier'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 facility 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;

- 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 2.5.5);

- The corrective action procedure has been followed when monitoring shows deviation from critical limits (refer 2.5.5);

- 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 2.1.2.4 i).

2.4.4   Food Quality Plan

What the SQF Code says

2.4.4.1 **(M)**   A food quality plan shall be developed, effectively implemented, and maintained in accordance with the HACCP method to outline the means by which the organization controls and assures food quality and legality. The food quality plan shall:

i.   Outline the results of a food quality risk analysis conducted to identify threats to achieving and maintaining product and process quality.

ii.   Prescribe those measures taken to apply the controls implemented that are critical to assuring, monitoring and maintaining food quality.

iii.   Include process controls at quality points in production to monitor product quality, identify when a process is deviating from set parameters and make corrections to keep a process under control;

iv.   Cover a food or food group and the associated processes; and

v.   Include documented Standard Operating Procedures (SOPs) and Work Instructions (WI) applicable to the organizations scope of certification.

2.4.4.2 Use of the SQF quality shield shall follows the requirements outlined in Appendix 3: SQF Quality Shield and Logo Rules of Use.

2.4.4   Implementation Guidance

What does it mean?

The SQF Code, edition 7 requires at Level 3, that the HACCP method be used to identify and control quality hazards as well as food safety hazards. Thus a HACCP Plan must be developed using the Codex or NACMCF method that identifies all food quality hazards, conducts a hazard analysis and implements measures to control identified quality hazards.

It is important to note that, for Level 3 certification, ALL quality hazards must be controlled using the HACCP method. Food quality hazards may include product weight, product count, size, color, moisture, defects, viscosity, head space, dwell time, batter pick-up, drain weight, free fatty acid concentration, salt level, packaging integrity and coding.

Only suppliers that are certified to Level 3 are allowed to use the SQF quality shield as outlined in the rules of use in Appendix 3 of the SQF Code. Deviation from this policy is only allowed with written permission from SQF.

What do I have to do?

(2.4.4.1 is Mandatory for certification at Level 3)The preparation and implementation of the Food Quality Plan (FQP) follows exactly the same methodology as the Food Safety Plan outlined in 2.4.3, with the following exceptions:

- The Food Quality Plan may be integrated with the Food Safety Plan if desired, as long as food safety hazards and their controls are clearly identified and differentiated from food quality hazards and their controls.

- Steps in the process where quality must be controlled are referred to as Critical Quality Points (CQPs).

- The HACCP team for the FQP may be the same as, or different from, the food safety team.

When using the SQF Quality Shield the supplier must understand the rules of use pertaining the certification number, color, size, and placement on product or marketing materials. If a Level 3 supplier is suspended or withdrawn, the use of the quality shield must cease upon certificate suspension.

2.4.4   Auditing Guidance

The HACCP Food Quality Plan shall be reviewed by the auditor at the initial desk audit to ensure all products within the scope are covered, all potential quality hazards are identified, and the HACCP implementation steps have been followed. The HACCP Food Quality Plan, plus changes to the HACCP plan, shall be reviewed in full at every subsequent facility 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 team 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 quality 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 quality 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;

- CQPs are correctly identified using a valid methodology;

- Critical quality limits are in place for every CQP, and are validated to ensure consistent product safety;

- All critical quality 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 poor quality product and action required to prevent recurrence (refer 2.5.5);

- The corrective action procedure has been followed when monitoring shows deviation from critical quality limits (refer 2.5.5);

- Staff with responsibility for monitoring, validation, verification of critical quality limits are aware of their responsibility, trained, and are carrying out their functions correctly;

The SQF practitioner ensures that the Food Quality Plan is effectively developed, implemented, maintained and verified (refer 2.1.2.4 i).

If the Level 3 facility uses the SQF quality shield then the auditor shall determine if the shield is used within the site according to the rules of use outlined in Appendix 3 of the SQF Code. This would include the use of the quality shield on products, packaging and other marketing materials.

2.4.5   Incoming Goods and Services

What the SQF Code says

2.4.5.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety and quality shall be supplied by an approved supplier.

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

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

2.4.5.4 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;

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 and quality 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.

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

2.4.5   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 and quality 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.

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 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 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 2.1.4.3) 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.

2.4.5   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 facility 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 and quality 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 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 2.1.4).

2.4.6   Non-conforming Product or Equipment

What the SQF Code says

2.4.6.1 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; and

   ii.   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

   iii.   All relevant staff is aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status.

   iv.   For producers, the procedure must document the grower, field name, quantity and final disposition of the unacceptable materials when applicable.

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

2.4.6   Implementation Guidance

What does it mean?

Non-conforming product is product at any stage in the process that does not meet agreed food safety and quality 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 facility that can impact product safety or quality, e.g. cleaning chemicals, processing aids.

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

Included in this element is the second reference to primary producers in module 2 (the other is in element 2.4.3.1 i). Where primary materials are non-conforming, the field name, quantity and final disposition must be recorded.

What do I have to do?

The supplier must document 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 supplier 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 supplier must detail how the condemned product is identified and disposed of.

The supplier 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 supplier 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.

2.4.6   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 facility 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

- Records of finished product testing that is out of microbial specification and how it has been resolved

- Records of product disposition;

- Records of repair of non-conforming equipment.

2.4.7   Product Rework

What the SQF Code says

2.4.7.1 The responsibility and methods outlining how the product is reworked (recycled or recouped) shall be documented and implemented. The methods applied shall ensure:

   i.   Reworking operations are supervised by qualified personnel;

   ii.   Reworked product is clearly identified and traceable;

iii.   Each batch of reworked product is inspected or analyzed as required before release;

iv.   Inspections and analyses shall conform to the requirements for verification outlined in element 2.5.6; and

v.   Release of reworked product shall conform to the requirements outlined in element 2.4.8.

2.4.7.2 Records of all reworking operations shall be maintained.

2.4.7   Implementation Guidance

What does it mean?

The objective of this element is to ensure the products which are reworked or are of the same quality and 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).

If the supplier'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 supplier must document that the product has been reworked or recouped under qualified supervision and under an approved procedure.

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.

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 and quality 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.

2.4.7   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 facility audit. Evidence may include:

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

- Where applicable, procedures and/or work instructions that detail reworking/recouping methods;

- Observation of reworking/recouping operations;

- Interview of operators and supervisors 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.

2.4.8   Product Release (M)

What the SQF Code says

2.4.8.1   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;

   ii.   Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met; and

   iii.   Once sensory analysis and other evaluations are satisfactorily completed to verify customer specifications have been met.

2.4.8.2   Records of all product release shall be maintained.

2.4.8   Implementation Guidance

What does it mean?

A product release program ensures that only compliant products are released to the market. The supplier must prepare a procedure outlining the responsibility and protocols for the release of products and effectively implement that procedure. At Level 3, this includes compliance with quality, including sensory, requirements.

Product release also applies to the procedures for releasing quarantined or held product (refer 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 supplier may do this by outlining in-line process measures that demonstrate that products are compliant with specified requirements. In this procedure, the supplier 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, the supplier must also outline the procedure for releasing products from quarantine or hold status.

In all cases, the supplier 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 supplier 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, confirmation of product checks, and the product disposition (e.g., release, quarantine, hold).

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.

2.4.8   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 facility 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.

2.4.9 Stock Rotation

What the SQF Code says

2.4.9.1 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

2.4.9.2 Procedures are in place to ensure that all ingredients, materials, work-in-progress, and finished product are utilized within their designated shelf-life.

2.4.9   Implementation Guidance

What does it mean?

This element is about how stock is controlled to ensure materials, ingredients, work in progress, and finished product does not get lost in the process and exceed its shelf life. It is dependent on an effective product identification system (refer 2.6.1).

What do I have to do?

The supplier must implement a stock rotation program and document that program in a written procedure. The position responsible for implementing and maintaining the program must be clearly defined and the procedure effectively implemented.

The program must meet the customer's needs as well as the requirements of the supplier.

The control of stock is not necessarily as simple as "first in, first out" (FIFO). The program must be designed to manage product shelf life and codes based on customer specifications, conditions of the product, storage locations and inventory management. The criteria that determine when products are not to follow the FIFO process should be defined so that proper stock rotation can be achieved by the facility.

2.4.9   Auditing Guidance

The stock rotation procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview and review of records at each facility audit. Evidence may include:

- 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.

2.5   SQF System Verification

2.5.1   Responsibility, Frequency, and Methods

What the SQF Code says

2.5.1.1   Validation and verification activities shall be conducted.

2.5.1.2   The frequency and methods used to validate and verify food safety fundamentals, critical limits, and other food safety and quality controls identified in food safety plans and food quality plans shall be documented and implemented and meet their intended purpose.

2.5.1.3   Records of all verification activities shall be maintained.

2.5.1   Implementation Guidance

What does it mean?

Definitions of validation and verification differ slightly from standard to standard. The GFSI Guidance Document version 6.2 defines validation as "an activity to obtain evidence that a requirement is controlled effectively" and verification as "a confirmation through the review of effective evidence that requirements have been fulfilled." SQF uses the Codex definition. In other words, validation applies to scientific authentication that the critical limits set for each CCP and CQP will achieve the intended results (refer 2.5.2). Verification applies to the entire SQF System and includes methods such as sampling, internal audit and re-validation to demonstrate that the SQF System is working and is effective.

What do I have to do?

The SQF practitioner is responsible for ensuring that all validation and verification activities are carried out. The SQF practitioner may utilize internal or external resources to conduct these activities, but takes responsibility for ensuring they are carried out.

Examples of verification activities shall include review of inspection records to ensure all monitoring tasks are completed at the frequency that is defined, ensuring that internal audits occur at the frequency defined, ensuring corrective and preventative actions are effectively implemented and product testing.

Examples of validation shall include studies to prove the effectiveness of critical limits. Examples could be reviewing product temperature on a scheduled thermal process, microbiological testing of product to ensure desired reduction of product rinse system and product quality panel reviews for finished product.

The SQF practitioner is responsible for establishing a frequency schedule and methods for validating and verifying all parts of the supplier's SQF System. An SQF consultant may be utilized by the facility to aid in verification activities, however ultimate responsibility for verification and validation must belong to the supplier management and the SQF practitioner.

Results of validation and verification activities shall provide input into the management review (2.1.4) and shall be used to upgrade the food safety and quality management system (2.1.3).

2.5.1   Auditing Guidance

Validation and verification 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 and verification activities and review of records at each facility audit. Evidence may include:

- The SQF practitioner understands the need for validation and verification activities and is competent to organize, or supervise validation and verification activities;

- There are adequate competent resources available to carry out validation and verification activities;

- A validation and verification procedure has been prepared (refer 2.5.3);

- The procedure indicates the frequency and methods used to validate and verify all applicable aspects of the SQF System including pre-requisite programs, control measures, critical limits, all quality control measures, and other aspects contained in the food safety plan and food quality plan (refer 2.5.2);

- Personnel conducting validation activities understand their roles and responsibilities (refer 2.5.2);

- The validation and verification procedures are effectively implemented;

- Records of all verification activities are current and accurate.

2.5.2 Validation & Effectiveness (M)

What the SQF Code says

2.5.2.1 The methods, responsibility and criteria for ensuring the effectiveness of pre-requisite programs, and validating critical food safety and quality limits to ensure they achieve their intended purpose shall be documented and implemented. The methods applied shall ensure that:

    i.   Pre-requisite programs are confirmed to ensure they achieve the required result.

    ii.   Critical limits are selected to achieve the designated level of control of the identified food safety hazard(s) or threat to the achievement of food quality; and

    iii.   All critical limits and control measures individually or in combination effectively provide the level of control required.

    iv.   Changes to the processes or procedures are assessed to ensure controls are still effective.

    v.   Critical food safety and quality limits are re-validated at least annually.

2.5.2.2 Records of all validation activities shall be maintained.

2.5.2   Implementation Guidance

What does it mean?

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

Validation involves testing over and above daily monitoring to ensure that established food safety and quality 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 and quality limits are said to be validated because they have been confirmed by scientific analysis. Pre-requisite programs and other food safety and quality 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 and quality 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 or threat to product quality. 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.

- 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 and quality: 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 quality of the product.

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

2.5.2 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 facility 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 and quality limits are validated annually or when changes to process occur;

- Methods used to validate critical limits ensure that the process step is safe (and quality criteria achieved) if critical limits are met;

- Critical limits effectively provide the designated level of control;

- Personnel conducting validation activities understand their roles and responsibilities (refer 2.5.1);

- Records of all verification activities are current and accurate.

2.5.3 Verification Schedule

What the SQF Code says

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

2.5.3 Implementation Guidance

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

The supplier 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.

2.5.3   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 facility 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.

2.5.4   Verification of Monitoring Activities

What the SQF Code says

2.5.4.1 The methods, responsibility and criteria for verifying the effectiveness of monitoring pre-requisite programs, critical control points, critical quality points and other food safety and quality controls identified shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each record verified.

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

2.5.4   Implementation Guidance

What does it mean?

Monitoring is the regular testing, or measurement of critical limits to ensure the process remains safe. The HACCP plan must identify for each CCP (and CQP), 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 (refer2.4.3).

Monitoring records must be checked for accuracy and timeliness by someone in a position of authority. In some special cases e.g. thermal processing, the person verifying the records may need to be an approved, qualified person.

Similarly, other control measures that must be monitored (e.g., temperatures of incoming goods) must also be checked for accuracy.

What do I have to do?

This element is mandatory.

The supplier must document the methods, responsibilities and criteria employed to verify the effectiveness of monitoring of pre-requisite, critical control points and critical quality points.

Examples of verification of monitoring include a review of temperature records to ensure that all monitoring activity tasks are completed and temperatures recorded are within critical limits. Other monitoring activities could include weight records, product testing records, cook temperature records and in-process quality checks.

Electronic records can be used for monitoring activities. Suppliers must be able to demonstrate how records are reviewed for verification purposes.   Each record must have secure access or a unique electronic signature so that it can be verified that records were recorded by individual as assigned.

2.5.4   Auditing Guidance

The verification 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 and verification activities and review of records at each facility audit (refer 2.5.1). Evidence may include:

- The SQF practitioner understands the need for verification activities and is competent to carry out, or supervise verification activities (refer 2.5.1);

- A procedure is documented to verify methods and responsibilities for monitoring activities (refer 2.5.1);

- The procedure adequately details the methods and responsibilities for verifying monitoring activities, including pre-requisite programs, critical limits, and other food safety and quality controls;

- Personnel conducting verification of monitoring activities understand their roles and responsibilities (refer 2.5.2);

- The procedures for verification of monitoring activities are effectively implemented;

- Records of all verification activities are current and accurate (refer 2.5.1).

2.5.5   Corrective and Preventative Action (M)

What the SQF Code says

2.5.5.1 The responsibility and methods outlining how corrections and corrective actions are investigated, resolved, managed and controlled, including the identification of the root cause and resolution of non-compliance of critical food safety and quality limits, and deviations from food safety and quality requirements, shall be documented and implemented.

2.5.5.2 Records of all investigation and resolution of corrections and corrective action shall be maintained.

2.5.5   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 and quality 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 and quality. 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.

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 facility that leads one to believe that product food safety or quality 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 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 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 or quality issues.

2.5.5   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 facility audit (refer 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 and quality 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 2.5.1).

2.5.6   Product Sampling, Inspection and Analysis

What the SQF Code says

2.5.6.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress, and for analyzing and assessing product quality and sensory attributes 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 are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements, are true to label and comply with weights and measure requirements after shelf life trials are completed; and
  iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.
  iv. Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard.
  v.   Sensory analysis and evaluations are completed after shelf life trials, as appropriate, and at intervals designed to demonstrate the products sensory characteristics are consistently being achieved;
  vi. Sensory evaluations comply with the relevant product sensory attributes specified by the customer; and
  vii. Sensory evaluations are conducted by trained personnel in accordance with established methods or as specified by the customer.

2.5.6.2 Records of all inspections, analyses, sensory evaluations and actions arising from inspections, analyses and sensory evaluations shall be maintained.

2.5.6   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 and to verify food safety and quality aspects.

The supplier 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 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 supplier 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 and quality. Inspections, test or analysis of finished product must be finalized before delivery to a customer. Finished product testing may be defined by the supplier and their customer.

The supplier 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 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), 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 facility.

If external laboratory analysis is used, the supplier 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.

The supplier will demonstrate that sampling of product for inspection or analysis is completed using recognized sampling methods.

The supplier 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.

2.5.6   Auditing Guidance

Product sampling and testing procedures shall be reviewed initially at the desk audit and compliance to this requirement by observation, interview with the SQF practitioner and other relevant staff responsible for sampling and testing, and review of records at each facility 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 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.

2.5.7   Internal Audit (M)

What the SQF Code says

2.5.7.1   The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System including facility and equipment inspections, pre-requisite programs, food safety plans, food quality plans and legislative controls shall be documented and implemented. The methods applied shall ensure:

i.   An internal audit schedule is prepared detailing the scope and frequency of internal audits;

ii.   Correction and corrective action of deficiencies identified during the internal audits is undertaken;

iii.   Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions; and

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

2.5.7.2   Staff conducting internal audits shall be trained in internal audit procedures.

2.5.7.3   Where possible staff conducting internal audits shall be independent of the function being audited.

2.5.7   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.

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 and quality 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 facility. 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.

2.5.7 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 facility audit. The SQF auditor will verify that the audit schedule is adequate based on the observations from the assessment of the facility. 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 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 2.1.4.1);

- Records are kept of internal audits and the corresponding corrective actions.

2.6 Product Identification, Trace, Withdrawal and Recall

2.6.1 Product Identification (M)

What the SQF Code says

2.6.1.1 The methods and responsibility for identifying 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, work in progress and finished product are clearly identified during all stages of receipt, production, storage and dispatch; 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 Implementation Guidance

What does it mean?

To allow for effective trace back (refer 2.6.2), recall (refer 2.6.3) and stock control and rotation (refer 2.4.9), materials and products at all stages of production must be labelled and identified. How the supplier 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 supplier 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 facility could use bin tags, pallet tags, colors, product tags, etc. The facility must be able to demonstrate how the product identification system works for incoming materials, work-in-progress and for finished product.

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.

The supplier 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 supplier 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 facility audit. The facility 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;

- 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 (M)

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 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 tested at least annually.

2.6.2.2 Records of raw and packaging material receipt and use, and 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 and quality.

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 facility 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 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 by observation, interviews with operational staff, and review of records at each facility audit. The facility 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 (M)

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 and expert advice; 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 and the certification body 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 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.

2.6.3.4 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 or quality 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.

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 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 facility 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 facility 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 2.5.5).

2.7   Site Security

2.7.1   Food Defense (M)

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 protocol shall be prepared and include:

i.   The name of the senior management person responsible for food defense;
ii.   The methods implemented to ensure only authorized personnel have access to crops, production equipment and vehicles, manufacturing and storage areas through designated access points;
iii.   The methods implemented to protect sensitive processing points from intentional adulteration;
iv.   The measures taken to ensure the secure storage of raw materials, packaging, equipment and hazardous chemicals;
v.   The measures implemented to ensure harvested crop and/or finished product is 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   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 facility 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 facility 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 facility (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 facility 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;

- 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.

2.8   Identity Preserved Foods

2.8.1   General Requirements for Identity Preserved Foods

What the SQF Code says

2.8.1.1 The methods and responsibility for the identification and processing of Kosher, HALAL, organic, Genetically Modified Organisms (GMO) food and other products requiring the preservation of their identity preserved status shall be documented and implemented.

2.8.1.2 Identification shall include a statement of the product's identity preserved status of all ingredients, including additives, preservatives, processing aids and flavorings.

2.8.1.3 Raw material and ingredient specifications to identity preserved foods shall include requirements for their handling, transport, storage and delivery prior to use.

2.8.1.4 Assurances concerning the raw material or ingredient's identity preserved status shall be by agreement with the supplier.

2.8.1.5 The process description shall allow for a product's identity preserved status to be maintained during manufacturing.

2.8.1.6 The processing of identity preserved foods shall be conducted under controlled conditions such that:

   i.   Ingredients are physically separated from ingredients identified as incompatible with the identity preserved food;

   ii.   Processing is completed in separate rooms; or scheduled as the first production run; or carried out after the completion of a thorough sanitation of the area and equipment; and

   iii.   Finished product is stored and transported in separate units or isolated by a physical barrier from non-specialty product.

2.8.1.7 The identity preserved status shall be declared in accordance with current legal requirements.

2.8.1.8 Customer requirements concerning identity preserved foods shall be included in the finished product specification described in 2.3.5, or label register, and implemented by the supplier.

2.8.1   Implementation Guidance

What does it mean?

Identity preserved foods are products that make a claim – e.g. religious, ethical or nutritional. This can include, but is not restricted to organic, Kosher, free range, Genetically Modified Organism (GMO) free, halal, etc. Note that allergen control is specifically addressed in 2.8.2.

Identity preserved (IP) food is required to be kept separate from non-IP product at all stages of production and storage. The supplier must ensure that foods claiming special attributes and raw materials used to achieve those special attributes are handled, stored, transported, segregated and properly labeled to prevent commingling with other foods and raw materials that do not have the same attributes.

What do I have to do?

The supplier must be aware of regulatory and customer requirements concerning product claims and have written procedures stipulating how it ensures that identity preserved products are not commingled (some retailers have specific requirements for labelling of retailer-branded product). The written procedures must detail how the supplier will accomplish the prevention of commingling of foods and raw materials claimed to have special attributes.

The supplier must have appropriate licenses, certification or contracts allowing them to use a specific logo or trademark, such as Kosher or organic certification.

The supplier must have written procedures detailing how raw materials that are processed in identity-preserved products are separated to prevent commingling with generic raw materials during handling, transport, storage and delivery prior to use.

Assurances concerning raw materials or an ingredient's identity preserved status shall be included in raw material specifications (refer 2.3.2). A product process description shall allow for a product's identity preserved status to be maintained with manufacturing carried out on dedicated equipment or scheduled to avoid cross-contamination. The identity preserved status shall be declared in accordance with regulatory requirements.

Identity preserved products should have their own dedicated Food Quality Plans (refer 2.4.4) with the process risk points for cross-contamination identified and controlled.

Customer requirements concerning identity preserved products shall be included in the finished product specification described in 2.3.5 and implemented by the supplier.

2.8.1   Auditing Guidance

The procedure for identifying and processing of identity preserved foods shall be reviewed initially at the desk audit and compliance will be assessed by observation, interviews with senior management, and review of storage and production records at each facility audit. Evidence may include:

- Claims made on, or on behalf of the product, requiring identity preserved status;

- Nutritional, religious, or ethical claims made meet regulatory requirements and are correctly certified or otherwise authorized;

- There is a procedure in place that identifies methods to preserve the integrity of identity preserved foods;

- Responsibility for IP integrity is assigned and authorized staff understand their roles and responsibilities;

- Documented methods are adequate to preserve the integrity of identity preserved foods;

- Documented methods are effectively implemented;

- Processing of identify preserved foods are conducted under controlled conditions, e.g., in separate rooms, scheduled as first run, or after a complete sanitation of the process line;

- Ingredients and materials for identity preserved foods are stored separately;

- Finished identity preserved product is stored properly and correctly labeled;

- Customer requirements regarding identity preserved foods are included in finished product specifications (refer 2.3.5).

2.8.2   Allergen Management

What the SQF Code says

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

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

    ii.   A register of allergens which is applicable in the country of manufacture and the country(ies) of destination;

    iii.   A list of allergens which is accessible by relevant staff.

    iv.   The hazards associated with allergens and their control incorporated into the food safety plan.

    v.   Instructions on how to identify, handle, store and segregate raw materials containing allergens provided to staff responsible for receiving those target raw materials.

    vi.   Provision to clearly identify and segregate foods that contain allergens,

    vii.   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.

    viii.   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.

    ix.   Separate handling and production equipment where satisfactory line hygiene and clean-up or segregation is not possible.

2.8.2.2 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.

2.8.2.3 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 used.

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

2.8.2   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 suppliers 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.

Suppliers must have procedures in place to identify and manage the risk of intentional or cross-contact allergens.

What do I have to do?

This element is not labelled as mandatory, as some SQF suppliers may not have any allergen exposure (e.g., packaging manufacturer). However it is essential that suppliers that may be exposed to intentional or cross-contact allergens have a management program in place to preserve the integrity of allergen containing and non-allergen containing materials and products. Ignorance is not an excuse. Suppliers must establish the allergen status of incoming materials and ingredients and have procedures in place to isolate and control materials and products containing allergens.

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.

2.8.2   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 facility audit.

Suppliers 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 management plan is documented and in place;
- 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 2.4.3);
- 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 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 2.6.1);
- The product trace system addresses materials, ingredients, work-in-progress and products containing allergens (refer 2.6.2);
- Products containing allergens are properly labeled to identify them as allergens, and meet regulatory requirements for allergen labeling;
- Staff is aware of the risk of allergens and the allergen management procedures.

2.9   Training

2.9.1   Training Requirements

What the SQF Code says

2.9.1.1 Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the SQF Level 3 System and the maintenance of food safety, regulatory requirements, and quality.

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, food quality 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 and quality. 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 2.1.2.8), procedures and work instructions (refer 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 2.9.2).

2.9.1   Auditing Guidance

Training requirements will be assessed at each facility 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 (M)

What the SQF Code says

2.9.2.1 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 Agricultural Practices, Good Aquaculture Practices, or Good Manufacturing Practices (as appropriate).
   ii. Applying food regulatory requirements;
   iii. Steps identified by the hazard analysis and other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety;
   iv. Steps identified as critical to effective implementation of the food quality plan and the maintenance of food quality; and
   v.   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 2.9.1), the supplier must ensure staff are 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 and quality 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

- Product quality and grading

- 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 facility 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 2.9.1);

- The employee training program covers all job descriptions required within the SQF System (refer 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;

- 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 explaining how all tasks critical to meeting customer specifications, regulatory compliance, the maintenance of food safety, quality 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, quality 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 repetitive (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 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 and quality 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 facility 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 and quality 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 and food quality plans

2.9.4   Implementation Guidance

What does it mean?

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

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 facility. 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 facility audit. Evidence may include:

- HACCP training has been provided for all staff associated with the development and maintenance of food safety and quality plans;

- All staff associated with the development and maintenance of food safety and quality plans understand HACCP principles and the HACCP method;

- All staff associated with the development and maintenance of food safety and quality 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 employee 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 facility;

- Consider the literacy level of all employees;

- Provide instructions (refer 2.9.3) related to the process, food safety or food quality in the common languages of employees;

- Provide training (refer 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 and work instructions at each facility 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 facility 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 the training was completed and that the trainee is competent to complete the required tasks.

2.9.7   Implementation Guidance

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 a 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 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 facility 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.

Appendix 1: Allergen Cleaning and Sanitation Guide

Introduction

The SQF Institute provides updates to expand on the meaning of the SQF Code, and provide further guidance on the important issues addressed in the SQF Code. The management of allergens is covered in in Module 2, section 2.8.2 of the SQF Code, edition 7. In this guide, SQFI addresses allergen management, with particular emphasis on cleaning and sanitation practices for allergen control.

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.

Allergens in food can be intentional (i.e. nuts in nut-based products, milk in milk-based products), or introduced via 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.

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.

Document the responsibility and methods used to control allergens and prevent cross-contact with any dissimilar allergenic or non-allergen containing materials.

Some food products contain ingredients that are known allergens and must be declared and labeled according to the regulatory labeling requirements in the country of origin and country of destination.

However, cross-contact allergens are more difficult to control. These are trace or occasional allergens that are not intended to be in the product and will not appear on the ingredient listing. They occur through incorrect formulation, poor line scheduling, rework, processing aids, or unexpected presence in ingredients (e.g. lactose used as a carrier for flavors). Cross-contact allergens can only be controlled through thorough and effective management practices within the plant.

(Note: Many retailers will not accept "may contain" labeling as a management control on retailer-branded products. Intentional inclusion of allergenic ingredients must be properly labeled. However cross-contact allergens must be prevented by means of proper management controls.)

2.8.2.1.i. The allergen management program shall include a risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants that contain allergens

A documented risk (hazard) analysis of all the ingredients, raw materials and processing aids that are used in the facility shall be conducted.

Each facility must know the intentional and cross-contact allergens that could occur, and the potential risk of occurrence. This includes ensuring suppliers of materials, ingredients, and processing aids (including food-grade lubricants) declare any allergenic substances in the materials they are supplying, including the potential for cross-contact allergens.

This not only applies to ingredients used in a particular finished product, but those used throughout the facility. The risk assessment must also apply to potential allergens in materials and products that are stored or produced on other lines in the same facility, or at other times on the same line. For example, a confectionery manufacturer may produce a number of product lines, but only one contains peanuts. The risk assessment must include the potential for peanut allergens to contaminate non-peanut products.

2.8.2.1.ii. The allergen management program shall include a register of allergens which is applicable in the country of manufacturer and the country (ies) of destination

A register (list) of allergens in the facility that are of concern in the country of manufacture and the country of sale shall be developed.

The list of regulatory allergens varies from country to country and food manufacturers must be familiar with the declarable allergens in the countries in which the products are sold, and ensure that the labeling laws in that country are met. They must also be aware of changes in legislation, as regulatory allergens change from time to time.

2.8.2.1.iii The allergen management program shall include a list of allergens which is accessible by relevant staff

A list of everything in the processing facility that contains allergens that can be accessed by the staff involved in production operations shall be outlined.

Staff awareness is critical to avoiding unintentional inclusion of trace amounts of allergenic material in products, and training must be provided that includes the consequences of unintentional consumption of allergens and the methods required to prevent contamination.

Trace amounts of allergenic materials can be transferred to products from clothes, incorrect ingredient selection, spillages, and inadequate cleaning.

2.8.2.1.iv. The allergen management program shall include the hazards associated with allergens and their control incorporated into the food safety plan.

The food safety plan must show the hazards (potential problems) associated with storage, movement, and use of allergens in the plant and how those hazards are controlled.

All identified intentional and cross-contact allergens must be included in the HACCP-based Food Safety Plan, and their controls identified. In some instances, allergen controls may be identified as CCPs due to the risk to public health, infringement of labeling regulations, and the potential for product recall. (Many recalls have occurred due to non-declaration of allergens.)

Controls may include, but are not limited to:

- Specifications for ingredients and raw materials;
- Receipt and separate storage of raw materials and ingredients;
- Separate storage of work in progress and finished products;
- Scheduling of allergen containing materials after non-allergen containing materials;
- Equipment design to avoid build-ups, bottle necks, and to allow for separation of highly allergenic materials;
- Control of rework;
- Allergen cleaning and sanitation procedures (refer below);
- Testing of products and equipment.

2.8.2.iv. The allergen management program shall include instructions on how to identify, handle, store and segregate raw materials containing allergens provided to staff responsible for receiving those target raw materials.

2.8.2.1.vi. The allergen management program shall include provision to clearly identify and segregate foods that contain allergens.

Instructions for the receiving and operational staff on how to identify, store, and keep separate non-allergenic materials and any materials known to contain allergens shall be documented.

SQF suppliers must identify all allergenic ingredients at receipt, and store them separately from non-allergenic materials, and from materials containing other types of allergens. Staff involved in receiving and storage must be fully aware of the presence and risk of allergens and the storage procedure.

All ingredients must be clearly labeled with the name of the allergenic substance and must be stored and transported to avoid spillage or leakage onto other non-allergenic materials.

2.8.2.1.vii. 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.

2.8.2.1.viii. 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.

Cleaning and sanitation procedures on lines producing allergenic and non-allergenic products must be effective and validated.

Effectively documented, implemented and validated cleaning procedures are essential to avoid cross-contact allergens transferring across products. This is discussed in greater detail in section 2.

2.8.2.1.ix. Separate handling and production equipment where satisfactory line hygiene and clean-up or segregation is not possible.

Where satisfactory cleaning cannot be implemented, separate handling and production equipment is required.

Where the allergen risk is greater (e.g. peanut protein can cause serious allergic reactions in minute trace quantities), or the processing equipment design does not permit adequate cleaning, separate and isolated production equipment must be provided to avoid cross-contact. Care must also be taken to avoid cross-contact due to air flow, transfer on tools or equipment, or staff movement from one line to the other.

Cleaning Validation and Verification

One of the areas of possible confusion is the requirements for allergen cleaning validation and verification.

Section 2.8.2.1.vii states; "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."

Section 2.8.2.1.viii states "Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitizing of areas and equipment in which allergens are used shall be effectively implemented.

Interpretation

The SQF Code requires validation and verification of cleaning and sanitizing procedures for the product contact equipment, and therefore the use of finished product testing for validation of cleaning is not considered adequate. A program of verification needs to be built on an initial validation study that identifies the target allergen(s), threshold levels, and the severity of contamination, and shows the cleaning process and testing used are effective to give the desired results consistently. Once the cleaning process has been validated as effective, a verification/monitoring/inspection program shall be established to assure that the validated cleaning process is being used, is maintained and effective.

Validation

The purpose of validation is to prove that the cleaning process employed is effective in removing the allergen of concern. This proof requires evidence that the specific allergen was in fact removed, or reduced to an acceptable level by the cleaning procedure. Therefore, only an allergen specific test will provide that evidence.

The acceptable validation testing methods involve the use of a test specific to the allergen being removed. These generally require the use of a test method which uses an antigen (the allergen) and an antibody specific to the antigen. One example of the antigen and antibody test is the enzyme linked immuno-assay or ELISA method. The ELISA method can be either quantitative or qualitative and can be conducted in a laboratory or with test kits available for in plant use; either is acceptable. ELISA test kits are available from several manufacturers and are commonly used in the food processing industry. Lateral flow test devices also use an ELISA-based method and are also effective in detecting specific allergens. While lateral flow devices are qualitative only, most have sensitivities around 10 parts per million (ppm) and are available for most of the common allergens and are designed for use in a plant environment.

Both the ELISA tests and lateral flow test kits have been accepted by recognized allergen research scientists and meet the requirements for sanitation validation of the SQF Code. It must be noted that there may be other 'acceptable' tests for validation methods that can be used but the test must meet the "allergen specific" criteria or provide some other evidence that the validation is effective. The SQF Institute does not endorse any particular technology or methodology and relies on the facility to provide the evidence of a scientifically validated and effective cleaning method.   Like any validation of any food safety control, periodic re-validation is required to account for any changes that may have occurred. Not all allergens have specific test kits available which includes some fin fish and allergens that have been modified by fermentation, heating or hydrolysis.

Verification

Once a validated cleaning method has been shown to remove the allergenic material of concern, the facility must verify that the validated procedures were used each time. This verification must be documented by a responsible person from the facility who has been trained in the validated cleaning method. The most common method used is direct observation of the validated cleaning procedure during the sanitation process.   Another acceptable verification method is the use of highly sensitive swabs that test for proteins. These recently developed swabs will detect total protein at approximately 20 ppm. Since these devices only test for total protein and not specific allergens, they are not acceptable for validation but will serve to verify that equipment has been thoroughly cleaned. There are also sensitive ATP test swabs available however the presence of ATP does not indicate the presence of protein which is the allergenic material. The use of these total protein swabs or the ATP sensitive swabs must be calibrated with the validated cleaning procedure by using them immediately after the validated method is used and recording the results of both the allergen specific test and the protein or ATP swab test.   It is also to ensure surface swabbing is occurring at corners, joins, and crevices in the equipment as well as open surfaces, to check for protein held up in equipment.

The purpose of a validated cleaning program is to confirm that the specifics of the cleaning process used are complete, effective, sufficient, and when implemented, will produce that same results every time.

- When there is a mixture of different allergens in use, the acceptable method for confirming the thoroughness of cleaning is to test for the highest risk allergens, the highest concentration allergens, or the ones that are most difficult to remove. Examples of difficult to remove allergens include milk proteins, such as in chocolates or caramels, and cooked eggs. In some cases, a supplier may choose to test for an allergen protein which is lower in concentration. Such is the case with low-fat peanut butters where the soy flour is used at a much lower concentration in the mixture with peanuts.

- Nearly all of the allergens of concern do have specific test kits available however, there are a few allergens that do not have a test kit. The supplier must record, in a detailed risk assessment, the procedures they are utilizing and use due diligence in confirming their procedures are appropriate for their application and products. There are currently no acceptable test kits for certain fish species, all tree nuts and some other allergens. In specific cases, the use of the highly sensitive protein swabs may prove to be an acceptable alternative. These tests are usually sensitive to 5-10 ppm of total protein. The supplier must be aware of the threshold levels (LOAEL or Lowest Observed Adverse Effect Levels) for each target allergen. They vary widely across all the allergens of concern.

- Suppliers using whole or partial nuts on their products, such as in a muffin topping, may have to verify removal of all the nuts fragments from the equipment based on visual inspection. Ground nuts and nut butters do require the use of a validated cleaning procedures and a recognized allergen specific cleaning test on equipment such as conveyors, augers, and other product transfer devices. This due to the presence small nuts particles and oil/protein residues.

- The SQF Code requires that facilities validate their cleaning methods against the allergens of concern in the country of manufacture and the country of destination. New allergens are emerging all the time so both the supplier and the auditor need to ensure they address the most current list.

- Finished product testing is not sufficient by itself to validate cleaning methods since any allergen present is diluted by the product and can become nearly undetectable thus rendering a questionable result. However, finished product testing can be useful when an allergenic ingredient might be mistakenly added to a product during the manufacturing process. Extensive finished product testing conducted in conjunction with visual inspections of operating equipment may provide the evidence that the allergen removal verification method is working. Further evaluation on a case by case basis may be needed in some of these situations.

- For those processors producing dry products, an inert product flush may be the most effective method to remove allergens. In this case, three product flushes may be required to assure removal of the material of concern.

Conclusion

It is the responsibility of the SQF supplier to validate their cleaning procedure to ensure it removes allergenic material of concern to prevent cross-contact with non-allergen or dis-similar allergenic foods. This must be accomplished to meet the regulatory requirements in the country of origin and the country of destination, as well as all customer requirements. The methods for validation and verification of the cleaning procedures as well as the other allergen safety procedures used in the facility must be documented as part of the food safety manual. The procedures must be scientifically valid and any exclusions or exemptions must be thoroughly documented with a detailed risk assessment. There must be a documented re-assessment of the allergen control program performed at least annually.